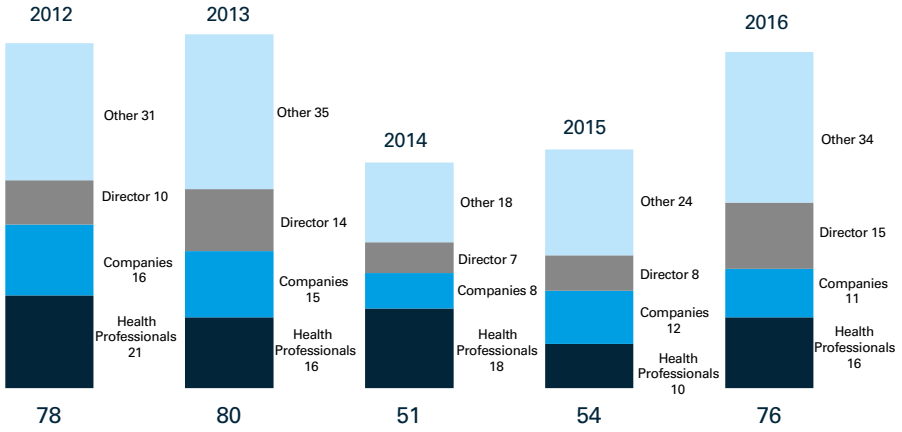
NUMBER 95 February 2017

CODE OF PRACTICE REVIEW

PMCPA | Prescription Medicines Code of Practice Authority

The Prescription Medicines Code of Practice Authority (PMCPA) was established by The Association of the British Pharmaceutical Industry (ABPI) to operate the ABPI Code of Practice for the Pharmaceutical Industry independently of the ABPI. The PMCPA is a division of the ABPI which is a company limited by guarantee registered in England & Wales no 09826787, registered office 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT.

COMPLAINTS IN 2016



In 2016 the PMCPA received 76 complaints, compared with 54 in 2015. There were 51 complaints in 2014, 80 in 2013 and 78 complaints in 2012.

There were 99 cases to be considered in 2016, compared with 66 in 2015 and 49 in 2014. The number of cases usually differs from the number of complaints because some complaints involve more than one company and others, for a variety of reasons, do not become cases at all.

The number of complaints from health professionals in 2016 (16) was more than the number from pharmaceutical companies (both members and non-members of the ABPI) (11). In addition there were eight complaints from anonymous health professionals. The more complex cases considered by the Authority are generally inter-company complaints which often raise a number of issues.

There were four complaints made by employees/ex-employees. Fifteen complaints were nominally made by the Director and thirteen arose from voluntary admissions by companies – a substantial increase on 2015, when there were four voluntary admissions. One arose from criticism in the media and the publication of a study looking at disclosure of clinical trial details led to another.

There were 20 anonymous complaints in addition to the eight from anonymous health professionals. Four were from anonymous employees and three were from anonymous ex-employees.

The details will be included in the PMCPA 2016 Annual Report in due course.

NHS CONFLICT OF INTEREST GUIDANCE

NHS England recently published guidance for staff and organisations on managing conflicts of interest in the NHS.

Continued overleaf...

THANK YOU JANE AND GOOD LUCK WITH YOUR NEXT CHALLENGE!

There will be big changes at the Authority as Jane Landles, the Secretary of the PMCPA retires after 21 years. Jane joined as Deputy Secretary in 1996 and was appointed Secretary in 2011. She has been to over a thousand Code of Practice Panel meetings and hundreds of Appeal Board meetings. In addition to considering and ruling upon cases she has provided advice, guidance and extensive training. Jane started with Case AUTH/391/1/96 and will finish at the end of March after over 2500 cases. When she started at the PMCPA respondent companies were notified of a complaint by facsimile machine and there was little email or internet access!

Jane is a pharmacist and spent the early part of her career in hospital pharmacy, then 10 years in the pharmaceutical industry, first as a medical information officer, later moving into the area of promotional affairs and was ultimately a nominated signatory before joining the PMCPA.

Jane has made an enormous contribution to self regulation during a time which has seen significant changes for the industry. Jane will be greatly missed by all her colleagues who no doubt will want to join the Authority in thanking Jane for her dedication and hard work and wishing her a very long and very happy retirement.

CODE OF PRACTICE TRAINING

Training seminars on the Code of Practice, run by the Prescription Medicines Code of Practice Authority and open to all comers, are held on a regular basis in central London.

These full day seminars offer lectures on the Code and the procedures under which complaints are considered, discussion of case studies in syndicate groups and the opportunity to put questions to the Code of Practice Authority.

The next Code of Practice seminar dates on which places remain available are:

Friday 19 May, 2017

Thursday 15 June, 2017

Short training sessions on the Code or full day seminars can be arranged for individual companies, including advertising and public relations agencies and member and non member companies of the ABPI. Training sessions can be tailored to the requirements of the individual company.

For further information regarding any of the above, please contact Nora Alexander for details (020 7747 1443 or nalexander@pmcpa.org.uk).

HOW TO CONTACT THE AUTHORITY

Our address is:
Prescription Medicines Code of Practice Authority
7th Floor, Southside, 105 Victoria Street, London SW1E 6QT

www.pmcpa.org.uk

Telephone: 020 7747 8880
Facsimile: 020 7747 8881

Copies of the Code of Practice for the Pharmaceutical Industry and of this Review can be obtained from Lisa Matthews (020 7747 8885 or lmatthews@pmcpa.org.uk).

Direct lines can be used to contact members of the Authority.

Heather Simmonds: 020 7747 1438
Etta Logan: 020 7747 1405
Jane Landles: 020 7747 1415
Tannyth Cox: 020 7747 8883

The above are available to give informal advice on the application of the Code of Practice.

The Authority rather than the ABPI is the contact point for information on the application of the Code.

NHS CONFLICT OF INTEREST GUIDANCE

(Continued from cover)

The guidance will come into force on 1 June and is the result of the work of the Conflict of Interest Task and Finish Group chaired by Sir Malcolm Grant, of which Mike Thompson the ABPI Chief Executive was a member.

It will be applicable to the following NHS organisations:

- Clinical Commissioning Groups
- NHS Trusts and NHS Foundation Trusts
- NHS England.

The guidance refers to the ABPI Code of Practice in areas of gifts and hospitality. It also includes that NHS organisations should seek to ensure that relevant staff are aware of and comply with wider transparency initiatives such as ABPI's Disclosure UK.

CASE AUTH/2828/3/16

CLINICAL NURSE SPECIALIST v VIFOR

Conduct of representatives

A hospital clinical nurse specialist in nutrition complained about the conduct of Vifor representatives. Vifor marketed Ferinject (ferric carboxymaltose for injection/infusion) for the treatment of iron deficiency when oral iron was ineffective or could not be used.

The complainant explained that the trust currently used Ferinject and the two Vifor employees were looking for the complainant's colleagues from the inflammatory bowel disease (IBD) team. Some of the departments in the trust were looking at Monofer (iron isomaltoside), a competitor of Ferinject, marketed by Pharmacosmos. The complainant's colleague was not available to talk so the complainant introduced herself. In response to questions from the representative and his senior colleague as to why the trust might be switching to Monofer, the complainant explained that her colleagues should not have to justify their decision and certain departments would be looking at Monofer for a number of reasons, including a benefit to the patients. The complainant alleged that the representatives became very 'aggressive' in their manner/talk and started to tell her that [Monofer] was very dangerous and was not safe and queried how the complainant knew that it would be safe for patients. The complainant's colleague then interrupted to assist the complainant and reiterated that the trust wanted to do what was best for its patients. Eventually the complainant managed to ask the representatives to leave by offering her email address and stating that any concerns could be emailed to her. The complainant felt very upset and angry with the representative who had confused her and her colleague.

Once the Vifor employees left the complainant emailed her consultant to let him know that their behaviour and the way they just turned up to her department was inappropriate and unprofessional. The complainant discovered that the Vifor employees had, on more than one occasion, similarly upset several colleagues in other departments and had 'scaremongered' many of the trust's nursing teams with regard to the medicine [Monofer] it was trying to implement. The complainant provided details.

The complainant stated that the Vifor representatives had tried to email her safety data suggesting that she had requested information but she had not. The complainant believed they had requested the information be sent to her themselves.

The complainant noted that the Vifor employees had subsequently turned up to her consultant's office and were told to leave and not come back. Future meetings with Vifor had been cancelled. The representatives were told that they had upset a few departments and although they wanted to apologise to the complainant they were told to stay away from the trust for a while.

The detailed response from Vifor is given below.

The Panel noted that there were differences between the parties' accounts about what had been stated at the meeting and about the information which was subsequently sent to the complainant; it was extremely difficult in such cases to know exactly what had transpired. The complainant bore the burden of proof on the balance of probabilities. A judgement had to be made on the available evidence bearing in mind the extreme dissatisfaction usually required before an individual was moved to complain. The Panel noted Vifor's submission that its representatives' accounts were consistent but different to that of the complainant. In that regard the Panel noted that statements from the complainant's colleagues were very similar to her own.

The Panel noted that the complainant had alleged that the Vifor representatives had described Monofer as 'very dangerous' and 'not safe'. A colleague alleged that the representatives had tried to discredit Monofer 'in an intense way' and that they had referred to centres that had swapped from Ferinject to Monofer and 'had big reactions'. In this regard the Panel noted that in an account of the meeting one of the representatives stated that when asked if any centres had tried Monofer, he had replied that a couple had but then had to switch back. In response to a request for further information, Vifor submitted that when the nurses asked why the centres had switched back, the representative stated that he said he thought it was because of reactions. The Panel noted that following the meeting with the complainant, the consultant gastroenterologist had subsequently informed the representatives that there had been complaints from the infusion and IBD nurses although no details were given. The consultant had told the representatives that they should not have seen the nurses without seeing him.

The Panel noted Vifor's submission that during initial training, representatives were briefed not to discuss competitor products in detail and that questions about competitors' medicines should be referred to the relevant company. At the December 2015 sales conference, Vifor representatives were specifically reminded not to discuss the safety of competitor products. A briefing document approved in December 2015, however, stated on the concluding slide that safety and tolerability was a key factor in choosing an intravenous (IV) iron. Representatives were informed that 5 named accounts had switched back to Ferinject from Monofer. No reason was stated for the switch but it was reasonable that representatives would assume that it was to do with safety and tolerability given that was the heading to the slide. The slide also referred to the Lareb report and quoted the following from it: 'special attention should be given to the comparison of the safety profile of the different intravenous iron-containing

medicines and in particular to the safety profile of iron isomaltoside [Monofer]'. Finally representatives were told to 'Be proactively reactive. If a customer asks about the detailed safety of Ferinject beyond the SPC, please refer them to medical Information who can provide detailed information and investigate further if necessary'.

A briefing document approved in January 2016 (Questions and Answers. Reactive) listed customers' comments about Monofer and stated 'What we need to do is reactively discuss the FACTS in an accurate and balanced way, to allow the customer to make an informed decision'. The final message of the document was 'The Ferinject proposition is strong, be confident, we have the best treatment'.

Also in January 2016 the representatives had been given a slide set which specifically differentiated Ferinject from Monofer and was for proactive use in threatened accounts that were considering switching to Monofer and in accounts that had switched to Monofer. Again, the briefing material for that tool stated, in summary, that 'The Ferinject proposition is strong, be confident, we have the best treatment'. In the Panel's view the briefing material was at odds with Vifor's submission that it did not permit representatives to discuss comparative safety in a promotional environment. The complainant was shown the tool in response to a query about using 2g of Monofer in a single visit. The slide shown to the complainant, and marked as such by Vifor, stated that the way in which the Monofer dose was calculated (the Ganzoni formula) was 'recognised as inconvenient, prone to error, inconsistently used in clinical practice, and it underestimates iron requirements'. The briefing on this slide referred to Ganzoni-based dosing as being problematic.

In the Panel's view, there was no doubt that Vifor was specifically targeting Monofer sales and that the representatives had been briefed to discuss, or solicit ('be proactively reactive') questions about the comparative safety of Ferinject vs Monofer and to view the Lareb report as a resource in that regard even if they could not distribute it themselves. As noted above, the representatives had also been informed, in a slide headed 'Safety and tolerability', that 5 accounts had switched back to Ferinject from Monofer.

The Panel considered that on the balance of probabilities, given the strident tone and content of the sales materials and briefings, the representatives had started to spread doubt amongst infusion nurses about the safety of Monofer as alleged and in that regard had offered misleading comparisons with Ferinject. Breaches were ruled which were upheld on appeal by Vifor. The Panel considered that the briefing material advocated a course of action which was likely to be in breach of the Code. A breach of the Code was ruled and upheld on appeal by Vifor.

The Panel noted that the complainant had been sent a copy of the Lareb report which she stated she had not requested. Vifor submitted that she had asked for comparative safety data and that the Lareb report was the most appropriate document to send as there was no head-to-head clinical trial data of Ferinject vs Monofer. The Panel noted from a short email exchange between the complainant and one of the representatives that it seemed clear that issues about the safety of Monofer had been raised by the representative, not by the complainant. The Panel noted Vifor's submission that the complainant questioned the safety data and asked for comparative safety data. In that regard the complainant's request for more information was not unsolicited. The representative subsequently emailed the medical information department and stated that the complainant had 'kindly requested a copy of the Lareb report'. This was not so. In response the medical information department replied with a link to the Lareb report; the only substantive statement in the email was that '…Lareb has received concerns from multiple Dutch hospitals in relation to [Monofer] after the switch from [Ferinject]. Doctors and nurses reported an increase in the severity and incidence of allergic reaction. The report has not mentioned any specific safety concerns with [Ferinject]'. The latter statement was untrue as the report detailed 7 reports of hypersensitivity/anaphylacsis associated with the use of Ferinject.

The Panel noted that the query was not unsolicited and that the representative had misrepresented to the medical information department what the complainant had asked for. Further the email from the medical information department did not put the results of the Lareb report in to context and did not note that there were no direct head-to-head comparisons of Ferinject and Monofer. The statement that the report had not mentioned any specific safety concerns with Ferinject was inaccurate. The Panel thus considered that the email from medical information could not take the benefit of the exemption to the definition of promotion, it was neither unsolicited nor fair and balanced. The complainant had thus been sent a promotional email without her prior permission. A breach of the Code was ruled.

The Panel noted that the Code did not prevent representatives 'cold calling' on health professionals provided that the frequency and duration of such calls was appropriate and that the representatives respected the wishes of those upon whom they called and observed the arrangements in force at the establishment. The complainant had not provided any evidence that the representatives had not observed the arrangements in force at the hospital neither was there evidence to show that the representatives had not respected the complainant's wishes. No breach of the Code was ruled.

The Panel noted its rulings and comments above and considered that the representatives had not maintained a high standard of ethical conduct. In that regard high standards had not been maintained. Breaches of the Code were ruled. Vifor appealed the ruling that high standards had not been maintained. It only accepted the ruling insomuch as the representatives had not maintained a high ethical standard in relation to the provision

of the Lareb report. The Appeal Board considered this ruling encompassed the whole case and insofar as the point was raised ruled against it. The Appeal Board upheld the Panel's ruling that high standards had not been maintained.

The Panel noted that a ruling of a breach of Clause 2 was a sign of particular censure. The Panel was concerned that the two representatives appeared to be cold calling on infusion and IBD nurses specifically to solicit discussion about Ferinject vs Monofer. The representatives had not called upon the relevant consultant – although the Panel noted that securing a meeting with him was not easy. The promotional tool which they had been given was specifically for proactive use in, *inter alia*, threatened accounts that were considering switching to Monofer; the hospital trust in question appeared to be one such account. The Panel noted the complainant's and her colleagues' views that the representatives had been scaremongering and that their approach was challenging and aggressive. The representatives had ensured that the complainant had received a copy of the Lareb report and in the Panel's view the covering medical information email had been promotional. The Panel noted its rulings and comments above and considered that, on the balance of probabilities, Vifor's activities and materials associated with the promotion of Ferinject had been such that they brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of the Code was ruled which was upheld on appeal by Vifor.

A hospital clinical nurse specialist complained about the conduct of Vifor representatives. Vifor marketed Ferinject (ferric carboxymaltose for injection/ infusion) for the treatment of iron deficiency when oral iron was ineffective or could not be used.

COMPLAINT

The complainant explained that a representative and his senior colleague visited her on Thursday, 10 March. The complainant's trust currently used Ferinject and the two Vifor employees were looking for the complainant's colleagues from the inflammatory bowel disease (IBD) team. The complainant stated that some of the departments in her trust were looking at a Monofer (iron isomaltoside), a competitor of Ferinject, marketed by Pharmacosmos. The complainant's colleague was not available to talk so the complainant introduced herself. The representative and his colleague informed the complainant that they had heard the trust might be switching to Monofer and wanted to know why. The complainant explained to the representative that her colleagues should not have to justify their decision and certain departments within the trust would be looking at Monofer for a number of reasons, including a benefit to the patients. The complainant alleged that the representative and his colleague became very 'aggressive' in their manner/talk and started to tell her that [Monofer] was very dangerous and was not safe and queried how the complainant knew that it would be safe for patients. The complainant's colleague then interrupted to assist the complainant and stated yet again that the trust wanted to do what was best for its patients. Eventually the complainant managed to ask the representatives to leave by offering her email address and stating that any concerns could be emailed to her in writing. The complainant felt very upset and angry with the representative who had made her and her colleague very confused.

Once the Vifor employee and his colleague left the complainant emailed her consultant to let him know that their behaviour and the way they just turned up to her department was inappropriate and unprofessional. The complainant spoke to a few other departments and discovered that the two Vifor employees visited several of the complainant's colleagues in other departments (on more than one occasion) and had also upset them. They too asked the complainant to complain and the Vifor representatives had now 'scaremongered' many of the trust's nursing teams with regard to the medicine [Monofer] it was trying to implement. The complainant provided copies of complaints that her colleagues asked her to share:

> 'I too had one of these unannounced visits from them, and totally agree that they were scaremongering.'
>
> 'Well I was accidentally involved with them when I attended […] visit for what I though[t] was a Monofer training session. I stayed for at least 20 minutes, not only were they fishing for information on what is happening they were also trying to discredit the drug in quite an intense way. Referring about big centres that have swapped from Ferinject to Monofer and had big reactions scaring a bit more of the infusion team than anything else. I stood my ground on that but in the end even I was doubtful of dosings and number of visits and more confused than what I was. I made it clear that no matter what this is happening and if they have concerns they need to take it directly to the lead pharmacist for gastro and who is the one I'd ask for safety data. In the end I [made] it very clear to them that if our team is happy with this drug it is the drug we are going to use. Then they ended up in the office not quite sure on what they wanted more … since definitely uninvited and [a colleague] intervened and the rest is what you've already read.
>
> I think more than the comments the approach is quite intense and can even be perceived as aggressive in terms of challenging. I personally had seen at least one of them before where people just pop into the office and referred him to the right people to discuss their issues. I see no point in carrying on with the same type of visits of just being questioned why do you want to change the drug and what is happening … they really need to get their research and talk to the right people as I've mentioned multiple times.
>
> Sorry about the moan, but last Thursday even I was confused with all of this. And if havoc was what they were going for they managed …'

The complainant stated that the Vifor representatives had tried to email her safety data suggesting that

she had requested information but she had not. The complainant believed they had requested the information be sent to her themselves.

The complainant noted that the Vifor employees had subsequently turned up to her consultant's office and were told to leave and not come back. Any future meetings with Vifor had been cancelled. The representatives had been informed that they had upset a few departments and wanted to apologise to the complainant personally but they had been told to stay away from the trust for a while.

When writing to Vifor, the Authority asked it to consider the requirements of Clauses 7.2, 7.4 and 7.9 in relation to the alleged statements made about Monofer and Clause 15.9 in relation to any associated briefing material. The Authority asked Vifor to consider the requirements of Clause 15.4 in relation to the specific allegation and closely similar allegations that 'the way they just turned up to our department in the trust was inappropriate and unprofessional' and Clause 9.9 in relation to the email about safety data which the complainant alleged she had not requested.

Vifor were also asked to respond in relation to Clauses 2, 9.1 and 15.2 in relation to each of the above and cumulatively.

In response to a request for information, the complainant provided a copy of the email she sent to her consultant, and copied to her colleagues, describing her concerns regarding the behaviour of the two Vifor representatives. The consultant replied asking others visited by the representatives to email an account of their experiences.

The complainant also provided copies of emails from her colleagues which showed that one had stated, in full that:

> 'I too had one of these unannounced visits from them and totally agree that they were scaremongering. Stating that more than 1g of Monofer could only be given in one dose with the over 100Kg patient and not with those with bleeding.
>
> It was unprofessional and I agree that a complaint is a good idea.'

RESPONSE

Vifor submitted that it was committed to adhering to the Code and deeply disappointed that a health professional had felt the need to complain to the PMCPA about the conduct of Vifor representatives.

Vifor appreciated the seriousness of the allegations and had thoroughly investigated the points outlined by the complainant. Given the seriousness of the complaint, Vifor initially interviewed both representatives separately and provided a comprehensive account of the meetings in question. Vifor noted that at the beginning of the interviews the only information provided was the date and location of the meetings in question and the complainant's name. Full details of the complaint were only disclosed after the representatives' recollections of the meetings had been recorded. Subsequent comments were then invited and recorded. The statements produced were consistent. Vifor noted that the two independently collected statements differed significantly from the complainant's account.

This complaint has arisen following a pre-planned hospital meeting which two named Vifor representatives attended. During the meeting they became aware that the hospital in which the complainant was employed was about to switch from Ferinject to Monofer, based primarily on erroneous dosing information given by Pharmacosmos representatives.

Vifor noted that in Case AUTH/2694/1/14, Pharmacosmos refused to cooperate with the industry's self-regulated complaints process and made it very clear that it had never considered itself to be included on the list of those companies that agreed to comply with the Code. Vifor was greatly concerned that a company that had clearly and publicly stated it would not agree to abide by the ethical regulations of the Code, operated in its therapeutic area as a competitor.

Vifor submitted that in this instance, a Pharmacosmos representative had informed multiple hospital staff that nearly all patients who required intravenous (IV) iron could receive 2g of Monofer in one visit. This led to subsequent confusion on the part of the hospital staff when Vifor representatives informed them that they had been incorrectly advised in relation to Monofer dosing. Further meetings occurred on the same day and in the subsequent week.

Vifor submitted that both of the representatives had stated that it was the health professional who proactively asked about comparative safety data and shared information about Monofer dosing she had received from the Pharmacosmos representative.

Notwithstanding these points, Vifor accepted that compliance with the Code was critically important to the successful relationship between industry, the health professions and the public and that it was Vifor's responsibility to uphold the highest standards at all times.

Vifor clarified the identities and roles of the two Vifor employees referred to by the complainant: one was a trust account manager (TAM) and the other, his line manager was a regional business manager (RBM). Copies of both job descriptions were provided. Both roles satisfied the definition of a representative and both employees had passed the ABPI examination.

Statements made about Monofer (Clauses 7.2, 7.4, 7.9, 15.9, 15.2, 9.1 and 2)

With regard to an alleged breach of Clause 7.2, the complainant alleged that Vifor representatives referred to Monofer as 'very dangerous', 'it's not safe' and 'how do I know that it will be safe to our patients'. The Vifor representatives in question were

highly experienced and aware of the need to provide a balanced view to enable health professionals to make up their own mind on the therapeutic value of a medicine whilst clearly avoiding emotive and sensationalist language. They had not just acquired that knowledge through experience but the point was also made in Vifor's training slides on adherence to the Code. Vifor referred in particular to a training slide which listed the qualities that all promotional material must fulfil and another which made it clear that the Code applied to written and verbal communication and that information provided should be sufficiently complete to allow recipients to make up their own minds about the value of a medicine.

Vifor submitted that Ferinject was the market leader in IV iron therapy and promotional tools and briefing materials provided an accurate and balanced view of the product. As evidenced in 'Questions and Answers, reactive responses to competitor messages', a document which was briefed to all Vifor representatives at the January 2016 sales and marketing conference, the last slide instructed all to 'Be professional, never disparage the competition', and 'Discuss the facts in an accurate and balanced way'. This briefing was part of the introduction of the Intravenous Iron Differentiator tool, a document based on current summaries of product characteristics (SPCs) and information which could be substantiated. This tool was certified and first used in January 2016 so it was up-to-date.

The TAM stated that Monofer was discussed only in response to the fact that the health professionals had stated that it could be used as a single dose compared with Ferinject in all patients receiving over 1g. The certified Intravenous Iron Differentiator tool was then used to show this was incorrect.

Vifor noted that one of the complainant's colleagues had stated '… they were also trying to discredit their drug in quite an intense way. Referring about big centres that have swapped from Ferinject to Monofer and had big reactions scaring a bit more of the infusion team than anything else'. The response of the TAM clearly stated that it was the customers who had asked if any centres had tried Monofer. The TAM replied that some had, but had switched back; he did not state anything more and did not state that centres had switched back because of 'big reactions'.

Vifor submitted that with regard to an alleged breach of Clause 7.4, the only information that was referred to in the discussions was the slide of the Intravenous Iron Differentiator tool in which the comparison of dosing was based on the relevant product's SPC. A copy of the Ferinject SPC was provided and the Monofer SPC was available on Pharmacosmos's website. The contents of that slide and tool were fully substantiable from those SPCs.

Vifor submitted that with regard to the alleged breach of Clause 7.9, its representatives received limited training on competitor products from the medical advisor during the initial training course (ITC). During this training they were verbally briefed not to discuss competitor products in detail. This briefing included the instruction that for non-Vifor products, customers were to be referred to the product's SPC or advised to contact the marketing authorization holder's medical information department. The representatives were instructed that Vifor's medical information department could not provide information on competitor products, only on Vifor products. Vifor submitted that the week 2 agenda of its current 4 week ITC, showed that the competitor SPC workshop took place for only two hours on day 9.

During an open Q&A session at the December 2015 sales conference, Vifor representatives were specifically reminded not to discuss the safety of competitor products. If a customer requested comparative safety data, the representatives were briefed to inform the customer that they could not discuss such matters and offer a referral to medical information.

Both statements provided by the Vifor representatives during investigation of this case clearly demonstrated that the only references to Monofer were in response to questions on dosing and comparative safety. Firstly, this was in response to the misconception that all patients could receive 2g of Monofer as a single dose in one visit. The complainant was shown the Intravenous Iron Differentiator tool which confirmed not all patients could receive 2g of Monofer in one visit. The complainant commented that this was not what she had been led to believe by the Pharmacosmos representative, this was not, however, mentioned by the complainant.

Secondly, both statements clearly showed that the complainant had specifically asked for comparative safety data during the meeting. Both Vifor representatives told the complainant that they were unable to provide such information but could refer the request to the medical department. The complainant agreed to this and gave the TAM her email address, and conducted a subsequent email dialogue with Vifor about a visit from the medical department (copies of emails were provided).

Vifor submitted that with regard to an alleged breach of Clause 7.9, it provided briefing material to all of its representatives for the Intravenous Iron Differentiator tool. This document had been certified and a copy of the approval certificate along with the materials in question was provided. It was also clear that the verbal briefings from the medical advisor both during ITCs and in relation to comparative safety data were followed. Vifor found no evidence that either of the employees in question acted contrary to company briefings.

Vifor denied a breaches of Clauses 7.2, 7.4 and 7.9.

In summary, Vifor found no evidence that either representative had commented negatively about Monofer, particularly in relation to safety. Vifor could not account for why the complainant's version of events was so different to its representatives' versions, which were independently collected, but were nonetheless extremely consistent. Furthermore, the interviews were conducted such that there could have been no

pre-agreement on what should be said during the investigative interviews.

Vifor submitted that based on its employees' accounts, it found no evidence to suggest that either had failed to maintain high standards of ethical conduct and both had acted within the relevant requirements of the Code. Both had maintained high standards throughout these incidents. Vifor therefore denied breaches of Clauses 15.2 and 9.1. Vifor submitted that its representatives' activities had not brought discredit upon or reduced confidence in the pharmaceutical industry and it therefore refuted a breach of Clause 2.

Manner in which the representative visited the complainant (Clauses 15.4, 15.2, 9.1 and 2)

On joining Vifor, all representatives were required to undergo training, written validation and be certified before they were permitted to see customers. Within this training, one day was spent on the Code with specific reference to field related activities. All attendees were reminded of the requirements of the number of unsolicited calls and Clause 15.4 in that '… frequency, timing, duration and manner of calls must not cause inconvenience' (relevant highlighted slides were provided). No other standard operating procedures (SOPs) or policies mentioned these requirements.

Both of the Vifor employees in question were experienced and highly regarded. No concerns had never been raised either within Vifor or by other health professionals about either individual or the manner in which they called upon customers.

With regards to simply 'turning up', Vifor submitted that on Thursday, 10 March there were two main interactions to note; the first was a lunch meeting with a group of infusion nurses and the second was the interaction with the complainant referred to in the complaint.

Vifor explained that the lunch meeting was pre-planned, booked in person on an earlier visit. As it was booked in person there was no written confirmation of this with the hospital although Vifor provided a print out from its customer relationship management (CRM) system that showed that the entry for this meeting was created on 7 March.

The interaction with the complainant took place after the lunch meeting whilst the Vifor employees were still in the building scheduling other appointments with an IBD nurse and a consultant gastroenterologist. The purpose of this interaction was purely administrative and they were not looking to engage in any product discussions but during the conversation on future appointments the discussion, prompted by the nurse, turned to the topics of that morning's meeting, a conversation in which the complainant, who was also in the room at the time, then actively included herself. Vifor submitted that it was difficult to consider that as representatives 'just turning up'.

Other phrases found in the complainant's letter referred to 'unannounced visits', popping into the office and being 'definitely uninvited'. During the investigation, the TAM was asked about the frequency and manner of visits to other departments within the hospital and indicated that as a normal part of the role there were visits to several other departments, approximately once a month, but within the constraints of the Code for solicited and unsolicited calls with care and consideration for health professionals' time and availability and always with acceptance of customers' wishes in the arrangements.

With regard to the manner of the call, Vifor noted that the complainant alleged that both Vifor employees visited several colleagues in other departments (on more than one occasion) and upset them.

Vifor highlighted that the RBM visited this hospital four times in total, every time accompanying the TAM as follows:

Tuesday 16 February: The TAM and RBM visited the department and met with the infusion nurse team. The nurses were very happy to see them and discussions centred around how well patients were doing on Ferinject and that the hospital had decided against using Monofer. It was at this meeting that their attendance was booked for the 10 March lunch meeting.

Thursday 10 March: The pre-planned lunch meeting. Both Vifor employees saw a small group of infusion nurses who talked about how pleased they were with the Ferinject service. A third nurse walked into the office. The discussion turned to the possible hospital switch to Monofer due mainly to their (inaccurate) belief that all patients could be given 2g in one visit. The TAM stated that this was incorrect, not all patients could be given this dose in one visit. When the third nurse explained that 'that's not what we were led to believe on Monofer dosing' the TAM helped the nurse understand the correct dosing using the Intravenous Iron Differentiator tool. When the nurse asked for the correct Monofer dosing information and the Monofer SPC it was explained that he/she would need to speak to the Pharmacosmos representative or visit the Pharmacosmos website for that information; before leaving the room the nurse confirmed that the website would be checked for confirmation of dosing. The nurses voiced their disappointment with the proposed switch. Both Vifor employees then left the room.

A 'cold call' haematology meeting held with a nurse who confirmed to another staff member they were happy to see them before they were let into the office. The nurse was in charge of IV iron training within the hospital and confirmed that the haematology, renal and maternity departments were all happy with Ferinject and that the nurse had no plans to support a change of product.

Within the detailed account of the afternoon meeting with the complainant and the third nurse, the TAM clearly recalled that it was the third nurse who prompted the discussions on Monofer, informing them that the Monofer website had been reviewed and that the dosing information was different to

that given by the Pharmacosmos representative. The complainant introduced herself and stated that she was the person who the Vifor representatives needed to talk to. Before this interaction the TAM was unaware of the complainant or of her position. It was clear that the two health professionals had had a discussion following the morning meeting and the complainant proactively asked to see the dosing information in the Intravenous Iron Differentiator tool to which the response was 'That's interesting, that's not what we've been led to believe, I'm a nurse practitioner, it's important I get the full picture'. The third nurse stated that an email would be sent to the pharmacist for clarification on the dosing issue. The complainant then questioned the safety data and directly asked for comparative safety data. The TAM answered that a representative was unable to discuss anything like this but could arrange for a medic to visit to discuss any queries that there were on this topic. The complainant then commented about a potential switch to Monofer at some larger centres, issues which neither Vifor employee had any knowledge on so did not pass comment (it later transpired that there was no truth in these statements). The complainant then asked again for safety data and the TAM responded by reiterating a representative's promotional status and that any such data could not be provided but that it could be requested from medical information or from a member of the medical team on a visit. This latter suggestion was taken up by the complainant who opened the diary and requested a visit as soon as possible, agreeing on a date in April. The complainant asked for the TAM's business card and at the same time sent the TAM a blank email to check that email would get through the hospital's firewall so follow up with a direct request for a visit could be made. When asked about the complainant's manner during the call the TAM stated that the complainant was very questioning at first but became friendlier on the realisation that both Vifor representatives were there to provide help. As they left, the complainant was very positive about the medic visit and stated that the main issue was the dosing. The complainant then winked at the representatives as she stated that cost was not the issue.

Monday 14 March: Both Vifor employees visited the department to check the complainant had received the email from the Vifor medical information team (considering the firewall issues that were mentioned). They had just missed the complainant who had gone home but the third nurse was there. They were greeted as usual, the TAM described the third nurse as being chirpy and cheerful, and also confirmed that the complainant had received the email and was planning on forwarding it to other colleagues. No mention was made of any dissatisfaction on the complainant's part that the information had been received. The representatives left, stopping to ask the secretary if they could book an appointment; they were advised to turn up in the morning, before 7.30am.

Tuesday 15 March: As recommended the day before, the Vifor employees turned up just before 8am and the consultant gastroenterologist agreed to see them. The consultant informed them there had been complaints from the infusion and IBD nurses (although there was no elaboration on this) and said they should not have seen the nurses without seeing the consultant. The nurses had challenged the proposed switch to Monofer. Both the RBM and TAM apologised and explained that the TAM had tried to see the consultant previously but all booked times were cancelled or the consultant was not available, a point which was acknowledged. Both Vifor employees were surprised that the nurses felt this way, nevertheless they accepted this and offered to apologise to the nurses in person. The consultant was happy to accept the apology but advised that a visit to the nurses was not necessary and asked the TAM to 'lie low' for a few weeks but to keep in contact, stating that continuity of contact would be appreciated. The consultant promised to let the TAM know about a meeting that had been booked for later in March but stated that the April meeting booked with the complainant was no longer needed, as in light of the corrected Monofer dosing information in line with its SPC the hospital now only planned to give Monofer to the small number of patients where one visit actually applied. It was not thinking of a wholesale switch (it never was) and each department would make its own mind up about which medicine it used. The other departments were happy with Ferinject. In the short term, all contact should be with the consultant. Vifor noted that the breakfast meeting was later cancelled and an email notification was sent to the TAM advising of this and the process for re-booking. This cancellation appeared to have no relation to this conversation or any issues raised within.

Vifor submitted that in all of the instances mentioned above, neither the TAM nor RBM could recall any dissatisfaction with their conduct being mentioned directly to them by any of the customers seen, although clearly there was an issue raised by the consultant which took them by surprise.

Referring specifically back to the Thursday, 10 March afternoon meeting, in relation to the perceived manner of the Vifor employees referred to by the health professional, at no time in those discussions did the TAM or RBM feel that the conversation, tone or body language of the complainant or any colleagues indicated that they were unwelcome or that they were anything but professional. They recognised that there was some frustration and upset on the health professionals' sides but they perceived that as stemming from the confusion caused by the Pharmacosmos representative providing incorrect dosing information in conflict with the [Monofer] SPC. Throughout the time in the complainant's presence, the TAM felt that he had answered the questions about dosing and safety appropriately and that the complainant welcomed the information and clarity he brought to the situation.

The complainant was very keen to ensure that the TAM received the email, taking the time to send a blank one immediately in the TAM's presence. The content, tone and speed of response (the complainant and the TAM exchanged four additional emails by 10am the next morning) seemed at odds with the claims that firstly the complainant had managed to ask the representatives to leave by

offering the email address and that any concerns could be emailed to the complainant in writing and secondly that once the Vifor representatives had left the department that afternoon the complainant emailed the consultant about their 'inappropriate and unprofessional behaviour'.

Vifor noted that the complainant referred to the last interaction between the Vifor employees and the consultant but there were clear discrepancies between both Vifor employees' experience of the meeting and the complainant's version of what happened.

In summary, Vifor conducted an in depth investigation into the allegations. The conduct of the investigation was such that neither Vifor employee was aware of the subject of the investigation. Both produced remarkably similar accounts in relation to a large number of events. The two similar accounts, however, differed significantly from the complainant's account. Based on the Vifor employee accounts, Vifor found no evidence to suggest that the frequency, timing and duration of calls or the manner in which they were made, had caused any inconvenience and it denied a breach of Clause 15.4.

Vifor submitted that it found no evidence that either Vifor employee had failed to maintain high standards of ethical conduct; both had acted within the relevant requirements of the Code. Vifor therefore refuted breaches of Clauses 15.2 and 9.1.

Furthermore, Vifor submitted that the activities carried out by its promotional staff has not brought discredit upon or reduced confidence in the pharmaceutical industry and therefore refuted a breach of Clause 2.

Safety data sent to the complainant (Clauses 9.9, 15.2, 9.1 and 2)

Vifor submitted that according to the TAM, it was the complainant who asked for the TAM's business card and, as they both stood there, sent a blank email to check that it would get through the hospital's firewall. This clearly illustrated that the complainant was happy to provide her email address. Vifor provided a copy of the email correspondence with the complainant and submitted that it indicated, in addition to concerns about dosing, the complainant was very concerned about the safety of the products given to patients and that was the focus of the proactive questioning. Both Vifor employees recalled that the complainant asked for comparative safety data between Ferinject and Monofer and both said that the medical information department would have to deal with the request.

In response to the TAM's email notifying the complainant that a written request for a medic to visit was required, the complainant reiterated the request for safety information: 'Can you just highlight to me the issues that *you mentioned* re: safety of Monofer etc.? That *you raised* yesterday'. This request, whilst only mentioning Monofer, was actually in relation to comparative safety data. In response, the TAM confirmed that the request had been referred to the medical department which would be in touch with more detailed information within a few days. The complainant acknowledged this with 'Ah ok fair enough I will await to hear from them', which indicated approval for information on this topic to be sent to her directly from the medical information department. In her emails to the TAM, the complainant never indicated that contact was not wanted by email or that she no longer wanted the information requested. The complainant was quick to respond to the TAM's emails (the two exchanged five emails between 16.25 on Thursday and 09.54 the following day). If the complainant was not happy with this correspondence it seemed odd that this was not highlighted at any point, either by email or by telephone (the TAM's contact details were clearly stated in the emails).

The RBM emailed the medical information team to request that a copy of the Lareb report be sent to the complainant which was subsequently sent. This report was the most appropriate document to send in response to a request for comparative safety data given that there was no direct head-to-head clinical trial data on Ferinject and Monofer. This report came from a highly respected information source, The Netherlands Pharmacovigilance Centre, Lareb. Lareb collected and analysed reports of adverse reactions to medicines and vaccines. Health professionals, patients and also manufacturers could report an adverse reaction. Anonymous copies of reports were sent to the European Medicines Agency and the World Health Organisation.

The specific report in question was entitled 'Intravenous iron preparations and allergic reactions' and compared Ferinject, Monofer and Diafer and was not specific to only Monofer. It provided objective, factual line listing reports of allergic reactions to the three medicines and concluded that 'special attention should be given to the comparison of the safety profile of the different intravenous iron-containing medicines and in particular to the safety profile of iron isomaltoside'. Vifor considered the report was of good standing and relevant to health professionals.

As highlighted in the account from both Vifor employees on the interactions with the complainant's colleague when they returned to see the complainant to check the information requested had been received, no mention was made of any dissatisfaction on the complainant's part or that information that was sent was not requested. Indeed they assumed that as the colleague had stated that the information would be forwarded to other health professionals, it was felt it was useful to share and the complainant was entirely happy with the information.

In summary, Vifor disputed the alleged breach of Clause 9.9. There was a clear email trail which indicated that the recipient had provided an email address, had requested safety information from this email address and acknowledged that the request was passed to the medical department and would be responded to.

Vifor also disputed the alleged breach of Clause 15.2. The Vifor employees in question had maintained a high standard of ethical conduct in their behaviour

in that they complied with the health professional's wishes and submitted the request to the medical team whilst keeping the complainant informed in a professional manner as evidenced in the email communications.

Subsequently, Vifor strongly believed that high standards had been maintained throughout and there had never been any concern that any action had brought discredit upon, or reduced confidence in, the pharmaceutical industry. Vifor thus denied breaches of Clauses 9.1 and 2.

Cumulative response to Clauses 15.2, 9.1 and 2

Vifor submitted that cumulatively, this complaint was composed of three components involving the conduct of two of its representatives allegedly making false claims about a medicine, inappropriate and unprofessional behaviour in the manner of calls being made and the sending of unsolicited medical information. The accounts given by both employees in relation to the meetings at the hospital bore little resemblance to the details given in the complaint.

Both Vifor employees were surprised that the complaint came from this particular individual and even more surprised when they read the content of the account. They recognised that there was some negative feeling and confusion from the complainant and a colleague but both strongly perceived this to be because of misinformation provided about Monofer by the Pharmacosmos representative and not directed at them. Indeed, they considered that their help to the health professionals in assessing the SPC dosing information assisted their objective assessment of the medicines.

That said, the fact that the two Vifor accounts were so similar but very different to the complainant's account, suggested that one account was incorrect. The fact that the Vifor representatives did not know why they were being asked to provide a statement in an interview corroborated the information supplied by them in their individual statements. There was nothing within the accounts which indicated that they had individually or together failed to uphold Clause 15.2. Vifor's investigation supported the claim that both employees maintained a high standard of ethical conduct in the discharge of their duties and complied with all relevant requirements of the Code.

Subsequently, Vifor strongly believed that high standards had been maintained throughout and there had never been any concern that any action had brought discredit upon, or reduced confidence in, the pharmaceutical industry. Vifor thus denied any breach of Clauses 9.1 or 2.

Vifor appreciated the opportunity to respond to the health professional's concerns. It was regrettable that any health professional might view Vifor employees' interactions in that light but Vifor respectfully concluded that the weight of evidence showed there was no basis for any breach of the Code.

In response to a request for further information, Vifor submitted that the TAM and RBM agreed that the RBM would send the complainant's request to the medical information department; the TAM thought that it had been done when he notified the complainant that the request had been referred, but it had not so the TAM prompted the RBM to send it.

Vifor submitted that the complainant did not request a copy of the Lareb report by name; she requested comparative safety data. According to Vifor, the Lareb report was the most appropriate document to send in the absence of any direct head-to-head clinical trial data for Ferinject and Monofer. Vifor representatives were aware of the report and the request to medical information referred to Lareb rather than IV preparations and allergic reactions for ease of writing.

Vifor apologised for mistakenly omitting the briefing to the field force from 24 February which reiterated that the Lareb report was not to be communicated with health professionals. Vifor provided a copy of the competitor update which mentioned the Lareb report and stated that if a customer asked about the detailed safety of Ferinject beyond the SPC, they should be referred to medical information which could provide detailed information and investigate further if necessary. Vifor explained that the Lareb report was an objective, independently produced report and a substantiable document in its own right. Vifor did not consider that certifying it for promotional use was appropriate as it did not permit representatives to discuss comparative safety in a promotional environment. Vifor considered that the report could be used as part of the legitimate exchange of medical and scientific information through the medical information function and its distribution was limited to that channel. The RBM knew about the report and considered that it would most appropriately answer the complainant's query.

Vifor submitted that in response to a question asked in the open Q&A session at the December sales conference, representatives were reminded not to discuss the safety of competitor products; it was a verbal response and as such there was no written briefing.

Vifor submitted that there was some confusion and discrepancy between the dates of meetings. Contrary to the complaint, the TAM did not recall a visit for a Monofer training session and assumed that the individual had referred to the afternoon meeting on 10 March. The four times the TAM visited the hospital were detailed above and verified within the CRM system.

The TAM explained that hospital staff asked if any centres had tried Monofer to which he responded that a couple had but had then switched back to Ferinject. No hospital names were given, although the TAM was referring to two named hospitals. When asked why, the TAM replied that he thought it was because of reactions. According to the TAM, the complainant stated that there had been a meeting of four accounts; three named plus the complainant's hospital about moving to Monofer and that a fourth hospital was using Monofer too. This was news to both the TAM and RBM and so they did not comment

further. That was the extent of the conversation they had on centres switching.

Vifor submitted that the competitor update at the December sales conference named several centres that had switched from Monofer to Ferinject. It was the first time that information had been included in a conference session and it was stated that the centres had unsuccessfully tried Monofer and had therefore switched back to Ferinject. Normally that type of information was included in the general manager's regular monthly report sent to all staff informing them of ongoing business performance. This took the form of a general business update and included amongst updates on sales performance and personnel changes etc, information relating to hospitals switching from Ferinject to Monofer and vice versa. Vifor was not briefed in relation to the proactive use of that factual information but considered it important that all staff were informed about the company.

Vifor provided a copy of the briefing document for the differentiator tool; there was no briefing associated with the Questions and Answers – Reactive document.

Vifor reiterated that as its report and that of the complainant were very different, it would not be helpful in maintaining and/or re-establishing a constructive relationship with the hospital trust for its comments and enclosures to be sent to the complainant. Vifor was also concerned that the information which was confidential would be forwarded to competitors.

PANEL RULING

The Panel noted that there were differences between the parties' accounts about what had been stated at the meeting and about the information which was subsequently sent to the complainant; it was extremely difficult in such cases to know exactly what had transpired. The complainant, a nurse, bore the burden of proof on the balance of probabilities. A judgement had to be made on the available evidence bearing in mind the extreme dissatisfaction usually required before an individual was moved to complain. The Panel noted Vifor's submission that its representatives' accounts were consistent but different to that of the complainant. In that regard the Panel noted that the complainant had provided statements from her colleagues which were very similar to her own.

The Panel noted that the complainant had alleged that the Vifor representatives had described Monofer as 'very dangerous' and 'not safe'. A colleague alleged that the representatives had tried to discredit Monofer 'in an intense way' and that they had referred to centres that had swapped from Ferinject to Monofer and 'had big reactions'. In this regard the Panel noted that in an account of the meeting one of the representatives stated that when asked if any centres had tried Monofer, he had replied that a couple had but then had to switch back. In response to a request for further information, Vifor submitted that when the nurses asked why the centres had switched back, the representative stated that he said he thought it was because of reactions. The Panel noted that following the meeting with the complainant, the consultant gastroenterologist had subsequently informed the representatives that there had been complaints from the infusion and IBD nurses although no details were given. The consultant had told the representatives that they should not have seen the nurses without seeing him.

The Panel noted Vifor's submission that during initial training, representatives were briefed not to discuss competitor products in detail and that questions about competitors' medicines should be referred to the relevant company. During an open Q&A session at the December 2015 sales conference, Vifor representatives were specifically reminded not to discuss the safety of competitor products. A briefing document approved in December 2015 however (ref UK/FER/15/0279, Competitor update – Monofer SPC changes) stated on the concluding slide that safety and tolerability was a key factor in choosing an IV iron. Representatives were informed that 5 named accounts had switched back to Ferinject from Monofer. No reason was stated for the switch but it was reasonable that representatives would assume that it was to do with safety and tolerability given that was the heading to the slide. The slide also referred to the Lareb report and quoted the following from it: 'special attention should be given to the comparison of the safety profile of the different intravenous iron-containing medicines and in particular to the safety profile of iron isomaltoside [Monofer]'. Finally representatives were told to 'Be proactively reactive. If a customer asks about the detailed safety of Ferinject beyond the SPC, please refer them to medical Information who can provide detailed information and investigate further if necessary'.

A briefing document approved in January 2016 (Questions and Answers. Reactive responses to competitor messages, ref UK/FER/15/0274f) listed the comments and messages from customers regarding Monofer and stated 'What we need to do is reactively discuss the FACTS in an accurate and balanced way, to allow the customer to make an informed decision'. The final message of the document was 'The Ferinject proposition is strong, be confident, we have the best treatment'.

Also in January 2016 the representatives had been given a slide set which specifically differentiated Ferinject from Monofer (the Intravenous Iron Differentiator tool ref UK/FER/15/0274a) and was designed to be used proactively in threatened accounts that were considering switching to Monofer and in accounts that had switched to Monofer. Again, the briefing material for that tool (ref UK/FER/15/0274e) stated, in summary, that 'The Ferinject proposition is strong, be confident, we have the best treatment'. In the Panel's view the briefing material was at odds with Vifor's submission that it did not permit representatives to discuss comparative safety in a promotional environment. The complainant was shown the tool in response to a query about using 2g of Monofer in a single visit. The slide shown to the complainant, and marked as such by Vifor, stated that the way in which the Monofer dose was

calculated (the Ganzoni formula) was 'recognised as inconvenient, prone to error, inconsistently used in clinical practice, and it underestimates iron requirements'. The briefing on this slide referred to Ganzoni-based dosing as being problematic.

In the Panel's view, there was no doubt that Vifor was specifically targeting Monofer sales and that the representatives had been briefed to discuss, or solicit ('be proactively reactive') questions about, the comparative safety of Ferinject vs Monofer and to view the Lareb report as a resource in that regard even if they couldn't distribute it themselves. As noted above, the representatives had also been informed, in a slide headed 'Safety and tolerability' that 5 accounts had switched back to Ferinject from Monofer.

The Panel considered that on the balance of probabilities, given the strident tone and content of the sales materials and briefings, the representatives had started to spread doubt amongst infusion nurses about the safety of Monofer as alleged and in that regard had offered misleading comparisons with Ferinject. Breaches of Clauses 7.2, 7.4 and 7.9 were ruled. The Panel considered that the briefing material advocated a course of action which was likely to be in breach of the Code. A breach of Clause 15.9 was ruled.

The Panel noted that the complainant had been sent a copy of the Lareb report which she stated she had not requested. Vifor submitted that she had asked for comparative safety data and that the Lareb report was the most appropriate document to send given the absence of any direct head-to-head clinical trial data of Ferinject vs Monofer. The Panel noted that after sending the representatives a test email, the complainant received a follow-up email from one of the representatives that evening requesting the she send him 'a new email requesting what we discussed about our medic coming to see you in April'. The complainant replied stating 'No problem. Can you just highlight to me the issues *you mentioned* re: safety of Monofer etc? That *you raised* yesterday' (emphasis added). In that regard, the Panel considered that it seemed clear that issues about the safety of Monofer had been raised by the representative, not by the complainant. The Panel noted Vifor's submission that the complainant questioned the safety data and asked for comparative safety data. In that regard the complainant's request for more information was not unsolicited. In reply the representative stated that he had already referred the complainant's request to the medical department as he wanted to ensure that the reply was 'totally non promotional' and that the complainant received the information from a qualified medic. The representative, however, emailed the medical information department and stated that the complainant had 'kindly requested a copy of the Lareb report'. This was not so. In response the medical information department replied with a link to the Lareb report; the only substantive statement in the email was that '…Lareb has received concerns from multiple Dutch hospitals in relation to [Monofer] after the switch from [Ferinject]. Doctors and nurses reported an increase in the severity and incidence of allergic reaction. The report has not mentioned any specific safety concerns with [Ferinject]'. The latter statement was untrue as the report detailed 7 reports of hypersensitivity/anaphylactic reactions associated with the use of Ferinject.

The Panel noted that Clause 1.2 of the Code stated that replies made in response to individual enquiries from, *inter alia*, a health professional were not included in the definition of promotion but only if such replies related solely to the subject matter of the enquiry, were accurate and did not mislead and were not promotional in nature. Supplementary information to Clause 1.2 made it clear that the exemption was only in respect of unsolicited enquiries. In that regard the Panel noted that the query was not unsolicited and that the representative had misrepresented to the medical information department what the complainant had asked for. Further the email from the medical information department did not put the results of the Lareb report in to context and did not note that there were no direct head-to-head comparisons of Ferinject and Monofer. The statement that the report had not mentioned any specific safety concerns with Ferinject was inaccurate. The Panel thus considered that the email from medical information could not take the benefit of the exemption in Clause 1.2 to the definition of promotion, it was neither unsolicited nor fair and balanced. The complainant had thus been sent a promotional email without her prior permission. A breach of Clause 9.9 was ruled.

The Panel noted that the complainant alleged that the way that the two representatives 'just turned up' was 'inappropriate and unprofessional'; the representatives had visited the complainant in the late afternoon after completing a lunchtime meeting. The Panel noted that Clause 15.4 did not prevent representatives 'cold calling' on health professionals provided that the frequency and duration of such calls was appropriate and that the representatives respected the wishes of those upon whom they called and observed the arrangements in force at the establishment. The complainant had not provided any evidence that the representatives had not observed the arrangements in force at the hospital neither was there evidence to show that the representatives had not respected the complainant's wishes. Clearly she was unhappy about the tone and content of the conversation but she had not tried to refuse to see the representatives (indeed she acknowledged that she had introduced herself to them) nor did it appear that she had subsequently asked them to leave. The complainant had introduced herself to the representatives and in that regard the Panel considered that she had given tacit permission for the meeting to go ahead. Although the Panel noted that the consultant gastroenterologist had subsequently told the representatives that they should not see the nurses without seeing him, the Panel had no evidence before it to show that that arrangement was in force when the meeting took place. No breach of Clause 15.4 was ruled.

The Panel noted its rulings and comments above and considered that the representatives had not

maintained a high standard of ethical conduct. A breach of Clause 15.2 was ruled. In that regard high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted that a ruling of a breach of Clause 2 was a sign of particular censure. The Panel was concerned that the two representatives appeared to be cold calling on infusion and IBD nurses specifically to solicit discussion about Ferinject vs Monofer. The representatives had not called upon the relevant medical consultant – although the Panel noted that securing a meeting with him was not easy. The promotional tool which they had been given was specifically for proactive use in threatened accounts that were considering switching to Monofer and in accounts that had switched to Monofer. The hospital trust in question appeared to be considering the use of Monofer. The Panel noted the complainant's and her colleagues' views that the two had been scaremongering and that their approach was challenging and aggressive. The representatives had ensured that the complainant had received a copy of the Lareb report and in the Panel's view the covering medical information email had been promotional. The Panel noted its rulings and comments above and considered that, on the balance of probabilities, Vifor's activities and materials associated with the promotion of Ferinject had been such that they brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

During its consideration of this case, the Panel was concerned to note that two briefing documents (refs UK/FER/15/0274e and f) stated on their summary pages that 'The Ferinject proposition is strong, be confident, we have *the best* treatment' (emphasis added). The Panel noted the use of a superlative and queried its acceptability under the Code.

The Panel was also concerned to note that Vifor did not consider it appropriate to certify the Lareb report for promotional use as it did not permit representatives to discuss comparative safety in a promotional environment. Vifor considered that the report could be used as part of the legitimate exchange of medical and scientific information through the medical information function and its distribution was limited to that channel. Conversely, however, the Panel noted that an email to the salesforce dated 24 February 2016 reiterated what was stated at the December conference ie that the Dutch Lareb report was not to be communicated in any way with health professionals. Further, the Panel noted that the representatives' briefing material (ref UK/FER/15/0279) referred to the Lareb report and in that regard would encourage them to ensure that it was used given that they were informed that the report stated that special attention should be given to the safety profile of Monofer. In the Panel's view, the Lareb report was being used promotionally, albeit indirectly, despite not having been approved for such use.

The Panel was concerned to note Vifor's submission that the requirements of Clause 15.4 were only detailed during the ITC, they were not otherwise referred to in any standard operating procedures or policies. In that regard the Panel noted that Section 17 of the guidelines on company procedures relating to the Code, Representatives' Training, stated that representatives should be provided with written instructions on the application of the Code to their work, even if they were also provided with an actual copy of it.

The Panel asked that Vifor be advised of its concerns.

APPEAL BY VIFOR

Vifor appealed all breaches other than of Clauses 9.9 and 15.2 (as it applied to the Clause 9.9 breach) as it accepted that the way in which the Lareb report was distributed, and the content of the report described, could have been better. However, Vifor did not accept that either the company or its representatives had failed to maintain high standards in relation to any other of their activities. Vifor also submitted witness statements from the two representatives in question corroborated by statements of truth. Vifor submitted that these statements must be read together with its grounds for appeal.

Vifor had reviewed the Panel's ruling and the material submitted as part of the complaint and also the additional evidence from the complainant that was not provided until after the Panel's ruling. Vifor appealed the Panel's ruling on the basis that the evidence provided fell far short of proving that its representatives had described Monofer as 'very dangerous' and 'not safe' in a meeting with the complainant. The company's position (as reflected in the evidence from its internal investigation and also with the witness statement) was that its representatives did not make these statements. Vifor submitted that the Panel erred in placing greater weight on the complainant's evidence, particularly since that evidence appeared largely to be second-hand hearsay from colleagues who could not even be sure that they were talking about the same representatives and who were not present at the meeting at issue (see Ground 1: Burden of proof).

Vifor further submitted that the complainant did not complete the necessary conflict of interest declarations that had a bearing on the weight that could be attached to non-industry complaints. Vifor submitted that such declarations were particularly important in this case since Pharmacosmos (Vifor's main competitor) had clearly communicated with the complainant and its own complaint (Case AUTH/2830/3/16) was on largely the same issue. Vifor appealed, *inter alia*, on the basis that Pharmacosmos did not have standing to bring a complaint. In that situation, it would be in Pharmacosmos's interest to encourage a non-industry complaint so that it could ensure that at least one complainant would have standing.

Moreover, Vifor submitted that it was unable to review, comment and, if necessary, contradict all of the complainant's evidence since the PMCPA disclosed this evidence after it had taken the decision. These were not merely procedural niceties. They were written into the PMCPA Constitution and Procedure

(eg Paragraph 5.2) and also reflected fundamental principles of fairness (see Ground 2: Fairness).

Vifor appealed the Panel's ruling of breaches of Clauses 15.9 and 9.1 in relation to its briefing material. Vifor could not understand how the Panel could reasonably come to the conclusion it did based on the material provided (see Ground 3: Panel misinterpretation of Vifor briefing materials). Finally, Vifor also appealed the Panel's ruling of a breach of Clause 2, which it considered to be disproportionate based on the facts and circumstances of this case as well as the evidence submitted by the complainant (see Ground 4: Clause 2 and proportionality).

Notwithstanding the above, Vifor accepted that it should have handled the request for comparative safety data differently. Vifor accepted the rulings in that regard, including a breach of Clause 15.2 as it applied to the handling of that issue. Vifor had also updated its medical information processes to address this process flaw and ensure that this could not happen again and it had immediately put in place a system of having its senior managers and/or internal lawyers accompany some of its representatives to ensure that they conducted themselves to the highest ethical standards.

Finally, Vifor requested that the complainant agree a confidentiality undertaking before being sent the documents as some passages of the documents were confidential.

Grounds of Appeal

Ground 1: Burden of proof

Vifor did not accept the Panel's observation that this was a case where it was extremely difficult to know exactly what had transpired. Vifor strongly denied that its representatives had described Monofer as 'very dangerous', 'not safe', and that those centres that switched from Ferinject to Monofer 'had big reactions' (this latter comment came from a colleague of the complainant who was not a party to the case, had not signed the relevant declaration of interest forms and who the PMCPA could not question further). The burden of proof rested with the complainant and the Panel was wrong to find that the burden had been discharged with respect to the complainant's allegations.

Vifor noted that the standard of proof in the Panel's rulings was on 'the balance of probabilities'; the same test as in civil litigation. In Miller v Minister of Pensions [1947] 2 All E.R. 372, QBD, Denning J. explained the balance of probabilities as follows (at page 374):

> 'If the evidence is such that the tribunal can say "We think it more probable than not", the burden is discharged, **but if the probabilities are equal, it is not**.
>
> In essence, in order to satisfy the judge that one party's version of the events is the version to be accepted, **the judge has to be convinced** that this version is more likely than not to be true-that the balance of evidence is tilted in the client's favour. If this were to be expressed in simple mathematical terms, at least a 51 per cent probability in favour of the client must be demonstrated, as suggested by Lord Simon in Davies v Taylor [1974] A.C. 207, HL (at p.219). **If, on the other hand, the client's version is just as probable as the opponent's version, the client has failed to discharge the burden of proof**.'

Vifor's submitted that, at its worst, its version of events was just as probable as the complainant's. However, Vifor had since corroborated that evidence with statements of truth from the representatives who met with the complainant and so it would expect very clear reasons from the PMCPA (and indeed the complainant) if this account was not to be believed. Vifor noted that this matter stemmed from the fact that in the hospital in question there was significant confusion about Monofer dosing; this was what its internal investigation reported back and it seemed consistent with the evidence disclosed with the Panel outcome (evidence that had not been provided to Vifor prior to the Panel's ruling). Vifor submitted that clearly inaccurate statements from Pharmacosmos representatives had had some role to play in the creation of the confusion about appropriate dosing that was present in the hospital's own medical infusion unit.

Vifor noted that when the Appeal Board had had to consider the burden of proof (eg Case AUTH/2572/1/13) it indicated that where 'it is not always clear how/whether the material supported the complainant's allegation… the Appeal Board had to decide how much weight to attach to this evidence'. This passage from the Appeal Board ruling was relevant to this case because, by the Panel's own admission, the evidence was finely-balanced making it 'extremely difficult' to ascertain what was correct and what was not. In Case AUTH/2572/1/13 the Appeal Board considered that extracts from emails and excerpts from published papers were insufficient evidence. The Appeal Board made it clear that where the complainant failed to provide sufficient evidence to discharge the burden of proof, there should not be a ruling of a breach.

> '[where] there is insufficient evidence provided by the complainant …. The Appeal Board considered that the complainant had not discharged its burden of proof and it upheld the Panel's ruling of no breach ...'

Vifor submitted that this reflected a general and widely-acknowledged strand in the law of evidence that 'the weight of evidence depends on the rules of common sense' (R. v Madhub Chunder (1874) 21 W.R Cr. 13 at 19 (Ind) per Birch J).

Further, Vifor noted in Case AUTH/2824/2/16, that the Panel had to determine whether there was sufficient evidence to substantiate the allegation that representatives went to a named location contrary to the terms of a verbal undertaking. The Panel found there to be no evidence to substantiate the complainant's allegations that the representatives visited the named location and therefore no

breaches were ruled. The essence of this case was to demonstrate the difficulty of substantiating an event where there was competing anecdotal or hearsay evidence. Allegations should be substantiated. Such allegations were not substantiated in Case AUTH/2824/2/16 nor were they substantiated by the complainant in this case, but call records were provided by Vifor to substantiate their representatives' version of the timings and indeed occurrence of events (see point c below).

In considering the weight of the evidence, Vifor submitted that the Panel failed to properly take account of material points made by the company and/or manifestly misinterpreted the documents. Vifor also submitted that the Panel failed to take into account the robust nature of the investigation it carried out. Vifor had interviewed both representatives independently and without either knowing the substance of the complaint; the two accounts were strikingly similar. Vifor submitted, in particular:

a) The Panel did not give due weight, if at all, to the reactive rather than proactive nature of the conduct complained of. Vifor literature and guidance supported the fact that Vifor representatives were only ever reactive and were consistently instructed only to be reactive in situations such as those described.

b) The Panel had placed undue emphasis on the email from the complainant that the initiative was taken by the Vifor representative. Vifor noted email correspondence between the complainant and one of the Vifor representatives, dated 10 and 11 March 2016 which showed that initial contact was made by the complainant. The first response from the representative clarified that any future meeting would be a 'totally non-promotional meeting and purely a medical meeting on iv irons'. When the complainant asked the representative for information on the safety of Monofer the representative replied to confirm that the query would be handled by the 'medical department' so that the answer could be supported by 'the best form of clinical knowledge' that would better enable the complainant to make a 'clinically informed decision'. Again, the representative emphasised that he wanted to 'keep this totally non promotional and you receive the information from a qualified medic'. Vifor had accepted that this request should have been handled differently and had accepted a breach and addressed this issue by revising its medical information request processes.

c) Vifor submitted that there was also clearly confusion about who attended which meetings and when. Vifor stated that it had provided all account activity backed by call records (see discussion of Case AUTH/2824/2/16 above) for the two representatives concerned and that this account activity simply did not match the complainant's account of the evidence. Yet the Panel ignored this material evidence in favour of the complainant's hearsay evidence.

Vifor submitted that the Panel also appeared to have ignored or have placed limited weight on a number of facts already before it that militated against its findings (note, these points were also relevant for Ground 3: Panel misinterpretation of Vifor briefing materials).

a) Vifor had emphasised that its representatives were briefed not to discuss comparative safety data beyond the SPC. The SPC key information approved by the regulatory body and the information contained within the SPC was, therefore, accurate, balanced, fair, objective and unambiguous and based on an up-to-date evaluation of all the evidence. Vifor did not draw any of its own conclusions from the SPC comparison but presented the data side-by-side (as in the SPC comparator) to allow health professionals to make their own decisions. Vifor encouraged the Appeal Board to read all of its briefing material and not merely the statements selected by the Panel which had been misinterpreted and taken out of context to suggest a culture of non-compliance within the company when in fact the opposite was true.

b) Vifor submitted that during an open Q&A session at the December 2015 sales conference, Vifor representatives were specifically reminded not to discuss the safety of competitor products. In fact, the briefing documents in question covered only 2 hours of a 32 hour conference.

c) Vifor representatives were told:

> 'Be proactively *reactive*. If a customer asks about the detailed safety of Ferinject beyond the SPC, please refer them to medical information who can provide detailed information and investigate further if necessary' (emphasis added).

d) Vifor noted that its briefing document, approved in January 2016 (ref UK/FER/15/0274f), listed the comments and messages received from customers and was intended to be reactive responses to customer questions about Monofer. The document stated that 'What we need to do is reactively discuss the FACTS in an accurate and balanced way, to allow the customer to make an informed decision'. Even without the emphasis, it was clear that the salesforce was being encouraged to be responsive and reactive and, even then, in a way that was factual and accurate. Good practice was again reinforced in the summary slide at the end: 'Be professional, never disparage the competition' and 'Discuss the facts in an accurate and balanced way'.

e) Vifor submitted that there remained some uncertainty over the nature of the conduct complained of. In its ruling the Panel correctly set out Vifor's representatives' approach as 'proactively reactive'. There should be no confusion here; the verb was 'reactive', the adverb was 'proactively'. The adverb merely described the action that was the verb in this instance; the adverb 'proactively' did not change the meaning of the phrase to mean that the representatives ceased to behave reactively. Vifor encouraged its

representatives to be experts in their field so that they could respond actively, fully, factually and in a timely manner to all requests for information by health professionals. It was clearly in the best interests of the medical profession and patients to get timely, factual and complete responses to an enquiry rather than some of the information in an inefficient manner. It was fundamentally important that messages were communicated reactively in response to enquiries. The use of the adverb 'proactively' in this context was a clear call to representatives to actively take time to learn all facts, data, SPCs etc, relevant to their therapy area so they could respond to customer enquiries in an efficient, factual, constructive and complete manner.

Vifor submitted that contrary to the complainant's allegations and the Panel's findings, any briefing materials, properly certified, were measured and complied with the Code. Vifor's numerous policies and training materials ensured that its staff were reliably informed about the practises required for compliance with the Code and in that regard Vifor noted its ethics and compliance initial training course slide presentation. There was repeated emphasis throughout this presentation that when promoting (whether verbally or in writing) products, due regard should be had to numerous factors, including that the information was accurate, balanced, not misleading or exaggerated and should be capable of substantiation. Moreover, staff were told that they should 'remember that frequency, timing, duration and manner of calls must not cause inconvenience'. In addition, the briefing material clearly stated 'Be professional, never disparage the competition'. The content of this material, if properly certified as briefing material, was far from 'strident'.

Vifor took umbrage in the Panel's purported reliance on its statement (found at the end of some briefing materials as a signing-off statement rather than in the midst of the instructions) to its salesforce that 'The Ferinject proposition is strong, be confident, we have the best treatment'. Far from anything else, this statement was solely intended as a signing-off statement to give the salesforce confidence in the product that it would then attempt to sell. In any event, the Panel was wrong to place as much emphasis as it had done on this given that the preceding bullet point stated 'Customers have chosen Ferinject to be the market leading IV iron in the UK' which, itself, vindicated the statement that had caused the Panel to express concern. The internal statement did not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code.

Vifor submitted that the industry commonly used such statements to motivate the salesforce or employees more generally by instilling belief in the product or services. An appropriate and every-day analogy would be speeches or 'pep-talks' given on staff appreciation or away-days to motivate a salesforce. It was important to note that neither the statements such as the ones complained of nor the analogous examples offered here prevented or precluded representatives discussing comparative safety in a promotional environment or advocated, directly or indirectly, any course of action which would be likely to lead to a breach of the Code.

Vifor submitted that to conclude on this point, the Panel had a duty to take into account the material submitted by the respondent (see, R v Manchester Metropolitan University, ex parte Nolan [1990] ELR 380). If the Panel had taken Vifor's evidence into account, Vifor could not see a rational basis for finding this evidence inferior to the evidence submitted by the complainant and the evidence purportedly in support. In giving undue weight to the evidence against Vifor, the Panel had breached principles of natural justice. It was well established that a finding of fact was unreasonable if the evidence in support was insufficient to warrant such a finding (see R v Ealing London Borough, ex parte Richardson (1982) 4 HLR 125).

Ground 2: Fairness

(a) Conflict of interest declarations

Vifor submitted that during discussions with the PMCPA about the handling of a parallel complaint (Case AUTH/2830/3/16 – Pharmacosmos v Vifor), it became clear that Vifor had not been provided with all the evidence submitted by Pharmacosmos. Therefore, in its notice of appeal in the present case, it asked the PMCPA to reveal any additional evidence sent through by the complainant that it had not seen. Vifor also asked for copies of the applicable conflict of interest declarations from the complainant since this was a specific constitutional requirement pursuant to Paragraph 5.2 of the Constitution and Procedure.

Vifor noted that the PMCPA responded with the emails provided by the complainant which hitherto it had not seen. Further, the PMCPA confirmed as follows:

'The [complainant]…was asked, in a standard letter (dated 23 March), sent by the case preparation manager [named] whether she had any direct or indirect commercial, financial or other interest in the matter of complaint such as being an ex-employee of Vifor Pharma, one of its competitors to any other pharmaceutical company. *No reply was received to that question but it is not unusual for that to happen. Lack of such a response does not preclude a complaint proceeding…There is nothing in the correspondence in either case to suggest that [complainant] did other than complain in her own right as an independent health professional*. That she had contact with Pharmacosmos is not unexpected given the therapy area. There may only be a temporal relationship between the two complaints but this could be a matter for you to address in your appeal.' (emphasis added).

Vifor submitted that these comments were quite remarkable for four reasons. First, the absence of a completed declaration form must be a key factor when the Panel assessed the evidence and decided what weight should be attached to it. In Vifor's view, the absence of this declaration meant that considerably less weight should be attached to the complainant's evidence. Second, the PMCPA's

failure to follow-up on this declaration could not be taken as read that there was no conflict, despite the PMCPA requesting additional information from the complainant in July 2016 which would have been the ideal time to ask for the completed conflict of interest declaration to be sent. Otherwise, it risked rendering redundant this specific requirement to declare conflicts in the Constitution and Procedure (Paragraph 5.2). Third, the statement that there was nothing in the correspondence to suggest that there might be a conflict was a non-sequitur since plainly the complainant did not respond to this key question despite several exchanges of correspondence between the PMPCA and the complainant. Fourth, Vifor would expect the temporal relationship between the two apparently related complaints to make the need for a conflict of interest declaration even more acute. As such, the omission of this declaration in the correspondence was a key concern for Vifor.

(b) Email correspondence from the complainant and her colleagues

The PMCPA disclosed additional evidence from the complainant that Vifor had not seen prior to the Panel's ruling. The PMCPA's explanation of this was that:

> '... the Panel considered it would be helpful to see if further context to the complaint could be gleamed from [the complainant's] emails with her colleagues. In the Panel's view, the additional material *did not add anything substantive to the information already submitted*; [the complainant] had clearly copied much of her colleagues' comments into her letter of complaint which was sent to you on 23 March and the email to her consultant did no more than echo her letter to the Authority. As the additional information *neither changed the complaint nor added further context*, I disagree that not sending it to you sooner has rendered the complaints process manifestly unfair as you allege' (emphasis added).

However, Vifor respectfully disagreed in relation to the general position of fairness but also as to the substantive points given that this case hinged on the balance of probabilities. In relation to general fairness, the unfairness created by not providing Vifor with these documents before the Panel's ruling was best characterised by Lord Denning in one of the leading cases in this area that the accused person:

> '... must know what evidence has been given and what statements have been made affecting him; and he must be given a fair opportunity to correct or contradict them...It follows, of course, that the judge or whoever has to adjudicate must not hear evidence or receive representations from one side behind the back of the other. The court will not inquire whether the evidence or representations did work to his prejudice, sufficient that they might do so. The court will not go into the likelihood of prejudice. The risk of it is enough.' (Kanda v Government of the Federation of Malaya [1962] AC 322).

Vifor submitted that the mere fact that the PMCPA failed to disclose these documents rendered the process unfair.

Regarding the substantive and contextual aspects, Vifor considered that the omitted emails were highly relevant. It was not until being notified of the Panel's ruling (and subsequently confirmed when Vifor asked for the evidence) that it became clear that the PMCPA had selectively extracted content from one of the emails to support its finding that the representatives were scaremongering and that the complainant's colleagues had provided statements 'very similar to her own'. The original complaint that Vifor was asked to respond to only included the selected quotation: 'I too had one of these unannounced visits from them, and totally agree that they were scaremongering'. However, the Panel's ruling went on to provide the full content of the email as follows: 'I too had one of these unannounced visits from them, and totally agree that they were scaremongering. Stating that more than 1g of Monofer could only be given in one dose with over 100Kg patient and not with those with bleeding. It was unprofessional, and agree that a complaint is a good idea'. If Vifor had been given the full information, it could have responded to it in full. It was very clear from the revised full statement, that there was indeed a discussion about dosing which was consistent with the representatives' unprompted version of events. Vifor's representative statements made clear that they were addressing misconceptions and confusion on the correct dosing of Monofer, which was reflected in the health professional account, which incorrectly referenced the 1g dose of Monofer; Vifor representatives understood that this reference would be 2g as was clear in the witness statement from the representative:

> 'The discussion turned to the possible hospital switch to Monofer due mainly to their (inaccurate) belief that all patients could be given 2g in one visit. I stated that this was incorrect, not all patients could be given this dose in one visit. When the third nurse explained that "that's not what we were led to believe on Monofer dosing", I helped the nurse understand the correct dosing using the Intravenous Iron Differentiator tool.'

Vifor submitted that had it had sight of these documents, it could, for example, also have queried the veracity of the evidence from the complainant's colleagues since the internal emails from the complainant referred to '[named representative] and his colleague'. In that situation, how could those other colleagues (let alone Vifor or the Panel) be absolutely sure who they were commenting on (other than the named representative). This point was made as part of Vifor's response to these very specific aspects.

Vifor submitted that for example, in response to the allegation that 'the representative and his colleague visited *several* of my other colleagues in other departments (on more than one occasion) and have also upset them' (emphasis added), the company's internal investigation found as follows:

[named RBM] has not met any other departments with me where they have been upset and the time he did visit the infusion nurse with me they commented how polite he was.' (Documented comment from the representative).

Vifor submitted that in response to the allegation that 'I too had one of these unannounced visits from them, and totally agree that they were scaremongering', its internal investigation found as follows (backed up by call report records which was material evidence):

'I do not know who would have said this as [named RBM] has only seen the IBD nurses with me and as I have already mentioned they commented on how nice he was. [named RBM] has only been at the hospital once with me before on 16 February where we saw the infusion nurse team. They were very happy to see us ....' (Documented comment from the representative).

Vifor submitted that rather than scaremongering, the representatives were trying to address incorrect information, which appeared to be recognised by the health professionals involved following the information provided by its representatives, as described in the representative's witness statement:

'It was clear that some discussions between the two healthcare professionals had been held following the morning meeting and the complainant (the third healthcare professional) proactively asked to see the dosing information in the Intravenous Iron Differentiator tool to which the response was "that's interesting, that's not what we've been led to believe, I'm a nurse practitioner, it's important I get the full picture." The third nurse stated that an email would be sent to the pharmacist for clarification on the dosing issue.'

Vifor's representatives - to the extent that they were present at the alleged meetings - engaged in factual, balanced and reactive discussions about dosing. Vifor did not agree that having such discussions was unprofessional or constituted scaremongering. It was in fact very important to get dosing right in the interests of patient safety. This was particularly important given that there appeared to be widespread confusion within the hospital on this issue and that some of the confusion might have resulted from internal miscommunications or misunderstandings.

Vifor concluded that the manner in which this information was disclosed to it after the Panel's ruling had been made was manifestly unfair. Now that Vifor had briefly seen those documents, it was clear that they did alter the substance (at least from a burden of proof perspective) and, in its view, significantly weakened the complainant's case.

Ground 3: Panel misinterpretation of Vifor briefing materials

Vifor appealed against the Panel's ruling that it was in breach of Clause 15.9. Vifor submitted that it did not understand how the Panel could reasonably conclude that its briefing material advocated a course of action that would be likely to lead to a breach of the Code. This was tantamount to saying that the company had a culture of briefing its representatives to be non-compliant. This could not be further from the truth.

Vifor was committed to adhering to the Code and accepted that compliance with the Code was critically important to the successful relationship between industry, the health professions and the public. The company had a responsibility to uphold the highest standards in itself, its own employees and activities at all times.

Vifor submitted that the PMCPA was fully aware of the company's compliance activities and the seriousness with which Vifor took compliance with the Code and these had only been strengthened since the PMCPA audited Vifor's procedures in relation to the Code in October 2012. Vifor had invested a huge amount of time and resource into building a compliant culture and all staff attached great importance in maintaining this. Vifor stated that the Panel's comments about the requirements of Clause 15.4 had now been incorporated into Vifor's Field Force meetings SOP which was currently under review as part of its regularly scheduled SOP updates. Specifically, Vifor had:

- Code of Practice training for all new starters
- Regular review of SOPs
- Internal audits
- Regular 'Lunch and Learn' sessions covering PMCPA cases
- Regional compliance liaisons (an individual from each of our regional teams who work closely with compliance and ensures effective communication of compliance-related information)
- Quarterly 'Getting it Right' compliance newsletter
- Vifor Code compliance website
- Advanced Code training for marketing and medical
- Final signatories forum
- Externally led training sessions for key staff
- Electronic training system.

Vifor submitted that all staff were very proud of its compliant culture and this was a central thread in all of its operations. However, Vifor noted that it effectively operated in a two company therapy area. Vifor agreed to abide by the Code and Pharmacosmos did not. This fact notwithstanding, it was inevitable that in a two product therapy area, health professionals would ask both companies' representatives for comparative data. It was in exactly this situation that Vifor's compliance culture and briefing documents to the sales team became exceptionally important and guided field-based employees in particular on how they should handle such situations.

Vifor submitted that the Panel's decision was not one that a reasonable decision-maker faced with the same briefing materials would take and it encouraged the Appeal Board to read the materials at issue in full. The Panel appeared to have focussed almost exclusively on the phrase 'The Ferinject proposition is strong, be confident, we have the best treatment' found at

the end of one of Vifor's briefing documents (ranging from 14 to 26 pages in length), and so needed to be read in context of the briefing document as a whole and previous briefing documents.

Vifor submitted that UK/FER/13/0201 dated back to 2013 but gave an objective overview of changes to the SPCs for both Ferinject and Monofer and recent clinical studies within the relevant therapy area and concluded (without any mention of Monofer) that '… we have the most documented evidence …'.

Vifor submitted that UK/FER/15/0015b was created in mid-2015 to introduce the SPC comparator, which was a simple factual re-representation of the SPCs of all the IV irons. It did not editorialise or comment upon the content in any way and the direction given to its use was simply '… use when asked specific questions about the Vifor irons and those of our competitors …' illustrating again the objectivity of the material provided. Vifor remained perplexed as to why the Panel took exception to the instruction '… you can also project this from your iPad for use with multiple HCPs at meetings …' [in Case AUTH/2830/4/16] as this was common practice within the industry.

Vifor noted that the Panel ruling commented on a briefing document UK/FER/15/0279, in which it stated:

> 'Five accounts had switched from Ferinject to Monofer. No reason was stated for the switch but it was reasonable that representatives would assume that it was to do with safety and tolerability given that was the heading to the slide.'

Vifor considered it appropriate to share factual information and knowledge about events and developments in the market with its representatives. All of the content on the briefing slide in question was factual and accurate. Vifor submitted that it knew that the representatives invariably discussed occurrences such as this between themselves. The purpose of providing this sort of update was to prevent inappropriate use of such knowledge. The briefing document did not give reasons for the mentioned accounts switching from one product to another, nor did it instruct the representatives to use this information proactively with health professionals, quite the opposite.

Vifor submitted that the Ferinject Differentiation from Monofer slide set (ref UK/FER/15/0274a) and its accompanying briefing document (ref UK/FER/15/0274e) were created in January 2015 for use at a sales conference. They covered randomized clinical trials in the therapy area and the respective products' SPCs in depth. The associated briefing document was objective and factual and whilst it instructed that the slides were designed to be used in accounts that were considering and in those that had switched to Monofer, nothing in either the slides or briefing document was inconsistent with the facts of either the clinical trials or SPCs of the products in question and representatives were encouraged '… if additional information is requested, complete the Medical Information request form' (the Panel's comments on the statement '… The Ferinject proposition is strong, be confident, we have the best treatment …' were addressed below). Vifor was perplexed by the Panel's reference to the statement that the Ganzoni formula used to calculate the Monofer dose was '… recognised as inconvenient, prone to error, inconsistently used in clinical practice, and it underestimates iron requirements'. The briefing on this slide referred to Ganzoni-based dosing as being problematic …'. Ganzoni-based dosing was problematic and it was not misleading to say so, as substantiated by the citation supporting that conclusion.

Vifor submitted that the briefing document UK/FER/15/0274f was also created for the January 2015 sales conference and was a pivotal document in both the PMCPA's interpretation of the actions it had allegedly encouraged its representatives to take and in Vifor's defence. It was important to read this document in full. The heading of the briefing was 'Reactive Responses to Competitor Messages'; the first slide of the document was headed 'Customer Reported Monofer Messages' and listed below the headline were 10 comments that had reportedly been stated by Monofer representatives to customers and upon which the Vifor representatives needed clarity.

Vifor submitted that the first slide of the deck clearly stated '… what we need to do reactively is to discuss the FACTS in an accurate and balanced way, to allow the customer to make an informed decision …'. The remainder of the briefing document then covered each one of the 10 reported misinformation topics and presented the facts regarding this misinformation in a clear, objective, fully compliant appropriate way. The summary slide stated, in full:

- Be professional, never disparage the competition
- Discuss the facts in an accurate and balanced way
- If the customer wants extra information on Ferinject, offer the Medical Information service
- Following this advice will build the customers credibility and respect for you
- The Ferinject proposition is strong, be confident, we have the best treatment.'

Vifor submitted that the single, final summary statement could not simply render all of its briefing materials as being in breach of Clause 15.9, disparaging the competition, and contributing to a ruling of a breach of Clause 2. The final statement was simply the logical progression of all the previous information, ie if the Vifor representatives concentrated on the facts in an accurate and balanced way, acted professionally they would build credibility and respect with their customers and not disparage the competition. The final statement simply reinforced that if they did all of the above they could have confidence that their customers would choose Ferinject based on the facts as the facts would illustrate that it had the best treatment. The statement itself was purely motivational for internal use and did not appear in any promotional materials. If the Appeal Board considered that this type of statement could not be included in context in Vifor's internal communications, it would appreciate a thorough explanation in the case report for transparency purposes in light of the fact that the ABPI itself and several companies represented on the ABPI Board included public-facing motivational

statements eg Vifor noted (since the ABPI president was the general manager of Amgen), the company's missions and values on the UK website stated:

> *'Compete Intensely and Win* -- We compete against time, past performance and industry rivals to rapidly achieve high quality results. *Winning requires taking risks*. We cannot be lulled into complacency by previous achievements. *Though we compete intensely, we maintain high ethical standards and demand integrity in our dealings with competitors, customers, partners and each other*' (emphasis added).

Vifor submitted that pharmaceutical companies should, in the right context, be able to motivate its representatives in an appropriate manner. This was far removed from advocating a course of action which would be likely to lead to a breach of the Code.

In summary, Vifor disagreed with the Panel's conclusion '… In the Panel's view, there was no doubt that Vifor was specifically targeting Monofer sales and representatives had been briefed to discuss, solicit ("be proactively reactive") questions about, the comparative safety of Ferinject vs Monofer…'. This was simply not true.

Ground 4: Clause 2 and proportionality

Vifor was particularly concerned about the Panel's ruling of a breach of Clause 2. Such a finding was manifestly disproportionate bearing in mind all of the points made above, in particular the comments made in Grounds 2 and 3 above. The matter in question related to an isolated incident that did not reflect how the company conducted itself generally or had any bearing on the company's very positive compliance culture.

As noted by the Panel, a ruling of a breach of Clause 2 was a sign of particular censure. It was plain that a finding of breach carried with it, in and of itself, qualities that were punitive in nature. The supplementary information to Clause 2 stated that:

> 'Examples of activities that are likely to be in breach of Clause 2 include prejudicing patient safety and/or public health, excessive hospitality, inducements to prescribe, inadequate action leading to a breach of undertaking, promotion prior to the grant of a marketing authorization, conduct of company employees/agents that falls short of competent care and multiple/cumulative breaches of a similar and serious nature in the same therapeutic area within a short period of time.'

Vifor submitted that whilst the above list was non-exhaustive and non-determinative, it provided guidance as to the type of activities likely to be in breach of Clause 2. If this case fell within one of the above activities, if at all, it was that the conduct of the Vifor's representatives fell short of the standard of 'competent care', which Vifor had already accepted a ruling in relation to Clause 15.2. Vifor submitted that the circumstances of this case were far removed from other cases where the Panel and the Appeal Board had ruled a breach of Clause 2. Such cases involved conduct or actions that were particularly egregious and involved situations where patient safety had been prejudiced or compromised or involved companies inappropriately paying doctors to attend largely social events. Conversely Vifor submitted that this case related to the perception among the complainant and her colleagues that the approach of two of Vifor's representatives (only one of whom was identifiable in any of the evidence submitted by the complainant) had been scaremongering and that their approach was challenging and aggressive. Vifor did not condone its representatives behaving in a way that made health professionals feel 'upset and angry' or indeed 'confused'. Further, Vifor completely disagreed that the internal company documentation suggested that the company or its representatives would adopt a strident tone in this regard. Vifor submitted that the Panel had taken those aspects out of context and/or fundamentally misinterpreted them.

Vifor submitted that in cases where disparate or finely-balanced hearsay evidence was advanced and there was paucity of agreed or clear evidence one way or the other, the Panel should be more cautious than would otherwise be the case before ruling a breach of Clause 2. This was particularly relevant given the nature of a breach of Clause 2 and the sanctions that went with it. On the facts of this case (and in particular given the additional statements of evidence enclosed with this appeal that were corroborated with statements of truth), Vifor submitted that a breach of Clause 2 in all the circumstances would be disproportionate.

Comments from the complainant

After referral to, and a decision by, an independent referee the complainant was provided with the 'Intravenous Iron Differentiator Briefing Guide' and the 'Competitor Update December 2015'.

The complainant thanked the PMCPA for being available when she had had any queries over this case. The complainant stated that she had found this whole experience 'stressful' and it was very hard for her to do but she felt the way that the company approached her and her colleagues that day was not professional and it was her senior colleagues who felt she should complain to the PMCPA (the complainant did not know that such a process existed until now).

In the complainant's response to this appeal (and she stated that she found it overwhelming with all the paperwork and some legalities that she just did not understand), she had informed her gastroenterology consultants so that she could receive some support and guidance on this but the complainant gave assurances that she had not disclosed any of the confidential paperwork as requested.

- The complainant agreed with the Panel's findings and was satisfied (as was her hospital) with the outcome and the breaches of the Code ruled in relation to Vifor's conduct. The complainant felt 'bullied' by the Vifor representatives and still stood with her complaint as did her colleagues

from the emails she had disclosed and if needed the complainant and her colleagues would be happy to re-iterate this;

- Secondly, the complainant felt that she had a very good relationship with her gastroenterology consultants who had supported her with this process. All the gastroenterology consultants within the trust made decisions with arranging meetings with any external company representatives and it was the consultants who had decided to use Monofer with her group of patients for reasons that did not need to be explained here. The complainant and her colleagues did not make these decisions however, they might be asked to attend teaching sessions or asked for feedback etc.

- Lastly, the complainant and her colleagues who assisted with this complaint stressed that they did not know that Pharmacosmos had complained to the PMCPA. As stated above all decisions about medicines were taken by the consultants and she and her colleagues rarely met with pharmaceutical representatives.

The Chairman of the Appeal Board noted that in the complainant's response to the appeal, she had not commented on the representative's assertion that she had *winked* as she stated that cost was not the issue (emphasis added). The Chairman considered it would be helpful to have the complainant's comments, if any, on this part of the statement.

In response, the complainant stated that she did not know how she had missed this comment, but she stressed that she did not state that cost was not an issue or indeed wink. The complainant found this comment upsetting and it was totally untrue. Interestingly, the complainant stated that she was in an office with colleagues at the time and recalled staring at her computer screen and not facing the representatives; there was a large pillar in the middle as the representatives were over the other side of it speaking to her colleague at first. However, the complainant did realise that this might be a case of her word against the Vifor representatives but she would speak to her colleagues in the office if further comment on this statement was needed.

The complainant alleged that when she complained to the PMCPA from the beginning, her aim was to highlight how the Vifor representatives approached her and her colleagues and how they thought the representatives were unprofessional when visiting the hospital (and various departments). The representatives disrespected the current medicine the hospital was using and scaremongered her colleagues (as noted in colleagues' feedback/ statements). The complainant wanted Vifor to know that this was not the correct approach. No appointment was booked. The complainant and her colleagues had indeed reflected on how they would invite representatives to meet their teams in the future. But the complainant totally understood that Vifor needed to visit on occasions if the trust was using its products.

The complainant stated that if it was not for standards like the PMCPA, hospitals like hers would not be able to complain about such issues when companies had approached them in an incorrect manner. The complainant and her colleagues felt they were 'bullied' and that the Vifor representatives could have been less aggressive.

APPEAL BOARD RULING

The Appeal Board noted that there were differences between the parties' accounts of the meeting and thus it was difficult to know exactly what had transpired. Nonetheless, the complainant had consistently submitted that the representatives had scaremongered and discredited Monofer 'in an intense way'. The Appeal Board noted Vifor's submission about the consistency of its representatives' accounts of the meeting, even though they had been interviewed separately without being told the substance of the complaint. In that regard, however, the Appeal Board noted that five days after the meeting at issue the two representatives had met the consultant gastroenterologist who had told them that there had been complaints from the infusion and IBD nurses. The Appeal Board considered that it was likely that following that exchange the two representatives would have at least discussed the meeting at issue between themselves. The Appeal Board doubted that the representatives had actually stated that Monofer 'was very dangerous and not safe' but clearly the complainant's perception was that the representatives had aggressively attacked Monofer even if that was not the representatives' view of events. The Appeal Board did not consider that Vifor's account of the complainant winking at the representatives was otherwise in accord with the rest of her complaint. The complainant was clearly very dissatisfied and a judgement had to be made on the evidence submitted by the parties. The Appeal Board noted that the complainant had neither confirmed nor denied any conflict of interest.

The Appeal Board noted Vifor's concerns that it had not seen all of the information submitted by the complainant until it was advised of the Panel's rulings. Vifor submitted that the statement 'Stating that more than 1g of Monofer could only be given in one dose with over 100kg patient and not with those with bleeding' showed that there was a discussion about dosing which was consistent with its representatives' version of events. This information had been provided to Vifor when it was advised of the Panel's rulings on 12 July. Copies of the emails provided by the complainant were subsequently provided to Vifor on 29 July. The Appeal Board considered that it would have been preferable if Vifor had seen this information before the Panel made its ruling but noted that one of the complainant's colleagues had, at the outset, referred to being 'doubtful of dosings and number of visits' and in its response Vifor had referred to confusion on the part of hospital staff with regard to the dosing of Monofer. One of the representatives had stated in his witness statement that the health professionals' frustration and upset at the meeting in question was perceived to be due to Pharmacosmos providing incorrect dosing information for Monofer. Thus Vifor

acknowledged from the beginning that there was confusion regarding the dosing of Monofer. In any event, the Appeal Board noted that Vifor now had the additional comment from the complainant, and any remedy in it not being provided sooner lay in Vifor's ability to appeal.

The Appeal Board noted that although Vifor submitted that hospital staff appeared confused about the dosing of Monofer, the meeting at issue resulted in a paper about the safety of Monofer being sent to the complainant. In that regard, the Appeal Board was particularly concerned about the way Vifor had handled the provision of the Lareb report. The Competitor Update December 2015 (ref UK/FER/15/0279) referred to recent changes to the Monofer SPC which would have 'minimal impact on Ferinject'. The final slide headed 'Safety and Tolerability' referred to these properties as being a key factor in choosing an IV iron. The slide also drew particular attention to the Lareb report and included a quotation from it that 'special attention should be given to the comparison of the safety profile of the different intravenous iron-containing medicines and in particular to the safety profile of [Monofer]'. The slide urged representatives to be 'proactively reactive' and stated that if customers requested detailed safety information beyond that contained in the Ferinject SPC, they should be referred to medical information. No similar statement was given regarding Monofer although the Appeal Board noted Vifor's submission that representatives were verbally briefed on the initial training course not to discuss competitor products in detail and that Vifor's medical information department could only provide information on Vifor products, not on competitor products. For information on competitor products, representatives were to refer health professionals to the relevant SPC or to the relevant company's medical information department. The Appeal Board appreciated that the last slide of the Competitor Update was only one slide in many but it considered that the impact of a final summary slide could not be underestimated and was key to any presentation; these were the messages the audience had to take away even if they took nothing else. The Appeal Board was concerned about the phrase 'proactively reactive' and in its view the final slide encouraged representatives to use the Lareb report. The Appeal Board noted a follow-up email dated 24 February 2016 which referred to internal projects mentioned at the December conference which included the Lareb report and reiterated that 'as stated at the conference they are not to be communicated in any way with healthcare professionals'. No reasons for this were stated. Vifor confirmed that, despite the nature of the Lareb report, representatives had not received any comprehensive written briefing specifically about its use and nor, at the time of the meeting (10 March), was there a standard medical information letter to accompany requests for it. The Vifor representatives at the appeal explained that there was no standard medical information letter because it had not previously received requests for the Lareb report. The medical information letter sent to the complainant with the Lareb report was extremely poor.

The Appeal Board noted other briefing material and in particular Vifor's use of the claim 'The Ferinject proposition is strong, be confident, we have the best treatment' on the summary slide of the briefing document 'Reactive responses to competitor messages', and the instruction to representatives to use the intravenous iron differentiator tool **proactively** (emphasis added by Vifor) in threatened accounts or in those that had already switched to Monofer. Overall, the Appeal Board considered that the briefing material and the company's use of the Lareb report was consistent with the complainant's allegation of scaremongering. The Appeal Board considered that the briefing material advocated a course of action which was likely to be in breach of the Code; the Panel's ruling of a breach of Clause 15.9 was upheld. Given the content and tone of the briefing material, the Appeal Board considered that, on the balance of probabilities, the representatives had caused the infusion nurses to doubt the safety of Monofer and in that regard had offered misleading comparisons with Ferinject. The Panel's rulings of breaches of Clauses 7.2, 7.4 and 7.9 were upheld. The appeal on these points was unsuccessful.

The Appeal Board noted Vifor's submission that it had only accepted a breach of Clause 15.2 in as much as it related to the breach of Clause 9.9. In the Appeal Board's view, however, the ruling of a breach of Clause 15.2 encompassed the whole case and could not be sub-divided. Insofar as this point was raised on appeal, the Appeal Board ruled against it. The breach of Clause 15.2 would therefore be treated as a breach in the context of the case as a whole and not just in relation to the accepted breach of Clause 9.9.

The Appeal Board noted its rulings above and considered that high standards had not been maintained. The Panel's ruling of a breach of Clause 9.1 was upheld. The appeal on this point was thus unsuccessful.

The Appeal Board noted that a ruling of a breach of Clause 2 of the Code was a sign of particular censure and reserved for such. The Appeal Board noted its rulings and comments above; it was particularly concerned that the letter from medical information stated that the Lareb report had not mentioned any specific safety concerns with Ferinject; this was not so. It was absolutely imperative that communications from medical information were correct. Overall, the Appeal Board considered that Vifor's activities and materials were such as to bring discredit upon, and reduce confidence in, the pharmaceutical industry. The Panel's ruling of a breach of Clause 2 was upheld. The appeal on this point was thus unsuccessful.

Complaint received **21 March 2016**

Case completed **7 December 2016**

CASE AUTH/2830/4/16

PHARMACOSMOS v VIFOR PHARMA

Promotion of Ferinject

Pharmacosmos alleged that Vifor's promotion of Ferinject (ferric carboxymaltose for injection/ infusion) represented a clear and national pattern of misleading and disparaging claims about the safety profile of its product, Monofer (iron isomaltoside). Both medicines were for the treatment of iron deficiency when oral iron was ineffective or could not be used.

Pharmacosmos noted that there were no comparative efficacy or safety studies for Monofer and Ferinject. Further, a review of all medicines in the same class by the European Medicines Agency (EMA) concluded that there were no meaningful differences in the safety profiles of the available products.

Pharmacosmos stated that many of the issues that it had raised with Vifor in inter-company dialogue stemmed from comments made to it by health professionals. The health professionals were reluctant to be named and so it was difficult to substantiate their allegations. Pharmacosmos had recently raised six new examples with Vifor which it stated supported its position. Pharmacosmos recognised that the examples were anecdotal but that for clarity it had not made specific allegations for each one but wished to portray them as part of the overall picture to give credence to its concerns of a pattern of disparaging comments.

Pharmacosmos stated that although Vifor consistently denied inappropriate activity, it had made several commitments during inter-company dialogue including an agreement to brief all employees about the use of certain documents and the nature of discussions regarding the adverse events profile of Ferinject and Monofer. Unfortunately, however, a report from one health professional led Pharmacosmos to question the integrity of Vifor's commitments.

Pharmacosmos drew particular attention to an additional report it had received about a medical information email sent by Vifor to a named hospital specialist nurse who stated that she did not request the letter. The letter referred to a report from a pharmacovigilance body in the Netherlands; Pharmacosmos queried whether the UK nurse would know about or request such a report. Pharmacosmos noted that the medical information letter stated that a representative had asked for the report to be sent. Pharmacosmos alleged that Vifor had provided the information proactively and that as this was one example of a representative disparaging Monofer, it was likely that the other cited examples of disparagement were also true. Pharmacosmos stated that an appraisal of Vifor's representatives' training material would corroborate its concerns because it was likely to link the dextran-derived nature of the Monofer molecular structure to a higher (alleged) propensity for adverse events. Further, the nurse's experience referred to above raised doubts about the quality of investigations undertaken by Vifor and the effectiveness of the direction given to representatives with regard to comparing product safety profiles in response to concerns raised in inter-company dialogue.

Pharmacosmos alleged that Vifor had misled health professionals by implying there was a difference in the safety profiles of Monofer and Ferinject when no formal comparison between the two existed. The consistent and widespread pattern of comments from health professionals indicated that, on the balance of probability, Vifor representatives had proactively raised the safety profile of Monofer in order to imply differences between the products. Pharmacosmos referred to the six recent examples.

Pharmacosmos concluded that whilst it had hoped that Vifor had adequately and appropriately addressed the six alleged cases of disparaging and misleading claims highlighted during inter-company dialogue, it was shocked and concerned to learn that this activity had continued, as outlined in the nurse's first-hand account. Anxiety of clinical staff could increase the incidence of adverse events and given the nature of Vifor's alleged activities this was likely to have a direct impact on staff's confidence with Monofer and therefore put patients' lives at risk.

Pharmacosmos stated that the referenced incidents of alleged disparaging and misleading claims by Vifor representatives had all been raised verbally to Pharmacosmos by health professionals in the UK and Ireland. To provide further context to what and how the information was shared with Pharmacosmos the relevant members of the Pharmacosmos team were asked to provide written statements, copies of which were provided. For completeness, Pharmacosmos provided statements to each case referenced in its complaint and noted that it had anonymised the names of the health professionals as it did not have their permission to identify them. Pharmacosmos further stated that it was its interpretation that 'information from [named] Hospital' related to Grant *et al* (2013) that described a local hospital audit of Monofer.

The detailed response from Vifor is given below.

The Panel noted Pharmacosmos' allegation that Vifor representatives had disparaged Monofer and provided misleading information about Monofer safety by implying there was a difference in the safety profiles of Monofer and Ferinject when no formal comparison between the two products existed. Pharmacosmos provided six anecdotal examples and Vifor responded to each with specific details. The Panel did not consider these examples

per se when making its ruling as Pharmacosmos had not made specific allegations for each example but had cited them to substantiate its concerns of a pattern of disparaging comments.

The Panel noted that in addition Pharmacosmos provided a medical information email it alleged was sent proactively (not in response to a request) by Vifor to a specialist nurse at a named hospital as evidence that Monofer had been disparaged. The medical information email was the subject of Case AUTH/2828/3/16. The medical information email stated:

> 'Thank you for your enquiry on Ferinject (ferric carboxymaltose: FCM). I understand from my colleague, [named], that you have requested a copy of the Lareb report.
>
> The Netherlands Pharmocovigilance Centre, Lareb, has received concerns from multiple Dutch hospitals in relation to iron isomaltoside after the switch from iron carboxymaltose (FCM). Doctors and nurses reported an increase in the severity and incidence of allergic reaction. The report has not mentioned any specific safety concerns with FCM.'

The Panel noted that the latter statement was untrue as the report detailed 7 reports of hypersensitivity/anaphylactic reactions associated with the use of Ferinject.

The Panel noted Pharmacosmos' disbelief that a typical UK health professional would know about the Lareb report, which was a specific pharmacovigilance assessment of Monofer made by the Dutch pharmacovigilance authority. Pharmacosmos had also submitted that it was difficult to understand why a health professional would proactively request a copy of that report Pharmacosmos considered the provision of the Lareb report most likely occurred following a representative visit which included comments about the safety profile of Monofer.

The Panel noted Pharmacosmos' statement that an appraisal of material used to train Vifor representatives would corroborate its concerns because it was likely to draw attention to Monofer's adverse event profile.

The Panel noted Vifor's submission that during initial training, representatives were briefed not to discuss competitor products in detail beyond the SPC. This briefing included the instruction that for non-Vifor products, representatives had to refer a customer to the product's SPC. The Panel noted Vifor's submission that the Intravenous Iron Differentiator tool and the SPC Comparator were the only materials available to the representatives that mentioned Monofer. Otherwise the customer was advised to contact the medical information department of the product market authorization holder.

The Intravenous Iron Differentiator tool was a slide set which specifically differentiated Ferinject from Monofer and which was according to its briefing material designed to be used proactively in threatened accounts that were considering switching to Monofer and in accounts that had switched to Monofer. Two slides specifically compared the side-effects and contraindications of Ferinject and Monofer. The briefing regarding these two slides referred to confidence with Ferinject and in that regard implied a lack of confidence with Monofer. The briefing material stated, in summary, that 'The Ferinject proposition is strong, be confident, we have the best treatment'. In the Panel's view the briefing material was at odds with Vifor's submission that it did not permit representatives to discuss comparative safety in a promotional environment. The Panel noted Vifor's submission that the slide on the comparison of dosing was based on the relevant products' SPCs. The Panel noted that the slide also stated that the way in which the Monofer dose was calculated (the Ganzoni formula) was 'inconvenient, prone to error, inconsistently used in clinical practice, and it underestimates iron requirements'. The briefing on this slide referred to Ganzoni-based dosing as being problematic.

A briefing document approved in January 2016 (Questions and Answers. Reactive responses to competitor messages, listed the comments and messages from customers regarding Monofer and stated 'What we need to do is reactively discuss the FACTS in an accurate and balanced way, to allow the customer to make an informed decision'. It was stated on one slide that one of the benefits of Ferinject, in an implied comparison with Monofer, was confidence because it was the market leader. The document included an explanation that the misconception of the competitor claim 'Reformulation, old Monofer had [adverse events], new formulation is better' suggested that Pharmacosmos acknowledged Monofer had a problem with adverse events as the only reformulation Vifor was aware of was Diafer which was simply half strength Monofer. The final message of the briefing document was again 'The Ferinject proposition is strong, be confident, we have the best treatment'.

In the Panel's view, there was no doubt that Vifor was specifically targeting Monofer sales and that the representatives had been briefed to discuss the comparative safety of Ferinject vs Monofer.

The Panel noted Vifor's submission that Grant *et al* was included with an overview of all relevant papers in the 'Clinical papers' session of the initial training course. Vifor noted that the aim of including that information was to educate Vifor employees on the place Ferinject's data held within the broader context of other products. The emphasis was on Ferinject and representatives were instructed not to use the competitor data with customers unless the data contained information on a Vifor product.

The Panel noted Vifor's explanation that Grant *et al* was published as an abstract in Gut in September 2013. Grant *et al* was an audit of case notes of 40 patients who had received Monofer. The authors concluded 'Utilisation of Monofer in our clinical practice has shown a sub-optimal attainment of Hb target. Furthermore, the frequency of adverse

reactions was much higher than expected from those reported in the product SPC or previous studies in renal patients. In light of these observations we no longer use Monofer'.

A medical update was provided at the December 2013 sales conference which included information on recent publications for Ferinject and Monofer and included, *inter alia*, Grant *et al* and the authors' conclusion as stated above. The slide set for the session stated on the first slide that it was for internal use for training purposes. The cover slide did not state, as submitted by Vifor that the training session was for information only. The Panel considered that the slides contained material which Vifor would expect its representatives to use. No context had been given to the results from Grant *et al*.

The Panel disagreed with Vifor's submission that it only included safety information relating to Ferinject and Monofer in the Q&A document given that such comparisons appeared in the Intravenous Iron Differentiator tool and in the SPC Comparator tool. With regard to the latter, the Panel noted that the Ferinject and Monofer SPCs were being used by Vifor for a promotional purpose. The Panel noted that the briefing material stated that the tool had been designed to help representatives to directly compare different sections of the SPCs for the most prescribed IV irons including Ferinject and Monofer, it was to be used when asked specific questions about Vifor intravenous (IV) irons and those of its competitors. The briefing also stated that 'You can also project this from your iPad for use with multiple [healthcare professionals] at meetings'. There was no information on how to use the information provided in the tool and how to present the comparisons to a customer. The Panel noted Vifor's submission that representatives were briefed not to discuss competitor products in detail beyond the SPC. In the Panel's view, providing a tool which directly compared SPCs, implying that such direct comparisons of data were valid, went beyond that. The Panel also considered that the SPC Comparator tool went beyond the reminder given in December 2015 that representatives were not to discuss the safety of competitor products and that if a customer requested comparative safety data the request should be forwarded to medical information.

The Panel considered that on the balance of probabilities, given the strident tone and content of the sales materials and briefings, Vifor representatives had disparaged Monofer in promotional calls as alleged. The Panel further considered that on the balance of probabilities, Vifor representatives had provided misleading information with regard to the safety of Monofer as alleged. Breaches of the Code were ruled which were upheld on appeal from Vifor.

Pharmacosmos complained that the promotion of Ferinject (ferric carboxymaltose for injection/ infusion) by Vifor was misleading and disparaging in relation to the safety profile of its product, Monofer (iron isomaltoside). Both medicines were for the treatment of iron deficiency when oral iron was ineffective or could not be used.

COMPLAINT

Pharmacosmos noted that there were no comparative efficacy or safety studies for Monofer and Ferinject. In addition, the European Medicines Agency (EMA) formally reviewed all products in the class, including Monofer and Ferinject, and concluded that there were no meaningful differences in the safety profiles. Pharmacosmos stated that it had had a series of inter-company exchanges with Vifor over the last few years prompted by reports from health professionals which showed that Vifor representatives had disparaged the safety profile of Monofer by:

a) Proactively highlighting Monofer's dextran-derived molecule and implying it was likely to cause particular adverse events (Ferinject did not have a dextran-derived molecule)
b) Implying that comparative data existed between the products and that Ferinject had a relatively cleaner side-effect profile
c) Using an article published in Gut that included misleading comments about the respective safety profiles of Monofer and Ferinject.

Pharmacosmos highlighted the history of complaints it had made against Vifor in that regard. In particular Cases:

AUTH/2422/7/11 – Vifor was ruled in breach for claims that dextran-induced hypersensitivity reactions were common with Monofer

AUTH/2442/10/11 – Vifor breached its undertaking given in Case AUTH/2422/7/11

AUTH/2589/3/13 – Pharmacosmos alleged a further breach of the undertaking given in Case AUTH/2422/7/11 (this allegation was not upheld).

Pharmacosmos stated that it had had further inter-company dialogue with Vifor in relation to subsequent allegations which had been made about the safety profile of Monofer, copies were provided.

Pharmacosmos stated that many of the issues it raised in inter-company dialogue resulted from verbal comments it received from health professionals who were reluctant to be named, making the allegations difficult to substantiate. In the most recent exchange with Vifor, initiated in February 2016, Pharmacosmos highlighted five further such allegations that represented a clear and persistent national pattern of disparaging and misleading claims and gave credence to Pharmacosmos' long running concerns about the activities of Vifor's representatives. Pharmacosmos stated that Vifor consistently denied inappropriate activity, but had made several specific commitments in response to inter-company dialogue. Most recently, Vifor agreed to issue a communication to all of its employees about the use of certain documents and the nature of discussions in relation to adverse events with the two products. Regrettably, Pharmacosmos stated that it had since been told about an exchange between Vifor and a named health professional which implied that the

behaviour was continuing. The relevant details of the interaction were outlined below, and Pharmacosmos considered that the existence and nature of that exchange called into question the integrity of the commitments it had previously received from Vifor.

Pharmacosmos alleged that Vifor representatives had disparaged Monofer in promotional calls in breach of Clause 8.1 and had provided misleading information in respect of Monofer safety in breach of Clause 7.2.

Pharmacosmos noted the commitments made by Vifor in its most recent inter-company letter. Vifor specifically stated that it had:

- issued a reminder letter to all representatives (dated shortly before 3 March 2016)
- investigated all of Pharmacosmos' allegations with regard to specific hospitals and specific representatives but found no conclusive evidence
- not trained its representatives to imply that the dextran-derived structure of the Monofer molecule caused a particularly bad adverse event profile, or to compare adverse events between Monofer and Ferinject
- told its representatives not to use Grant *et al* (2013) (published in Gut) in their promotional calls (Vifor confirmed during inter-company dialogue in February/March 2014 that the article would not be discussed/provided either proactively or reactively by Vifor representatives).

Pharmacosmos stated that the very existence of an unsolicited medical information letter provided to a named health professional proved the likelihood that, on the balance of probabilities, conversations in relation to the respective safety of Monofer had occurred; and that the existence of specific adverse event reports had been proactively raised by Vifor representatives. Pharmacosmos found it difficult to believe that a typical UK health professional would be aware of the Lareb report, which was a specific pharmacovigilance assessment of Monofer made by the Dutch pharmacovigilance authority; it was also difficult to understand why a health professional would proactively raise a request to receive a copy of that specific pharmacovigilance assessment. Pharmacosmos considered the provision of the Lareb report most likely occurred following a representative visit which most likely included comments about the safety profile of Monofer; it was difficult to see any other circumstances in which Vifor would provide the report to a health professional.

Pharmacosmos highlighted that the exchange between the Vifor representative and the named health professional occurred after several assurances from Vifor that representatives were not trained to compare the safety profiles of the two products or to cast aspersions about the safety profile of Monofer and that all enquiries relating to Monofer were automatically referred to Pharmacosmos. Pharmacosmos stated that the existence of the letter sent to the named health professional called into question the effectiveness of (or existence of) the communications recently issued by Vifor head office to the sales teams. It also undermined Vifor's assurances that it had not trained/briefed representatives to discuss the safety profile of Monofer. Pharmacosmos advised Vifor that inter-company dialogue had been unsuccessful in this matter and that it would write to the PMCPA directly.

Pharmacosmos provided evidence in respect of each allegation as listed below.

Disparagement of Monofer (Clause 8.1)

Pharmacosmos alleged that the consistent and widespread pattern of comments from health professionals indicated that, on the balance of probability, Vifor representatives had proactively disparaged the safety profile of Monofer. Six new examples were cited in its recent exchange with Vifor including:

- At a named university NHS foundation trust (hospital 1), two health professionals expressed concern and frustration with the disparaging and misleading claims allegedly made by a named Vifor representative (representative 1) who allegedly stated that 'Monofer has a higher rate of adverse drug reactions than Ferinject' and that 'Monofer is a dextran-based iron compound'. This was reported to Pharmacosmos on 4 January 2016.
- At a second named university hospitals NHS trust (hospital 2), a health professional expressed concern and frustration with the disparaging and misleading claims made by a Vifor representative who had allegedly stated that 'Monofer has a higher rate of adverse drug reactions than Ferinject' and 'Monofer is a dextran-based iron compound'. This was reported to Pharmacosmos in November 2015.
- At a third NHS trust (hospital 3), a health professional explained how a Vifor representative allegedly spoke in great detail about Grant *et al* relating to Monofer. This was reported to Pharmacosmos in January 2015.
- At a fourth named NHS foundation trust (hospital 4), a health professional expressed concern that a colleague flagged to them a recent conversation with a Vifor representative who claimed that Monofer had more side-effects than Ferinject. This was reported to Pharmacosmos in February 2016.
- At a fifth named hospital in Ireland (hospital 5), a health professional expressed concern and frustration with the disparaging and misleading claims allegedly made by a Vifor representative who stated that 'Monofer has a higher rate of adverse drug reactions than Ferinject'. This was reported to Pharmacosmos in February 2016.
- At a sixth named hospital in Ireland (hospital 6), a health professional expressed concern and frustration with the disparaging and misleading claims allegedly made by a Vifor representative who stated that 'Monofer has a higher rate of adverse drug reactions than Ferinject'. This was reported to Pharmacosmos in December 2015.

Pharmacosmos recognised that the above examples were anecdotal and the final two related to Eire (hospital 5 and 6), however the promotional material used in Ireland was issued by and approved in the UK. For clarity, Pharmacosmos stated that it had

not made specific allegations for each example cited above but wished to portray them as part of the overall picture to give credence to its concerns of a pattern of disparaging comments.

In addition to the six examples cited, on 11 March 2016 Pharmacosmos was told about a medical information email sent by Vifor to, a named specialist nurse at a hospital. The nurse stated that she did not request the letter. Pharmacosmos wanted to use the letter as evidence that Monofer had been disparaged.

Pharmacosmos contended that it was unlikely that the nurse knew about, or requested a report conducted by a pharmacovigilance body in the Netherlands. Pharmacosmos alleged that Vifor provided the letter proactively (not in response to a request). The medical information letter stated that a named Vifor regional business manager asked for the letter to be sent. Since the nurse clearly stated that she did not request the letter, this was at least one example of a representative proactively disparaging the safety profile of Monofer. Pharmacosmos stated that on the balance of probability, the six other examples cited above were also therefore likely to be true. Pharmacosmos stated that an appraisal of material used to train Vifor representatives would corroborate its concerns because it was likely to draw attention to Monofer's adverse event profile.

Pharmacosmos stated that training material would link the dextran-derived nature of the Monofer molecular structure to a higher (alleged) propensity for adverse events. Further, the nurse's experience raised doubts about the quality of investigations undertaken by Vifor and the effectiveness of the direction given to representatives with regard to comparing product safety profiles in response to concerns raised in inter-company dialogue.

Pharmacosmos provided a copy of the email exchange, including the unsolicited email received and the attached Lareb report. Pharmacosmos alleged that it was clear that Vifor representatives had proactively raised concerns with regard to the safety profile of Monofer and had disparaged the product in breach of Clause 8.1.

Misleading statements (Clause 7.2)

Pharmacosmos alleged a breach of Clause 7.2 on the grounds that Vifor had misled health professionals by implying there was a difference in the safety profiles of Monofer and Ferinject when no formal comparison between the two existed. The consistent and widespread pattern of comments from health professionals indicated that, on the balance of probability, Vifor representatives had proactively raised the safety profile of Monofer in order to imply differences between the products. Pharmacosmos referred to the six recent examples cited above which had formed the basis of Pharmacosmos' recent exchanges with Vifor.

Pharmacosmos again referred to the anecdotal nature of the reports and restated that it was not making specific allegations for each example cited but wished to portray them as part of the overall picture giving credence to its concerns of a pattern of behaviour of misleading statements.

On 11 March 2016, Pharmacosmos found out about a medical information email sent by Vifor to a specialist nurse who stated that she did not request the letter. For now, Pharmacosmos relied upon the letter as evidence that Vifor had misled health professionals about the safety profile of Monofer. Pharmacosmos noted that it was unlikely that the nurse knew about, or requested information about, a report conducted by a pharmacovigilance body in the Netherlands. Pharmacosmos alleged that Vifor provided the letter proactively. The medical information letter stated that a named regional business manager had asked for the letter to be sent. Since the health professional stated that she did not request the letter, this was at least one example of a representative who had proactively communicated the safety profile of Monofer in a misleading manner. The medical information letter stated:

> 'Thank you for your enquiry on Ferinject (ferric carboxymaltose: FCM). I understand from my colleague, [named], that you have requested a copy of the Lareb report. The Netherlands Pharmocovigilance Centre, Lareb, has received concerns from multiple Dutch hospitals in relation to iron isomaltoside after the switch from iron carboxymaltose (FCM). Doctors and nurses reported an increase in the severity and incidence of allergic reaction. The report has not mentioned any specific safety concerns with FCM.'

This letter was clear evidence that Vifor had tried to compare the safety profiles of Ferinject and Monofer in a misleading manner. On the balance of probability, the six other examples cited above were also therefore likely to be true. Pharmacosmos considered that an appraisal of the material used to train Vifor representatives would corroborate its concerns because it was likely to draw attention to Monofer's adverse event profile in a misleading manner. Pharmacosmos alleged that the training material would link the dextran-derived nature of the Monofer molecular structure to a higher (alleged) propensity for adverse events, which was misleading.

Further, this raised doubts about the quality of investigations undertaken by Vifor and the effectiveness of the recent direction given to representatives with regard to product safety profile comparisons (in response to Pharmacosmos' concerns raised in inter-company dialogue).

Pharmacosmos alleged there was a clear pattern that Vifor representatives had proactively raised concerns about the safety profile of Monofer, which was misleading because there were no head-to-head comparisons and the EMA's review of data concluded that there was no evidence to indicate differences between the available products.

Pharmacosmos concluded that whilst it had hoped that Vifor had adequately and appropriately addressed the six alleged cases of disparaging and misleading claims highlighted during inter-company dialogue, it was shocked and concerned to learn that this activity

had continued, as outlined in the nurse's first-hand account. The EMA had stated that anxiety of clinical staff could increase the incidence of adverse events and given the nature of Vifor's alleged activities this was likely to have a direct impact on staff's confidence with Monofer and therefore put patients' lives at risk.

Pharmacosmos informed the Panel that it had cited an incorrect reference in its original response. Pharmacosmos referred to the EMA in relation to a review which linked clinical staff's anxiety in administering intravenous (IV) irons to an increased reporting of adverse events. Pharmacosmos stated that reference should have been made to the guideline article by Rampton *et al* (2014) which identified anxiety (patients or staff) as a factor increasing risk and/or severity of hypersensitivity reactions in patients given iron infusions.

In response to a request for further information, Pharmacosmos stated that the referenced incidents of alleged disparaging and misleading claims by Vifor representatives had all been raised verbally to Pharmacosmos by health professionals. To provide further context to what and how the information was shared with Pharmacosmos the relevant members of the Pharmacosmos team were asked to provide written statements, copies of which were provided. For completeness, Pharmacosmos provided statements to each case referenced in its complaint and noted that it had anonymised the names of the health professionals as it did not have their permission to identify them. Pharmacosmos further stated that it was its interpretation that 'information from [named] Hospital' related to Grant *et al* that described an audit of Monofer at that hospital.

RESPONSE

Vifor stated that it was committed to adhering to the Code and was disappointed to receive a complaint from Pharmacosmos. Vifor noted that Pharmacosmos refused to cooperate with the industry's self-regulated complaints process in Case AUTH/2694/1/14 and made it very clear that it had never considered that it was included on the list of those companies that agreed to comply with the Code. Vifor was concerned that a company that had clearly, and publicly, stated it would not agree to abide by the ethical regulations of the Code operated in its therapeutic area as a competitor.

Notwithstanding this situation, Vifor accepted that compliance with the Code was of critical importance to the successful relationship between industry, health professionals and the public as a whole and accepted that it had a responsibility to uphold the highest standards at all times.

Vifor submitted that it appreciated the seriousness of any such allegations and had thoroughly investigated the points detailed in the complaint. All representatives gave full accounts (copies provided) of each of the examples that Pharmacosmos, without substantiation, alleged took place. Vifor noted that Pharmacosmos alleged that it had breached Clauses 7.2 and 8.1 and responded as such.

Vifor noted some inaccuracies in Pharmacosmos' complaint which covered selected parts of the recent Code and regulatory authority discussions between the two companies. Firstly, Vifor strongly disagreed with Pharmacosmos' interpretation of the EMA report. The EMA concluded that any differences in safety in relation to hypersensitivity could not be established because some IV iron products did not have sufficient clinical data for meaningful comparative analysis. The statement that the EMA 'concluded that there were no meaningful differences in the safety profiles…' was incorrect. To confirm this, all IV iron marketing authorization holders throughout Europe were required by the EMA to conduct studies to gather safety data to confirm if any differences did exist.

Secondly, the reference to several past Code cases appeared to be an attempt to give credence to Pharmacosmos' submission that it had had long-running concerns about the activities of Vifor's representatives. Vifor noted that reference to these cases showed Pharmacosmos' inaccurate understanding of the reasoning behind the breaches ruled. Pharmacosmos' interpretation of Case AUTH/2422/7/11 was incorrect: Vifor was not ruled in breach for claims that dextran-induced hypersensitivity reactions were common with Monofer, but for claims solely in relation to Ferinject. The content of Case AUTH/2589/3/13, which was not upheld by the Panel, also reflected Pharmacosmos' lack of understanding of Case AUTH/2422/7/11. Vifor queried why not being found in breach should be cited as an illustration of a pattern of non-compliant behaviour.

Vifor assumed that Pharmacosmos was trying to negatively influence the Panel's view of Vifor by citing past cases and an ongoing case which was the subject of PMCPA review and inter-company dialogue and in so doing, disparaged Vifor. Vifor noted that there had also been several past (and ongoing) complaints against some of the promotional activities of Pharmacosmos but Vifor did not consider that these were relevant to the facts of this case.

Vifor had invested much time and resource into building a compliant culture and referred to the 'Compliance at Vifor' section from its new-starter training slides which showed the emphasis it put on maintaining that culture within the organisation. Not only did Vifor instil a compliant culture from the outset, but maintained it and regularly monitored compliance activities with internal audits, best practice sharing, discussion around recent Code cases (both in head office and the field), a compliance newsletter and a dedicated compliance website. Each of Vifor's regional sales teams had a regional compliance liaison member, volunteers were appointed to ensure the best possible sharing of good Code practice. Vifor submitted that the PMCPA was fully aware of the compliance activities Vifor undertook and the seriousness with which it took compliance with the Code and these had only been strengthened since the PMCPA audited Vifor's procedures in relation to the Code in October 2012.

With respect to the six exchanges by Pharmacosmos, Vifor submitted that the hospitals at issue were covered by four representatives, three of whom had passed the ABPI Examination.

In order to respond to the alleged breaches. Vifor appreciated that Pharmacosmos had not made specific allegations for each example cited but it considered that by responding to each in turn with specific details rather than unsubstantiated allegations, the PMCPA could be confident that there was no pattern of behaviour of disparaging or misleading comments as alleged.

Hospital 1

Vifor stated that representative 1 provided a thorough account of all activity on territory since joining Vifor (both face-to-face calls and meetings). The majority of discussions with health professionals focused solely on Ferinject. The one instance where a discussion about Monofer took place, the TAM used the relevant, fully certified SPC Comparator tool.

With regard to the alleged quotations, the TAM stated:

> 'The only explanation I can think of is that I have discussed Ferinject safety data and compared the safety data of Monofer with the SPC comparator reactively which states that due to limited data on Monofer the mentioned undesirable effects are primarily based on safety data for other parenteral iron solutions. This may have led to the health professional coming to the conclusion that there may be more side effects with Monofer based on the SPC Comparator.
>
> With regard to the dextran complaint – following my discussions around Ferinject's carbohydrate shell, some of my health professionals have initiated the question about dextran, and I have reactively answered more around the differences in the carbohydrate shells. I'm not sure which customers this complaint relates to.
>
> I would like to add that I have not knowingly disparaged and compared Ferinject vs Monofer. All my discussions have been based on company information and have been factual.'

Vifor noted that evidence of the above call records were available on request.

Hospital 2

Vifor stated that representative 1 provided a thorough account of all activity on territory since joining Vifor (both face-to- face calls and meetings). All of the discussions with health professionals focused solely on Ferinject. There was no instance recorded in the customer record management (CRM) system where a discussion about Monofer took place.

The same statement from the TAM applied here as it did above.

Hospital 3

Out of the four hospitals in this trust, representative 3 had only ever visited one while employed at Vifor.

The TAM in question researched all call reports and meetings in the CRM system and checked business mileage logs between January 2015 and February 2016 to establish when, if any, calls were made against customers of this trust in this time period.

The TAM stated:

> 'The last recorded call (face:face) in … against a customer in this trust was 24th February 2015, (well before the time period that Pharmacosmos are looking at), when 2 consultant haematologists and a transfusion practitioner was also seen. Discussions centered around the ongoing Ferinject formulary submission. There was no discussion about Monofer as they were solely about Ferinject and its current formulary application status at that time.'
>
> The last known date of travel to the … Hospital was .. August 2015 when the TAM stated 'No calls were recorded on this day in …. (CRM system) as I did not see anyone at the trust. An unsuccessful day in work terms.'

The search revealed that no meetings (departmental, stand or otherwise), in any therapy area, had ever been held by the TAM at the trust.

With regards to contacts with health professionals from the trust at other meetings, the TAM stated that between January 2015 and February 2016, there had been three large scale meetings where customers might have been in attendance:

- In June 2015, one consultant from the hospital visited the Vifor stand at the Digestive Disorders Federation Congress in London.
- At a stand meeting in July 2015, one specialist registrar attended (but had since rotated to another hospital).
- The TAM attended a regional meeting in October 2015 although no meeting contacts were recorded for anyone from the trust. Discussions at these meetings were about ensuring the appropriate use of Ferinject.

Vifor submitted that the TAM did not initially recognise the description of the 'publication in Gut regarding Monofer' but after conducting an internet search realised he/she knew of it by another name. The TAM was not aware it was published in Gut and had not presented the details of this publication to any health professional. The TAM stated:

> 'As stated above, there was no mention of Monofer as a product at [named] Trust, yet alone a discussion around a publication from Gut, in the time that I have been responsible for this trust and in the small number of calls made with health professionals from there. If it refers to any other Gut publication regarding Monofer then I don't know what the publication is.'

The TAM stated that the information given clearly demonstrated that this was a false allegation.

Hospital 4

Representative 3 for this trust was surprised and denied Pharmacosmos' claims.

The trust was not a target account for Vifor and so the TAM had never visited the hospital whilst employed by Vifor. Neither had the TAM spoken to any of the doctors or nurses at the trust about Ferinject or any IV iron product.

Looking back at all meetings in 2015, there was one consultant from the trust who attended a meeting in another hospital in November 2015 where the TAM was present. The TAM did not speak to the consultant at that meeting, nor did the TAM give a presentation to the group. Any conversations with other health professionals present centered around Ferinject and the current status (at the time) of the formulary application. There was no conversation about side-effects of any medicine, so it would be impossible for this health professional to have even overheard a conversation about side-effects.

The TAM did not recall any other discussions with a consultant from the hospital at any other venue.

More generally, with regards to alleged claims that the TAM claimed 'Monofer has a higher rate of adverse drug reactions than Ferinject' the TAM clearly stated that he/she would not make that statement as he/she did not know how many side-effects Monofer had. The TAM stated:

> 'It is the TAM's job to talk about Ferinject and that is the knowledge that I have. I am aware of Ferinject's tolerability profile and incidence of side effects, as described by Vifor Pharma. As I am unaware of the relative incidence of side-effects between the two products, it would not be possible for me to make the claim as suggested by Pharmacosmos.'

Vifor noted that evidence of the above call records were available on request.

Hospitals 5 and 6

Vifor submitted that these two allegations referred to alleged incidents that occurred in Ireland. The Irish country manager who in turn reported directly into the vice president & general manager, Vifor UK. Vifor was surprised that Pharmacosmos had included these incidents in its complaint. While Vifor accepted that compliance with the relevant country Code was critically important (in both the UK and Ireland) and was confident that its interviews with relevant staff had revealed that Pharmacosmos' unsubstantiated allegations were groundless, it would not be appropriate for Vifor to respond to the PMCPA about activities in Ireland. However, if necessary, Vifor would provide statements from the relevant staff about their activities in the centres in question.

Medical Information email sent to a nurse

Vifor submitted that this was currently the subject of Case AUTH/2828/3/16. The content of the response was also the subject of current inter-company dialogue with Pharmacosmos.

In Case AUTH/2828/3/16 the nurse asked for the TAM's business card and both verbally (supported by the account from a second Vifor employee present) and by email requested details of comparative safety data. A copy of these accounts plus the subsequent email correspondence were provided.

Vifor explained that following these requests, an email was sent to its medical information team requesting a copy of the Lareb report be sent to the complainant, which it subsequently was. Vifor stated that this report was the most appropriate document to send in light of the request for comparative safety data and the absence of any direct head-to-head clinical trial data on Ferinject and Monofer. This report came from a highly respected information source, The Netherlands Pharmacovigilance Centre, Lareb. Lareb collected and analysed reports of adverse reactions to medicines and vaccines. Health professionals, patients and also manufacturers could report an adverse reaction. Anonymous copies of reports were sent to the EMA and the World Health Organisation.

The specific report in question was entitled 'Intravenous iron preparations and allergic reactions'. It compared Ferinject, Monofer and Diafer and was not specific to only Monofer. It provided objective, factual line listing reports of allergic reactions to the three products. Vifor considered the report to be of good standing and relevant to health professionals. The report concluded that 'special attention should be given to the comparison of the safety profile of the different intravenous iron-containing medicines and in particular to the safety profile of iron isomaltoside'. The request by the Vifor representative to medical information specifically referred to 'Lareb' rather than 'intravenous iron preparations and allergic reactions' for ease of writing. Vifor representatives were aware of the existence of this report.

In addition to the responses above related to the instances cited by Pharmacosmos, Vifor highlighted the following:

- Vifor representatives were highly experienced and aware of the need to provide a balanced view to enable health professionals to make up their own minds on the therapeutic value of a medicine. Vifor submitted that they had not just acquired this knowledge through experience but this point was also made in Vifor's one day training session on adherence to the Code. Vifor noted that the relevant slide set listed the qualities that all promotional material must fulfil and made it clear that the Code applied to both written and verbal communication and that information provided should be sufficiently complete to allow recipients to make up their own minds about the value of a medicine.

- Vifor representatives received limited training on competitor products from the medical advisor during the initial training course (ITC). The training took the form of a workshop, with no materials other than SPCs. During this training they were verbally briefed not to discuss competitor products in detail beyond the SPC. This briefing included the instruction that for non-Vifor products, representatives had to refer a customer to the product's SPC. Vifor produced an SPC Comparator

and a Differentiator tool for use by representatives. Otherwise the customer was advised to contact the medical information department of the product market authorization holder. The representatives were instructed that the Vifor medical information department could not provide information on competitor products, only on Vifor products, unless there was comparative information which included Vifor products. The competitor SPC workshop took place for only two hours on day 9 of the 4 week ITC. This was compared to the ABPI compliance component of the ITC, which was one full day and included a quiz on individuals' knowledge of the Code.

- Vifor's Intravenous Iron Differentiator tool and the SPC Comparator were the only materials available to the representatives that mentioned Monofer. The slide on the comparison of dosing was based on the relevant products' SPCs. The Ferinject SPC was provided and Vifor stated that the Monofer SPC was available on Pharmacosmos' website. The contents of that slide and tool were fully substantiable from those SPCs and were certified for Vifor representatives to use. The tool was certified and first used in January 2016 so was up-to-date.

- Ferinject was the market leader in IV iron therapy and promotional tools and briefing materials provided an accurate and balanced view of the product. As evidenced in 'Questions and Answers, reactive responses to competitor messages', a document which was briefed to Vifor representatives at the sales and marketing conference on 19 January 2016, the last slide instructed all to 'Be professional, never disparage the competition', and 'Discuss the facts in an accurate and balanced way'. This briefing was part of the introduction to the Intravenous Iron Differentiator tool.

- During an open questions and answers session at the December 2015 sales conference, representatives were specifically reminded not to discuss the safety of competitor products. If a customer requested comparative safety data, they were briefed to inform the customer that the representative could not discuss such matters and offer a referral to medical information.

- Following the original inter-company dialogue that resulted in Case AUTH/2830/4/16, in the spirit of the Code, and as a reassurance to Pharmacosmos, an email was sent from the senior managers at Vifor to all representatives to reiterate what was stated at the December sales conference and confirming their obligations in relation to questions on the comparative safety of Ferinject.

Taking into account all of the above, Vifor denied breaches of Clauses 7.2 or 8.1.

Vifor submitted that it found no evidence from any representative that any negative statements about Monofer, particularly in relation to its safety, had been made.

Vifor did not know why Pharmacosmos had cited unsubstantiated anecdotal evidence from anonymous health professionals who coincidentally provided not just consistent but identical quotations across four of the six related examples. Vifor stated that it also did not know why Pharmacosmos had referred to past cases as well as ongoing inter-company dialogue. Furthermore, Vifor submitted that it was concerned about Pharmacosmos' apparent lack of knowledge of the Code and its misleading interpretation of the conclusions from the EMA report.

Vifor appreciated the opportunity to respond to Pharmacosmos' concerns and concluded that the weight of evidence showed there was no basis for any breach of the Code.

In response to a request for further information, Vifor submitted that Grant *et al* was included with an overview of all relevant papers in the 'Clinical papers' session of the ITC. A summary of that session was provided; no slides for the session existed. Vifor noted that the aim of including that information was to educate Vifor employees on the place Ferinject's data held within the broader context of other products. The emphasis was on Ferinject and representatives were instructed not to use the competitor data with customers unless the data contained information on a Vifor product.

Vifor explained that Grant *et al* was published as an abstract in Gut in September 2013. A medical update was provided at the December 2013 sales conference which included information on recent publications for Ferinject and Monofer and included, *inter alia*, Grant *et al*. The training session was for information only as stated on the cover slide (copy provided).

During inter-company dialogue in March 2014, Pharmacosmos queried whether Vifor representatives had used Grant *et al*. Vifor had no evidence that any representative had referred to the publication and concluded that the December 2013 conference had successfully addressed the article. In the spirit of inter-company cooperation, Vifor decided to brief all new representatives not to use the publication as it did not include information on Ferinject. The briefing took place during the clinical paper session of the ITC. Vifor submitted that its representatives had never used the article with health professionals.

Vifor submitted that it should have been clearer in its initial response; representatives were briefed to avoid discussing comparative safety data beyond the SPC. At the 2015 sales conference, as part of normal practice, representatives were again specifically reminded not to discuss the safety of competitor products; if health professionals asked for comparative safety data, representatives were briefed to refer them to medical information.

Vifor submitted that further evidence of this was that it only included safety information relating to the respective products' SPCs and Public Assessment Report (PAR) in the Q&A document (ref UK/FER/15/0274f). The PAR provided the

scientific discussion around the products' marketing authorizations and SPC contents. The Q&A document was confidential, for personal use only as indicated by the statement on the first slide, 'Confidential. Internal use only. Do not share or distribute.' It provided information that representatives might need to be able to reactively discuss facts in an accurate and balanced way by drawing on information from the respective products' SPCs. In addition to safety, the document also referred to price, clinical trial data, and a statement on the EMA IV iron report. There was no further briefing associated with the document.

Vifor explained that the SPC comparator was an app which could only be viewed on certain devices. The app was updated the week commencing 16 May due to some minor updates to several of the SPCs contained within it. It could still be appreciated how it would be used by a representative and viewed by a customer but the content might differ to that of the printed version provided.

Vifor also provided the briefing document for the differentiator tool.

PANEL RULING

The Panel noted that in 2014 Pharmacosmos UK had declined the offer to join the PMCPA list of non-member companies and no longer wished to accept the jurisdiction of the Authority but stated that it would continue to be fully committed to the ethical promotion of its products.

The Panel noted the comments from both parties regarding Cases AUTH/2422/7/11, AUTH/2589/3/13, and AUTH/2422/7/11 and noted that each case was considered on its own particular merits.

Turning to the current case, the Panel noted Pharmacosmos' allegation that Vifor representatives had disparaged Monofer in promotional calls in breach of Clause 8.1 and had provided misleading information in respect of Monofer safety in breach of Clause 7.2 by implying there was a difference in the safety profiles of Monofer and Ferinject when no formal comparison between the two products existed. Pharmacosmos provided six anecdotal examples and Vifor responded to each with specific details. The Panel did not consider these examples *per se* when making its ruling as Pharmacosmos had not made specific allegations for each example but had cited them to substantiate its concerns of a pattern of disparaging comments.

The Panel noted that in addition Pharmacosmos provided a medical information email it alleged was sent proactively (not in response to a request) by Vifor to a specialist nurse at a named hospital as evidence that Monofer had been disparaged. The medical information email was the subject of Case AUTH/2828/3/16. The medical information email stated:

> 'Thank you for your enquiry on Ferinject (ferric carboxymaltose: FCM). I understand from my colleague, [named], that you have requested a copy of the Lareb report.
>
> The Netherlands Pharmocovigilance Centre, Lareb, has received concerns from multiple Dutch hospitals in relation to iron isomaltoside after the switch from iron carboxymaltose (FCM). Doctors and nurses reported an increase in the severity and incidence of allergic reaction. The report has not mentioned any specific safety concerns with FCM.'

The Panel noted that the latter statement was untrue as the report detailed 7 reports of hypersensitivity/anaphylactic reactions associated with the use of Ferinject.

The Panel noted Pharmacosmos' disbelief that a typical UK health professional would be aware of the Lareb report, which was a specific pharmacovigilance assessment of Monofer made by the Dutch pharmacovigilance authority. Pharmacosmos had also submitted that it was difficult to understand why a health professional would proactively raise a request to receive a copy of that specific pharmacovigilance assessment. Pharmacosmos considered the provision of the Lareb report most likely occurred following a representative visit which included comments about the safety profile of Monofer.

The Panel noted Pharmacosmos' statement that an appraisal of material used to train Vifor representatives would corroborate its concerns because it was likely to draw attention to Monofer's adverse event profile.

The Panel noted Vifor's submission that during initial training, representatives were briefed not to discuss competitor products in detail beyond the SPC. This briefing included the instruction that for non-Vifor products, representatives had to refer a customer to the product's SPC. The Panel noted Vifor's submission that the Intravenous Iron Differentiator tool and the SPC Comparator were the only materials available to the representatives that mentioned Monofer. Otherwise the customer was advised to contact the medical information department of the product market authorization holder.

The Intravenous Iron Differentiator tool (ref UK/FER/15/0274a) was a slide set which specifically differentiated Ferinject from Monofer and which was according to the briefing material (ref UK/FER/15/0274e) designed to be used proactively in threatened accounts that were considering switching to Monofer and in accounts that had switched to Monofer. Two slides specifically compared the side-effects and contraindications of Ferinject and Monofer. The briefing regarding these two slides referred to confidence with Ferinject and in that regard implied a lack of confidence with Monofer. The briefing material stated, in summary, that 'The Ferinject proposition is strong, be confident, we have the best treatment'. In the Panel's view the briefing material was at odds with Vifor's submission that it did not permit representatives to discuss comparative safety in a promotional environment. The Panel noted Vifor's submission that the slide on the comparison of dosing was based on the relevant products' SPCs. The Panel noted that the slide also stated that the way in which the Monofer dose was calculated (the Ganzoni formula) was 'inconvenient,

prone to error, inconsistently used in clinical practice, and it underestimates iron requirements'. The briefing on this slide referred to Ganzoni-based dosing as being problematic.

A briefing document approved in January 2016 (Questions and Answers. Reactive responses to competitor messages, ref UK/FER/15/0274f) listed the comments and messages from customers regarding Monofer and stated 'What we need to do is reactively discuss the FACTS in an accurate and balanced way, to allow the customer to make an informed decision'. It was stated on one slide that one of the benefits of Ferinject, in an implied comparison with Monofer, was confidence because it was the market leader. The document included an explanation that the misconception of the competitor claim 'Reformulation, old Monofer had [adverse events], new formulation is better' suggested that Pharmacosmos acknowledged Monofer had a problem with adverse events as the only reformulation Vifor was aware of was Diafer which was simply half strength Monofer. The final message of the briefing document was again 'The Ferinject proposition is strong, be confident, we have the best treatment'.

In the Panel's view, there was no doubt that Vifor was specifically targeting Monofer sales and that the representatives had been briefed to discuss the comparative safety of Ferinject vs Monofer.

The Panel noted Vifor's submission that Grant *et al* was included with an overview of all relevant papers in the 'Clinical papers' session of the ITC. A summary of that session was provided; no slides for the session existed. Vifor noted that the aim of including that information was to educate Vifor employees on the place Ferinject's data held within the broader context of other products. The emphasis was on Ferinject and representatives were instructed not to use the competitor data with customers unless the data contained information on a Vifor product.

The Panel noted Vifor's explanation that Grant *et al* was published as an abstract in Gut in September 2013. Grant *et al* was an audit of case notes of 40 patients who had received Monofer. The authors concluded 'Utilisation of Monofer in our clinical practice has shown a sub-optimal attainment of Hb target. Furthermore, the frequency of adverse reactions was much higher than expected from those reported in the product SPC or previous studies in renal patients. In light of these observations we no longer use Monofer'.

A medical update was provided at the December 2013 sales conference which included information on recent publications for Ferinject and Monofer and included, *inter alia*, Grant *et al* and the authors' conclusion as stated above. The slide set for the session stated on the first slide that it was for internal use for training purposes. The cover slide did not state, as submitted by Vifor that the training session was for information only. The Panel considered that the slides contained material which Vifor would expect its representatives to use. No context had been given to the results from Grant *et al*.

The Panel disagreed with Vifor's submission that it only included safety information relating to Ferinject and Monofer in the Q&A document (ref UK/FER/15/0274) given that such comparisons appeared in the Intravenous Iron Differentiator tool and in the SPC Comparator tool. With regard to the latter, the Panel noted that the Ferinject and Monofer SPCs were being used by Vifor for a promotional purpose. The Panel noted that the briefing material stated that the tool had been designed to help representatives to directly compare different sections of the SPCs for the most prescribed IV irons including Ferinject and Monofer, it was to be used when asked specific questions about Vifor IV irons and those of its competitors. The briefing also stated that 'You can also project this from your iPad for use with multiple HCPs [healthcare professionals] at meetings'. There was no information on how to use the information provided in the tool and how to present the comparisons to a customer. The Panel noted Vifor's submission that representatives were briefed not to discuss competitor products in detail beyond the SPC. In the Panel's view, providing a tool which directly compared SPCs, implying that such direct comparisons of data were valid, went beyond that. The Panel also considered that the SPC Comparator tool went beyond the reminder given in December 2015 that representatives were not to discuss the safety of competitor products and that if a customer requested comparative safety data the request should be forwarded to medical information.

The Panel considered that on the balance of probabilities, given the strident tone and content of the sales materials and briefings, Vifor representatives had disparaged Monofer in promotional calls as alleged. A breach of Clause 8.1 was ruled. The Panel further considered that on the balance of probabilities, Vifor representatives had provided misleading information with regard to the safety of Monofer as alleged. A breach of Clause 7.2 was ruled.

APPEAL BY VIFOR

Vifor appealed the Panel's rulings of breaches of the Code.

Vifor reviewed the Panel's rulings, the material submitted as part of the complaint and also the additional evidence from Pharmacosmos that was not provided to it until after the rulings. Vifor submitted that despite requests that it do so, the PMCPA had not confirmed that Pharmacosmos would bear administrative charges if its complaint was unsuccessful. Nor had it provided Vifor with all the information requested in its notice of appeal, namely the Protocol of Agreement referred to in the introductory section of the Code [provided to Vifor on 11 August 2016] that set out the relationship between the ABPI and the PMCPA. Vifor requested sight of the Protocol of Agreement since it might help inform whether a non-member pharmaceutical company that had not submitted to the jurisdiction of the PMCPA – indeed one that had refused to accept a PMCPA ruling and had walked away from the self-regulatory scheme – could bring a complaint under the PMCPA process (and not be responsible for any

administrative charges). Vifor was unaware of this issue ever having been addressed specifically in a prior appeal. Vifor's notice of appeal referred to the 1997 Code of Practice Review because this was when the Protocol of Agreement first entered into force and the Review made clear that 'it is available on request'. The PMCPA did not provide Vifor with the Protocol of Agreement. Instead, it suggested that everything it needed to confirm the independence of the PMCPA was in Paragraph 1 of the Constitution and Procedure and the Introduction to the Code. However, these documents referred to the Protocol of Agreement which, unreasonably, had not been provided.

Nevertheless, Vifor gave its detailed grounds of appeal below and reserved its right to update or amend them as new material became available. Vifor's primary case was that the case preparation manager should not have presented the case to the Panel for review since Pharmacosmos did not have standing to bring a complaint through the Constitution and Procedure (see Ground 1: Pharmacosmos lacks standing). The Appeal Board's determination on this point would also be relevant to ABPI members and other non-members that had agreed to submit to the jurisdiction of the PMCPA. However, the fact that Vifor had raised the issue of standing should not be interpreted as implying that it did not wish to defend its position. If the Appeal Board found that Pharmacosmos did have standing, then Vifor appealed on the basis that the process conducted to date had been manifestly unfair given that key evidence from Pharmacosmos was disclosed to it only after the ruling was made (see Ground 2: Fairness). Regardless of these points, on the evidence submitted (and that Vifor had had an opportunity to respond to), Vifor argued that Pharmacosmos had failed to discharge the burden of proof (see Ground 3: Burden of proof).

Finally, Vifor submitted that, as noted in its notice of appeal, certain passages in the internal documents concerned were highly confidential and could not be shared with Pharmacosmos (although Vifor had provided redacted versions that could be shared). Vifor noted from the PMCPA's letter of 29 July '… the general principle is that anything which the respondent company wishes the Appeal Board to consider has to be made available to the complainant'. Whilst Vifor generally agreed (since this supported its appeal against the Panel's decision under Ground 2), this was subject to issues of confidentiality. As the documents in question were internal company documents that revealed commercial strategies of Vifor *vis-à-vis* Pharmacosmos, there was a presumption that such documents were confidential and should not be disclosed. Since these documents were not themselves subject to the specific allegations of breach, Vifor failed to see what value (other than competitive value) these documents could be to Pharmacosmos' case.

Vifor fully expected that Pharmacosmos would not object to the redactions. If, notwithstanding this, the Director had considered that she could not determine the matter and that she needed to seek the involvement of an independent referee, Vifor wished to understand who would bear the administrative cost for that given that the issue of administrative charges was a key plank of its argument under Ground 1. Also, given that Pharmacosmos had already refused to accept the findings of the Panel and had turned its back on the self-regulatory scheme, Vifor asked what safeguards would be put in place to ensure that Pharmacosmos kept the information confidential since there was nothing at all to bind Pharmacosmos to an independent referee's decision (this again went to Ground 1).

Grounds of Appeal

Ground 1: Pharmacosmos lacks standing

Vifor understood that Pharmacosmos was neither an ABPI member nor a non-member that had agreed to submit to the jurisdiction of the PMCPA. Indeed, it was a company that had previously flouted a Panel ruling. Vifor submitted, therefore, that the Constitution and Procedure must be interpreted as meaning that such pharmaceutical companies could not benefit from the ABPI's independent adjudication process and the benefits that went with it. Rather, on receiving information about Vifor's activities from Pharmacosmos, the PMCPA case preparation manager should have checked whether Pharmacosmos was willing to re-engage with self-regulation and submit to the jurisdiction of the PMCPA and if not, the company should have been advised to take the complaint up with the Medicines and Healthcare products Regulatory Agency (MHRA), or indeed the applicable Irish authorities in relation to some of the points raised.

Context of the standing position

As previously stated, Vifor had assumed that since Pharmacosmos lodged a complaint, that it was a non-member company that had voluntarily agreed to comply with the Code and accept the jurisdiction of the PMCPA. However, the Panel's ruling on this point was not clear. The Panel merely noted 'that in 2014 Pharmacosmos had declined the offer to join the PMCPA list of non-member companies and no longer wished to accept the jurisdiction of the Authority but stated that it would continue to be fully committed to the ethical promotion of its products'.

Vifor understood that if a pharmaceutical company wished to complain or respond to a complaint through the PMCPA process, that it had to be either a member of the ABPI, or a non-member that had submitted to the jurisdiction of the PMCPA. Vifor fell under the second category.

Vifor noted, in particular, that the PMCPA had considered in previous cases involving Pharmacosmos whether Pharmacosmos had accepted the jurisdiction of the PMCPA (Case AUTH/2694/1/14). The Panel's ruling in that case was disturbing. Pharmacosmos UK accepted the rulings of breaches of the Code but decided that it no longer wished to accept the PMCPA's jurisdiction or give the undertaking the PMCPA had requested. The PMCPA noted that Pharmacosmos had previously agreed to be on the list of companies abiding by the Code and accepting the PMCPA's jurisdiction and that it

would be required to report the company to the Appeal Board. However, Pharmacosmos UK argued that its parent company, Pharmacosmos A/S, had agreed to comply with the Code and that, because the UK subsidiary was not on the list, it was not possible to remove it and there was no basis for a referral to the Appeal Board. This was notwithstanding that, as the PMCPA noted, 'both in terms of complaints received **and complaints submitted** and in that regard both [Pharmacosmos UK and Pharmacosmos A/S] appeared to consider themselves effectively, if not formally, on the non-members list' (emphasis added).

Vifor noted that in a letter dated 25 July 2016, the PMCPA stated that its:

> 'Constitution and Procedure allows complaints to be submitted from any source … The position remains that Pharmacosmos was entitled to submit a complaint and the Authority acted within its Constitution and Procedure in accepting it.'

Vifor submitted that the assertion that the Constitution and Procedure allowed complaints to be submitted by any pharmaceutical company source was misguided as, in fact, there was no clear reference to this in the Constitution and Procedure. Rather, information received must be processed by a case preparation manager in accordance with Paragraph 5.1 of the Constitution and Procedure and that case manager 'determines whether a case should go before the Panel'. That determination did not benefit from unfettered discretion. The case preparation manager should not put a case before the Panel if the complaint was from a pharmaceutical company that was not a member of the ABPI or that had not agreed to submit to the PMCPA jurisdiction. This position was also supported by the Memorandum of Understanding between the ABPI, PMCPA and MHRA, which stated:

> 'Compliance with the Code is a condition of membership of the ABPI and, in addition, about 60 pharmaceutical companies that are not members of the Code have agreed to comply with the Code and submit to the jurisdiction of the PMCPA. Members of the ABPI and **non-members of the ABPI who have agreed to comply with the Code should send their complaints to the PMCPA**' (emphasis added).

Vifor submitted that this passage clearly implied that non-members which had not agreed to comply with the Code should refer their complaints to the MHRA. The fact that the memorandum also stated that the MHRA and PMCPA 'deal with complaints whatever their source' simply meant that with respect to companies such as Pharmacosmos, the PMCPA's case preparation manager should refer the matter to the MHRA.

Consequences of allowing Pharmacosmos to participate in the complaints process

(a) Gaming the system

The standing position of Pharmacosmos was vitally important for Vifor (and it assumed other companies in its position, as well as ABPI members). If the PMCPA allowed pharmaceutical companies which were not members and which had not accepted the jurisdiction of the PMCPA (or refused to abide by its findings) to complain, this could clearly lead to a gaming of the self-regulatory system to the detriment of ABPI members and companies like Vifor (which paid the associated administrative charges and so forth) – gaming that Pharmacosmos had shown it was quite comfortable with.

Vifor firmly believed in self-regulation and compliance with the Code, but the rules had to be respected by all pharmaceutical companies which wished to participate in the PMCPA complaints process and the benefits that went with that system of self-regulation, in particular ensuring a level playing field in terms of the rules and the speed of determining complaints. Vifor noted in particular the following comments from the Chairman of the Appeal Board, in the PMCPA Annual Report 2008:

> '… one of the strengths of the current procedure is that cases **are resolved relatively speedily**. That is as it should be; justice delayed is justice denied… Every effort is made to complete consideration of cases as quickly as possible and publish the outcomes. **Transparency and openness are key requirements to maintain confidence**. The detail given in the published case reports serves the industry well and **demonstrates that the system operates without fear or favour**' (emphasis added).

From Vifor's perspective, this meant that Pharmacosmos could lodge complaints about companies subject to the framework with the *quid pro quo* that Vifor was itself subject to the framework when complaints were made against it (and hence all parties benefited from consistent decision-making using a relatively quick adjudication process). For example, Vifor could complain about another company's use of promotional aids or its disclosure of transfers of value (and expect complaints in return if a competitor had a cause for concern). Conversely, companies like Pharmacosmos could similarly complain to the PMCPA without fear of challenge in return since those rules were entirely voluntary (ie, promotional aids were still legally acceptable provided they were inexpensive and there was no obligation to disclose further transfers of value).

Vifor further submitted that the system of administrative charges (which could be quite significant for non-member companies) could deter companies from making frivolous complaints. When Vifor asked how the administrative charges would be applied to Pharmacosmos, it was dismayed at the PMCPA's lack of transparency and openness in its answer ('[the] imposition [of administrative charges] is not relevant to the consideration of the merits of a case' – letter from PMCPA of 26 July 2016). This non-response went against the spirit of transparent decision-making that the Chairman referred to above. Also, the PMCPA fundamentally missed the point. Vifor could appreciate why the imposition of administrative charges might not be relevant to the merits of a specific case, but the failure to address this point meant that Vifor was no longer confident that the PMCPA operated 'without fear or favour'.

Vifor noted that, as stated by the PMCPA, administrative charges were a contribution towards the general running costs of the Authority. If companies like Pharmacosmos could make a series of complaints that were unsuccessful, the cost of those complaints was borne by ABPI member companies and non-member companies who submitted to the jurisdiction of the PMCPA. That was simply unfair and Vifor could not imagine the ABPI Board would fully support that without debating the issue amongst its membership. The situation was completely different of course for complaints from outwith the industry, ie from health professionals, ex-employees, patient groups, the media, etc, since it was quite right that legitimate complaints from such groups should be covered. Indeed, this was why pharmaceutical companies paid administrative charges and those from outwith the industry did not.

For the avoidance of doubt, Vifor did not advocate that Pharmacosmos be deprived of any or all regulatory recourse in instances where it had a complaint about a competitor company. In fact, Pharmacosmos had such recourse at its disposal in that it could complain to the MHRA which administered UK law on behalf of the Health Ministers.

(b) Procedural safeguards during the PMCPA adjudication process

Vifor was also very concerned that a pharmaceutical company complainant which did not submit to the jurisdiction of the PMCPA would not be obligated to comply with the rules of the complaints procedure some of which were more subtle than what was written in the PMCPA Constitution and Procedure. For example, the Panel had made clear that 'Self-regulation relie[s] upon a full and frank disclosure of the facts' (Case AUTH/236610/10). For the reasons mentioned above regarding Pharmacosmos' precarious status as a complainant, it was impossible to guarantee that Pharmacosmos' complaint and documentation sent to the PMCPA was based on a full and frank disclosure of events, nor was Pharmacosmos bound to deliver as such nor were there any consequences should it not do so.

Vifor was also very concerned about documents that it had submitted in response to this complaint being sent to Pharmacosmos without any clear confidentiality undertakings being in place. Indeed, as set out above, Vifor still did not have any assurance from the Panel or from Pharmacosmos that it would respect the decision of an independent referee in deciding which of its documents were confidential or not (nor did it know who would bear the administrative cost of that procedure). [Vifor was informed that the costs of referring matters to an independent referee were paid by the PMCPA].

Ground 2: Fairness

Vifor stated that during a telephone discussion on 19 July 2016, it became clear that the Panel had not shared evidence in support of Pharmacosmos' complaint with Vifor prior to the Panel's ruling. On 21 July, the PMCPA disclosed the additional information, which comprised emails from individuals within the company that purported to provide an account of what health professionals had told Pharmacosmos about Vifor's conduct in various parts of the country.

Vifor was extremely concerned that the Panel ruled against Vifor on the balance of probabilities without giving the company an opportunity to review and, if necessary, comment and respond to that evidence. This was manifestly unfair, particularly in proceedings of this kind and was best characterised by Lord Denning in one of the leading cases in this area that the accused person:

> 'must know what evidence has been given and what statements have been made affecting him; and he must be given a fair opportunity to correct or contradict them ... **It follows, of course, that the judge or whoever has to adjudicate must not hear evidence or receive representations from one side behind the back of the other. The court will not inquire whether the evidence or representations did work to his prejudice, sufficient that they might do so. The court will not go into the likelihood of prejudice. The risk of it is enough**' (emphasis added).

Vifor submitted that in not making available the specific allegations and the evidence purporting to support those allegations, the Panel had breached a fundamental principle of natural justice that provided a party a right to respond to the charges (Vifor referred to Tudor v Ellesmere Port & Netson Borough Council (1987) Times, 8 May). Moreover, the process had frustrated Vifor's ability to provide a 'complete response' to the complaint, in accordance with Paragraph 5.2 of the Constitution and Procedure.

Vifor submitted that this position was also true in the criminal context. The Court of Appeal had made clear that being deprived of the opportunity of producing further evidence was fundamental and 'is not a matter of mere procedural nicety' (Musone v R [2007] EWCA Crim 1237).

Vifor submitted that had this information been disclosed during the proceedings, it would have commented upon and corrected such evidence and responded to it with its own evidence, including call reporting records and, if necessary, statements from company representatives corroborated with a statement of truth.

Ground 3: Burden of proof

Vifor submitted that the Panel found it in breach of Clauses 8.1 and 7.2 on the basis that the material provided by Pharmacosmos evidenced a 'pattern' of disparaging comments about Monofer. This decision was irrational since all of Pharmacosmos' evidence was anecdotal and Vifor had fully rebutted all but one point (and this was a point already accepted to some extent in Case AUTH/2828/3/16, in which Vifor had accepted that the manner in which the Lareb report was distributed and the manner in which the content of the report was described could have been better. Vifor had since changed the relevant processes and the manner in which it described the Lareb report).

Vifor submitted that a 'pattern' of behaviour must, on any sensible interpretation, mean more than an isolated incident. It suggested a company-wide pattern of non-compliance which could not be further from the truth. The Panel referred to three previous PMCPA cases in support of its conclusion that there was a 'pattern' of inappropriate behaviour. However, two of the cases the Panel cited were over 5 years old and the more recent case did not result in a finding of breach. Vifor did not accept that this evidenced a 'pattern', as the Panel suggested.

Vifor stated that it was committed to adhering to the Code. Vifor accepted that compliance with the Code was critically important to the successful relationship between industry, health professionals and the public and it was Vifor's responsibility to uphold the highest standards at all times.

Vifor submitted that the PMCPA was fully aware of the company's compliance activities and the seriousness with which Vifor took compliance with the Code and these had only been strengthened since the PMCPA audited Vifor's procedures in relation to the Code in October 2012. Vifor had invested much time and resource in building a compliant culture and many key staff, attached a great importance in maintaining this. Vifor stated that the Panel's comments about the requirements of Clause 15.4 had already been incorporated into its Field Force meetings SOP as this was under review when Vifor received the comments. Specifically, Vifor had:

- Code of Practice training for all new starters
- Regular review of SOPs
- Internal audits
- Regular 'Lunch and Learn' sessions covering PMCPA cases
- Regional compliance liaisons (an individual from each regional team who worked closely with compliance and ensured effective communication of compliance-related information)
- Quarterly 'Getting it Right' compliance newsletter
- Vifor Code compliance site
- Advanced Code training for Marketing and Medical
- Final signatories forum
- Externally led training sessions for key staff
- Electronic training system.

With this in mind, Vifor simply did not understand how the Panel arrived at a decision that suggested there was a pattern of non-compliance behaviour. The decision should therefore be set aside on the basis that Pharmacosmos had failed to discharge the burden of proof on the balance of probabilities. The evidence in support was not supported by verifiable evidence and based on anecdotal hearsay; further the Panel's interpretation of Vifor's documents provided in response to the complaint was flawed. In Case AUTH/2824/2/16, the Panel had to determine whether there was sufficient evidence to substantiate the allegation that representatives went to a named location contrary to the terms of a verbal undertaking. The Panel found there was no evidence to substantiate the complainant's allegations that the representatives visited the named location and therefore no breaches were ruled. The essence of this case was to demonstrate the difficulty of substantiating an event where there was competing anecdotal or hearsay evidence. Allegations should be substantiated. Such allegations were not substantiated in Case AUTH/2824/2/16 nor were they substantiated in this case. Examples included:

- Two of the cases relied on by the Panel were from Ireland and, therefore, irrelevant to the issue before the Panel but yet the decisions were quoted at length in purported reliance on them and as evidence of a 'pattern' of UK behaviour. Vifor Ireland was a separate, independent company with its own country manager and these components should have been disregarded from the outset, as had been requested by Vifor.

- In two of the cases, Vifor's documented call records and representative statements confirmed that no Vifor calls were made in the institutions mentioned within the relevant time period. In Case AUTH/2824/2/16 the Panel confirmed the acceptability of representative call records as evidence of non-activity. The Panel ignored this material evidence in favour of uncorroborated, anecdotal hearsay from a company not bound by the rules of full and frank disclosure.

- In another two cases, Vifor had found no evidence from the one representative concerned that he/she made any negative statements about Monofer, particularly in relation to its safety. The accounts of this representative were provided.

- One case related to the distribution of the so-called Lareb report. The company had already accepted a ruling in relation to the medical information process of sending the Lareb report in a parallel case (Case AUTH 2828/3/16) brought by the health professional concerned. But the Appeal Board would also be aware that Vifor was also appealing all other rulings in that case and it had its own unique set of facts. In any event, a single isolated incident (which must be taken in context) could not on any reasonable view support a finding of a 'pattern of behaviour.

Vifor submitted that the Panel appeared to have placed significant weight on the balance of representative briefing documents which it suggested had led to a pattern of behaviour that would lead representatives to denigrate Monofer. In doing so, the Panel reproduced a number of allegations by Pharmacosmos, without ever checking their accuracy or plausibility. The Panel restated Pharmacosmos' assertion that 'an appraisal of the material used to train Vifor representatives would corroborate its concerns because it was likely to draw attention to Monofer's adverse event profile in a misleading manner. Pharmacosmos alleged that the training material would link the dextran-derived nature of the Monofer molecular structure to a higher (alleged) propensity to adverse events, which is misleading'. Yet none of Vifor's briefing materials (all of which had been provided to the Panel) referred to dextran, the nature of the Monofer molecular structure or a higher propensity to adverse

events. Rather than simply appearing to accept this allegation for which no evidence whatsoever was found, the Panel should have weighed this inaccurate statement when determining whether Pharmacosmos had discharged its burden of proof and indeed whether the complaint might in some respects be vexatious.

However, Vifor submitted that it had been at pains to emphasise that its representatives were briefed not to discuss comparative safety data beyond the SPC. The SPC held key information approved by the regulatory body and the information contained within the SPC was, therefore, accurate, balanced, fair, objective and unambiguous and based on an up-to-date evaluation of all the evidence. Vifor did not draw any of its own conclusions from the SPC comparison but presented the data side-by-side (as in the SPC comparator) to allow health professionals to make their own decisions. Vifor was therefore perplexed by the Panel's ruling that the SPC comparison tool was misleading. It was merely a side-by-side restatement of the terms of the products' approved SPCs to be used as a basis for discussions with health professionals and to assist in responding to their questions. Vifor had not extracted portions of either SPC or presented them in a promotional manner.

In relation to the iron differentiator, Vifor submitted that it provided an accurate, balanced and up-to-date reflection of the evidence in this document. Vifor had summarised every Phase 3 and 4 trial in the listed therapy areas for each product and presented each in the same way so that health professionals could judge the clinical trial data for themselves. The date of last update was included on the overview slide to demonstrate that it was up-to-date. The differentiator tool acknowledged in a number of places that there were no head-to-head comparisons of the two products. The information about dosing and infusion was referenced to the product SPCs. The statement about the Ganzoni formula was clearly referenced to an independent, expert group. The sections on tolerability – undesirable events and contraindications – were referenced solely to the product SPCs. All of this information was factual, verifiable and fully substantiable.

Vifor therefore encouraged the Appeal Board to read all of its briefing material and not merely the statements selected by the Panel which had been misinterpreted and taken out of context to suggest a culture of non-compliance within the company when the opposite was true.

Vifor submitted that given the briefing materials, the Panel's decision was not reasonable and it encouraged the Appeal Board to read the materials at issue in full. The Panel appeared to have focussed almost exclusively on the phrase 'The Ferinject proposition is strong, be confident, we have the best treatment'. This phrase was found at the very end of one of many extensive briefing documents (ranging from 14 to 26 pages in length) and so needed to be read in context of the document as a whole and previous historical briefing documents.

Vifor submitted that UK/FER/13/0201 dated back to 2013 but it gave an objective overview of changes to the SPCs for both Ferinject and Monofer and recent clinical studies within the relevant therapy area and concluded (without any mention of Monofer) with the fact that '… we have the most documented evidence …'.

Vifor submitted that UK/FER/15/0015b was created in mid-2015 to introduce the SPC comparator, which was a simple factual re-representation of the SPCs of all the products in this therapy area. It did not edit or comment upon the content and the representatives were simply directed to '…use when asked specific questions about the [Vifor] irons and those of our competitors…' which again illustrated the objectivity of the material provided. Vifor remained perplexed as to why the Panel took exception to the instruction '…you can also project this from your iPad for use with multiple HCPs at meetings …' as this was common practice within the industry.

Vifor noted that the Panel ruling commented on a briefing document UK/FER/15/0279 which stated:

> 'Five accounts had switched from Ferinject to Monofer. No reason was stated for the switch but it was reasonable that representatives would assume that it was to do with safety and tolerability given that was the heading to the slide.'

Vifor submitted that it was appropriate to share information and knowledge about events and developments in the market with its representatives. All of the content on the briefing slide in question was factual and accurate. The representatives invariably discussed occurrences such as this between themselves. The purpose of providing this sort of update was to prevent inappropriate use of such knowledge. The briefing document did not state why the cited accounts had switched from one product to another, nor did it instruct the representatives to proactively use this information with health professionals.

Vifor submitted that UK/FER/15/0274a, Ferinject Differentiation from Monofer slide set, and its accompanying briefing document (UK/FER/15/0274e) were created in January 2015 [sic, it was certified in January 2016] for use at a sales conference. These covered in depth randomised clinical trials in the relevant therapy area and the respective products' SPCs. The associated briefing document was objective and factual and whilst it instructed that the slides were designed to be used in accounts that were considering, and in accounts that had switched to, Monofer nothing in either the slides or briefing document was inconsistent with the facts of either the clinical trials or SPCs of the products in question and representatives were encouraged '…if additional information is requested, complete the Medical Information request form' (the Panel's comments on the statement '… The Ferinject proposition is strong, be confident, we have the best treatment …' were addressed below). Vifor supported its statement that the Ganzoni formula used to calculate the Monofer dose was '…recognised as

inconvenient, prone to error, inconsistently used in clinical practice, and it underestimates iron requirements …The briefing on this slide referred to Ganzoni-based dosing as being problematic …'. Ganzoni-based dosing was problematic and it was not misleading to say so, as substantiated by the citation supporting this conclusion.

Vifor submitted that the briefing document UK/FER/15/0274f was also created for the January 2015 [sic, it was certified in January 2016] sales conference and was a pivotal document in both the PMCPA's interpretation of the actions Vifor had allegedly encouraged its representatives to take and in Vifor's defence. It was important to read this document in full. The heading of the briefing was 'Reactive Responses to Competitor Messages'; the first slide of the document was headed 'Customer Reported Monofer Messages' and listed below the headline were 10 comments that prior to the conference Vifor representatives had informed the company that customers had reported to them as being told to them by Monofer representatives and requested clarity upon.

Vifor submitted that the first slide of the deck clearly stated '…what we need to do **reactively** is to discuss the **FACTS** in an accurate and balanced way, to allow the customer to make an informed decision …' (bold not added). The remainder of the briefing document then covered each one of the 10 reported misinformation topics and presented the facts regarding this misinformation in a clear, objective, fully compliant appropriate way. The summary slide should also be considered in full. It stated:

- Be professional, never disparage the competition
- Discuss the facts in an accurate and balanced way
- If the customer wants extra information on Ferinject, offer the Medical Information service
- Following this advice will build the customers credibility and respect for you
- The Ferinject proposition is strong, be confident, we have the best treatment.'

Vifor submitted that the single, final summary statement could not render all of its briefing materials as 'strident' or disparaging of Monofer. This final statement was simply the logical progression of all the previous information; it reinforced to the representatives that if they concentrated on the facts in an accurate and balanced way and acted professionally they would build credibility and respect with their customers, not disparage the competition and have confidence that their customers would choose Ferinject because the facts would illustrate that Vifor had the best treatment. The statement itself was purely motivational for internal use and appeared in no promotional materials. If the Appeal Board considered that this type of statement could not be included in context in its internal communications, it would appreciate a thorough explanation in the case report for transparency purposes. Statements such as these were commonly used in the industry (and by the ABPI itself) to motivate the salesforce or employees more generally by instilling belief in the company, the product or services. An appropriate and every-day analogy would be where motivational speeches or 'pep-talks' were given on staff appreciation or away-days. It was important to note that neither the statements such as the ones complained of nor the analogous examples offered here prevented or precluded representatives from discussing comparative safety in a promotional environment. The statement did not directly or indirectly advocate either directly or indirectly any course of action which would be likely to lead to a breach of the Code.

Given the above, Vifor did not consider, that Pharmacosmos had discharged the burden of proof with respect to its allegations. In fact, by the Panel's own admission, Pharmacosmos had provided 'anecdotal examples' to 'substantiate its concerns'. Vifor submitted that anecdotal, unsubstantiated examples could not be given weight over verified, documented evidence.

Vifor submitted that the Panel acknowledged in its ruling that the appropriate standard was the 'balance of probabilities'. Vifor noted the burden of proof in the civil litigation context where 'the standard to be attained in most cases was that the court must be satisfied "on a balance of probabilities"' that the client's allegation was correct. In Miller v Minister of Pensions [1947] 2 All E.R. 372, QBD, Denning J. explained this as (at page 374):

> 'If the evidence is such that the tribunal can say "we think it more probable than not", the burden is discharged, but if the probabilities are equal, it is not.
>
> In essence, in order to satisfy the judge that one party's version of the events is the version to be accepted, the judge has to be convinced that this version is more likely than not to be true-that the balance of evidence is tilted in the client's favour. If this were to be expressed in simple mathematical terms, at least a 51 per cent probability in favour of the client must be demonstrated, as suggested by Lord Simon in Davies v Taylor [1974] A.C. 207, HL (at p.219). If, on the other hand, the client's version is just as probable as the opponent's version, the client has failed to discharge the burden of proof.'

Vifor submitted that at worst, its version of events was just as probable as that put forward by Pharmacosmos. In any event, Pharmacosmos had not demonstrated its evidence discharged the burden of proof on the balance or probabilities assessment, nor was the Panel entitled to rule as such.

Vifor noted that in Case AUTH/2572/1/13 the Appeal Board had had to consider the burden of proof and it indicated that where 'it is not always clear how/whether the material supported the complainant's allegation … the Appeal Board [had] to decide how much weight to attach to this evidence'. In that case, the Appeal Board considered that extracts from emails and excerpts from published papers were insufficient evidence and did not provide a 'fair and balanced reflection of the evidence available at the time'. The Appeal Board made it clear that where the

complainant failed to marshal sufficient evidence to discharge the burden of proof, there should not be a ruling of a breach.

> '[where] there is insufficient provided by the complainant …. The Appeal Board considered that the complainant had not discharged its burden of proof and it upheld the Panel's ruling of no breach ...'

Vifor submitted that this reflected a general and widely-acknowledged strand in the law of evidence that 'the weight of evidence depends on the rules of common sense' (R. v Madhub Chunder (1874) 21 W.R Cr. 13 at 19 (Ind) per Birch J).

Vifor submitted in conclusion that it was impossible, on a common sense view, to make a finding against it based on Pharmacosmos' evidence.

COMMENTS FROM PHARMACOSMOS

Pharmacosmos noted Vifor's appeal in relation to alleged disparaging and misleading claims about Monofer. In summary:

- Pharmacosmos agreed with the Panel's ruling. Vifor promoted Ferinject in a manner that was both misleading and disparaging;

- Pharmacosmos understood that there was a need for greater clarity in the process and it commented below in respect of Vifor's appeal submission.

The following sections addressed key considerations.

1 Panel's ruling

Pharmacosmos stated that in essence, the Panel determined that Vifor had presented the comparative safety profiles of Ferinject vs Monofer in an inappropriate manner that was disparaging and misleading.

Pharmacosmos stated that it had initiated inter-company dialogue because reports from health professionals indicated a centrally-driven message being disseminated by Vifor representatives. Such central messaging was difficult for a competitor to prove as most complaints relied on the written sales material. In an increasingly digital age such evidence was difficult to obtain. Pharmacosmos first attempted to resolve the matters by inter-company dialogue with Vifor leading to Pharmacosmos' initial acceptance of the actions communicated. (For further comments in relation to the inter-company exchanges see Section 2, below).

Pharmacosmos subsequently escalated its concerns to the PMCPA. Pharmacosmos did not make specific allegations concerning the examples cited in its previous correspondence with Vifor as it accepted that the PMCPA did not consider anecdotal reports *per se*. As stated, the allegation was that there was a pattern of similar activities, and it was important to demonstrate how Pharmacosmos had attempted to resolve matters through meaningful inter-company dialogue in the first instance as well as why it concluded that inter-company dialogue had failed.

When Pharmacosmos received the report from the nurse, in March 2016, it concluded that, on the balance of probability, it was unlikely that the three Vifor employees named (the representative, the regional business manager and the person from medical information), would have acted in the way they did if the supposed communication from senior Vifor directors to their teams less than two weeks earlier had been effective. As a consequence, Pharmacosmos lost confidence in previous statements made during inter-company dialogue.

Thus Pharmacosmos had urged the PMCPA to look at Vifor's training material. The PMCPA subsequently uncovered both training material and promotional material that directly and misleadingly compared Ferinject and Monofer. It was important to note the nature of the evidence cited by the Panel in ruling breaches of Clauses 7.2 and 8.1:

- Vifor's Intravenous Iron Differentiator tool
- Vifor's SPC Comparator tool
- The existence of these documents despite Vifor's submission that representatives did not discuss relative safety profiles
- Vifor's lack of clear briefing in how to use these tools appropriately
- Vifor's use of these documents specifically in accounts 'threatened' by Monofer
- That representatives were specifically targeting Monofer sales and had been specifically briefed to compare the side-effect profiles
- Vifor's failure to instruct sales representatives not to use material and information that had been provided to them (eg Grant *et al*)
- The 'strident tone' of Vifor's sales materials and briefings.

Pharmacosmos noted that Vifor's appeal stated that it could not recognise the pattern of non-compliant behaviour cited by Pharmacosmos owing to Vifor's credible compliance programme. Pharmacosmos alleged that this, perhaps, missed the point. Pharmacosmos merely argued that the pattern of attacks against Monofer's safety profile suggested central coordination and that this specific activity was non-compliant; the Panel's findings confirmed its allegation. It must be up to the authorities to decide whether Vifor's compliance system was effective or not.

Pharmacosmos noted that Vifor's appeal relied at least in part on explaining the specific circumstances surrounding the individual anecdotal health professional comments cited. However, Pharmacosmos submitted that was not the point; the main issue was that, in addition to the anecdotal reports, the material provided by Vifor was inappropriate and thus likely to directly lead to comments like those cited. Even if the dates cited did not exactly match the call reports of Vifor representatives, the simple truth was that Vifor representatives disseminated messages issued by Vifor's central office. Pharmacosmos made it clear in its complaint that it was more concerned with the pattern of disparaging and misleading behaviour than with the actions of individual representatives. The Panel's identification of the existence and use of

the Intravenous Iron Differentiator tool and the SPC Comparator tool confirmed its suspicions that Vifor representatives were directed centrally to compare the products in a misleading and disparaging manner. This was especially true given that these two tools had been issued and used in contradiction to the 'briefing' issued to Vifor representatives in 2015 that questions regarding comparative safety were to be referred to its medical information department. The accounts from the representatives interviewed by Vifor confirmed that they actively used the SPC Comparator and the Intravenous Iron Differentiator tools and also identified concerns with Monofer, rather than solely promoting the merits of their own product *per se*.

Pharmacosmos alleged that Vifor's appeal addressed the direction that Vifor representatives should be confident because they 'had the best treatment'. Pharmacosmos agreed that this was a motivational statement, however, Vifor failed to recognise that without substantiating evidence it was also misleading those representatives. As stated in the appeal:

> '… customers will choose Ferinject based on the facts as the facts will illustrate that we have the best treatment.'

Pharmacosmos alleged that this degree of belief in the product was admirable. However, if Vifor could not recognise the lack of comparative evidence (facts) to prove this point, then it was clear that the representatives were being instilled with a similar perception that did not recognise the relative merits of the clinical data that existed individually for the two products.

Pharmacosmos alleged that as it highlighted in its appeal, Vifor seemed not to understand that a side-by-side comparison of two SPCs was not a relevant clinical comparison. In fact, as the Panel indicated, Vifor clarified that it had not instructed its representatives in how to use the SPC Comparator tool – it simply asked them to show the SPCs and 'allow health professionals to make their own decision'. This was at the crux of the matter and appeared to be a key point in this case. Vifor did not recognise that the provision of information in this context was a promotional activity; or that clinical comparisons were necessary to promote clinical conclusions about the differences between products.

Pharmacosmos stated that further, the single example of the use of the Lareb report was not to be dismissed as Vifor suggested, but should be regarded as an example of the type of approach being employed by Vifor. In its appeal, Vifor clarified that it would continue to use the document, albeit in an amended form; thus issuing the Lareb report was not an isolated incident as Vifor contended.

Pharmacosmos alleged that Vifor's response to the Panel seemed to suggest that in the absence of head-to-head data, Vifor was entitled to selectively provide the Lareb report in order to build a perception of comparative differences between Monofer and Ferinject:

> 'This report was the most appropriate document to send in light of the request for comparative safety data and the absence of any direct head to head clinical trial data on Ferinject and Monofer'.

Pharmacosmos was concerned about the provision of the Lareb report in isolation because the data lacked context and failed to acknowledge the existence of contradictory reports from other health authorities, such as a Swiss Medic report which highlighted a high incidence of adverse drug reactions when Ferinject was introduced as new alternative IV iron in Switzerland.

Pharmacosmos also noted that when the Vifor representative wrote to the Vifor medical information department, the request was specifically for the provision of the Lareb report; it was not a request for the wider comparative safety data requested by the health professional. This was important because it showed that:

- Vifor representatives knew enough about the Lareb report to request it specifically
- Vifor medical information was not surprised to receive a request for this specific report, which implied it was not an unusual occurrence
- the Vifor representative concerned had deliberately requested a document that presented an unbalanced view of Monofer.

Pharmacosmos submitted that Vifor's provision of the Lareb report was clearly not in line with its inter-company commitment that requests for data about Pharmacosmos' products would be redirected to Pharmacosmos' medical information.

2 Inter-company dialogue

Pharmacosmos submitted that it had lost faith in the value of Vifor's commitments made during inter-company dialogue. The PMCPA was aware that, in the spirit of inter-company dialogue, Pharmacosmos had written to Vifor (16 February 2016) concerned about claims allegedly made by Vifor representatives in relation to the respective safety profiles of Monofer and Ferinject. The specific concerns were based on a number of incidents proactively brought to Pharmacosmos' attention by health professionals, and it had therefore strong reason to believe that disparaging and misleading claims were being made about Monofer by at least some Vifor representatives. In its response to Pharmacosmos dated 3 March 2016, Vifor stated that all its representatives:

> '…have been trained to forward any questions relating to the safety of Ferinject that go beyond the Summary of Product Characteristics or the comparative safety of Ferinject to our Medical Information Department.'

Vifor continued:

> 'As my colleague, [named] has stated in previous communications with the Pharmacosmos UK Medical Team, if we were to receive any questions relating to the comparative safety of Monofer

through Medical Information, the enquirer would be asked to contact Pharmacosmos Medical Information in relation to Monofer as there are currently no comparative data.'

Pharmacosmos alleged that however, it was clear from the evidence in this case that representatives had directed Vifor's medical information team to provide specific comparative data and had specifically requested the Lareb report. However, the Lareb report was not designed to provide comparative evidence.

Pharmacosmos alleged that with the information and materials exchanged between Vifor and the PMCPA as well as the communication by the medical information at Vifor it furthermore appeared that, contrary to Vifor's statement in inter-company dialogue that:

- Vifor intentionally briefed and enabled its sales team to make comparative claims between Ferinject and Monofer using its SPC Comparator tool and Intravenous Iron Differentiator tool;

- Vifor's medical information department made no attempt to refer enquirers to Pharmacosmos' medical information for information about Monofer. Instead the Vifor medical information officer proactively communicated safety information about Monofer to the named nurse, which was cherry-picked to be intentionally disparaging and completely ignored the specific safety reports related to Ferinject:

  'The Netherlands Pharmocovigilance Centre, Lareb, has received concerns from multiple Dutch hospitals in relation to [Monofer] after the switch from [Ferinject]. Doctors and nurses reported an increase in the severity and incidence of allergic reaction. The report has not mentioned any specific safety concerns with [Ferinject].'

Pharmacosmos submitted that these two points contradicted an inter-company confirmation that a communication from two senior Vifor directors was:

'… sent to all Vifor Pharma representatives in both the UK and Ireland confirming their obligations in relation to questions on the comparative safety of Ferinject.'

Pharmacosmos stated that another example of Vifor's seeming failure to adhere to commitments made in inter-company dialogue related to the continuous use of the GUT abstract by Grant *et al*. The PMCPA was aware that Vifor confirmed during inter-company dialogue in February/March 2014 that Vifor representatives would neither proactively nor reactively communicate this abstract. This had been agreed because the abstract, based on a single hospital audit, did not represent the balance of evidence. Despite its commitment, Vifor confirmed in its letter to the PMCPA dated 23 May 2016 that the company had continued to systematically introduce the abstract as part of its ITC for all new sales representatives. In the letter Vifor explained:

'The Grant *et al* publication in Gut is included with an overview of all relevant papers in the "Clinical Papers" session within the Vifor Pharma UK (VPUK) Initial Training Course (ITC) […]. Please note that the aim of including this information is to educate VPUK employees on the place Ferinject's clinical data holds within the broader context of other products.'

Pharmacosmos noted that anxiety amongst health professionals administering IV iron was a known risk factor for developing an adverse drug reaction. Rampton *et al* reported in 'Hypersensitivity reactions to intravenous iron: guidance for risk minimisation and management' that anxiety amongst either patient or staff was one of the 'factors increasing risk and/or severity of hypersensitivity reactions (HSRs) in patients given iron infusions'. According to Vifor's own briefing document the SPC Comparator tool and the Intravenous Iron Differentiator tool were designed 'to be used proactively in threatened accounts that were considering switching to Monofer and in accounts that had switched to Monofer' and which according to the PMCPA's ruling contained content that 'referred to confidence with Ferinject and in that regard implied lack of confidence with Monofer'. By causing anxiety amongst health professionals, particularly nursing staff responsible for the IV administration of Monofer, Vifor might have been responsible for increased incidence and/or increased severity of hypersensitivity reactions with Monofer. The following statements were extracted from the nurse's letter to hospital colleagues:

'… [named Vifor employee] and his colleague became very 'aggressive' and in their manner/talk and started to tell me that this 'new' drug is very dangerous and it's not safe and how do I know that it will be safe to our patients' (quotation by named health professional).

'I too had one of these unannounced visits from them [Vifor Pharma], and totally agree that they were scare mongering' (quotation by named health professional's colleague)

'… they were also trying to discredit the drug in quite an intense way. Referring to big centres that had swapped from ferrinject to monofer and had big reactions scaring a bit more of the infusion team than anything else' (quotation by named health professional's colleague).

Pharmacosmos noted that in its appeal Vifor submitted that the two anecdotal reports from Ireland were not relevant to this case as they were not managed by Vifor:

'Two of the cases relied on by the Panel were from Ireland and, therefore, irrelevant to the issue before the Panel but yet the decisions are quoted at length in purported reliance on them as evidence of a 'pattern' of UK behaviour. Vifor Ireland was a separate, independent company with its own country manager and these components should have been disregarded from the outset, as had been requested by Vifor.'

Pharmacosmos, however, noted that:

- Vifor had an open position for country manager Ireland listed on its website on 13 February 2016. The position reported to the general manager for UK and, to its knowledge, was a newly created position at that time (Pharmacosmos understood that Ireland was previously managed directly from the UK, as the following points would suggest);
- Vifor appointed [named] as Country Manager Ireland who would not take position until May 2016, ie months after the cited Irish reports;
- Vifor had open positions for national sales director and medical science advisor listed on its website in September 2015. Both positions had responsibility for UK and Ireland;
- Vifor's Ferinject website for Ireland (www.ferinject.ie) automatically redirected to its Ferinject website for the UK (www.ferinject.co.uk).

Pharmacosmos submitted that all of these factors indicated a considerable involvement by Vifor in its operations in Ireland. This might be underlined by the fact that the inter-company dialogue in relation to the two reports of alleged misleading and disparaging claims in relation to Monofer was not redirected to the Ireland office for management when Pharmacosmos raised its concern in its letter dated 16 February 2016.

3 The complaint process

Pharmacosmos noted that there had clearly been much interchange between Vifor and the PMCPA in respect of this case and in that regard it commented on points made in Vifor's appeal in relation to the Constitution and Procedure and corrected some points about Pharmacosmos' approach to compliance, its supposed 'lack of standing' and the allegation that it 'turned its back on the self-regulatory scheme'.

Pharmacosmos' position with regard to the PMCPA

Pharmacosmos stated that it fully accepted the jurisdiction of the PMCPA in relation to complaints from 2010 (when Pharmacosmos established its UK subsidiary) until April 2014. During this time, Pharmacosmos and Vifor were party to a number of shared cases - initiated by either by company and at all times acknowledged the rulings of the PMCPA. In 2014, Pharmacosmos started to receive anonymous complaints through the PMCPA from alleged health professionals characterised by having particularly detailed knowledge of the Code, the IV iron market in Europe and of Pharmacosmos. The cases resulted in a significant workload for Pharmacosmos without any risk or potential downside to the complainant; the opportunity for inter-company dialogue, that would normally precede a PMCPA complaint, was bypassed. As a result of this potential misuse of the self-regulatory scheme Pharmacosmos declined in April 2014 a formal invitation from the PMCPA to join its non-members list. Despite this Pharmacosmos was always fully committed to ethical promotion and to following the principles outlined in the Code.

Since opting out of the self-regulatory system Pharmacosmos submitted that it had not received any complaints – anonymous or otherwise – from any party other than from Vifor. Pharmacosmos had always responded duly in inter-company matters, and when reference had been made to the Code, Pharmacosmos always related to the specific rules in question.

Pharmacosmos strongly objected to Vifor's allegation that it was 'gaming the system'. On the contrary, Pharmacosmos accepted the fact that decisions of the MHRA could be far-reaching and have serious consequences and it submitted to its authority directly.

For clarity, Pharmacosmos submitted that it would never hide behind anonymity and should it bring an unfounded complaint to the PMCPA it would pay the requisite administration charge. Indeed, Pharmacosmos hoped never to have to complain to either the PMCPA or MHRA, but that relied on the proper activities of its competitors. In that regard Pharmacosmos operated transparently and without fear or favour. As such, it was disappointed that the language used in Vifor's appeal implied that Pharmacosmos would do anything other than give a full and frank disclosure in any dealings with the PMCPA or the MHRA. As Vifor, the PMCPA and the MHRA were aware, Pharmacosmos had responded comprehensively on all complaints from named persons or named organisations.

Pharmacosmos accepted that there were some aspects of the Code that went beyond the MHRA's Blue Guide and yet it reassured the Authority that it still followed the principles of the Code itself; including, for example, the fact it had disclosed transfers of value in accordance with the Code's requirements, albeit on its website as it was not permitted to access the central platform. Nor did Pharmacosmos issue promotional aids other than those permitted by the Code. However, Vifor made important points in this regard as matters covered solely by the Code did not in fact have an enforcement mechanism beyond the PMCPA itself. Such aspects were not directly relevant to the rulings in this case, but they were important constitutional points to be considered.

Constitution and Procedure

Pharmacosmos stated that it would not comment on Vifor's views about the Panel's integrity or that the complaints procedure had been inappropriately applied by the PMCPA (including the reference to comments from Lord Denning from a case against the Malayan government 55 years ago). That said, Pharmacosmos considered that the quotation of legal rulings in this matter was misguided.

Pharmacosmos noted that the ruling in Tudor v Ellesmere Port & Neston Borough Council essentially rested on the fact that the Crown Court made a decision without giving the appellant the right to defend herself against a decision made based on evidence the appellant had not seen. Pharmacosmos submitted all the evidence to the PMCPA and, so far,

as it knew everything pertinent was passed on to Vifor. Additionally, the Masone case quoted by Vifor was largely about procedural errors in a criminal case and was not relevant here.

Pharmacosmos noted Vifor's summary that in its view Pharmacosmos had failed to establish the burden of proof. Vifor extended the discussion to encompass material that might be considered by the Appeal Board. Vifor had failed to understand that proof did not have to be provided solely by the complainant, but that the ruling was made on the balance of probability based on a combination of the complaint and the response. By centrally driving representatives to raise concerns about Monofer's side-effect profile, Vifor had disparaged a licensed product. Pharmacosmos would have no problem with the presentation of a clinical head-to-head study showing that one product or the other had fewer side-effects, however Vifor's strategy was to selectively raise doubts about Monofer based on a biased comparison of the two products – as indicated in the material it submitted to the Panel.

Pharmacosmos noted that Vifor had highlighted two further legal cases to explain the meaning of the balance of probability in civil cases. Combined, these cases indicated that if the tribunal (PMCPA) was satisfied that one version of events was the more likely, then the ruling could be made; if the situation was not clear then a ruling of 'no breach' should be given. The simple truth was that the PMCPA found evidence that representatives were instructed to target Monofer accounts and to raise doubts about the safety profile of Monofer using materials provided by head office and backed up with inappropriate materials issued by medical information. The probability that Monofer was disparaged in a misleading manner would therefore appear to be somewhat beyond the 51% required in the civil test as cited in the legal cases highlighted by Vifor.

In conclusion, Pharmacosmos believed that the Panel's rulings were correct. Vifor's centrally created materials and briefings had created a situation where competing products had been compared in a manner that was misleading and disparaging.

FURTHER COMMENTS FROM PHARMACOSMOS

The discussions regarding confidentiality of documents meant that some of Vifor's material was provided at different time points. On each occasion Pharmacosmos was given the opportunity to supplement its response to the appeal set out above.

Pharmacosmos alleged that the additional Vifor material supported the Panel's ruling which found Vifor in breach for:

- disparaging Monofer in promotional calls (in breach of Clause 8.1 for the pattern of behaviour).
- providing misleading information in respect of Monofer safety (in breach of Clause 7.2 for the pattern of behaviour).

Pharmacosmos alleged a consistent pattern of misleading and disparaging promotion of Ferinject with respect to Monofer in absence of comparative data. The pattern was evidenced in all of Vifor's promotional materials and internal briefings that had been shared with Pharmacosmos.

Pharmacosmos reiterated that the alleged misleading and disparaging conduct by Vifor's representatives had, in recent years, been the key point in a series of inter-company dialogues and Code cases between Pharmacosmos and Vifor. In some of the Code cases the Panel had ruled in support of Pharmacosmos and in others, where there had been insufficient evidence for Pharmacosmos to have made its case conclusively, the Panel had ruled in support of Vifor. Vifor had in these instances consistently argued that its representatives were clearly instructed, in the absence of comparative data, not to discuss competitor products and to refer health professionals who asked for comparative information to its medical information department, which in turn, Vifor had consistently argued, had been instructed to refer health professionals to Pharmacosmos' medical information department, when queries related to Monofer.

Pharmacosmos alleged that the Vifor materials provided in this case clearly showed that representatives were systematically being trained to focus promotional activity on attacking Monofer, rather than simply promoting Ferinject, despite the absence of comparative data. This resulted in misleading and disparaging comments about Monofer because the company's training material and promotional content was misleading.

At the core, Pharmacosmos was deeply concerned with the description of a Vifor culture that demonstrated a clear disrespect for the self-regulatory system and the Code; and which seemingly had taken no fundamental learnings from past rulings of serious Code breaches and subsequent audits by the Authority (the Appeal Board ruled in Cases AUTH/2411/6/11 and AUTH/2422/7/11 that Vifor should be audited by the Authority; Vifor was audited in November 2011, March 2012 and October 2012).

Pharmacosmos presented some examples from the Vifor material in evidence of this case that further supported the Panel's ruling that there was a pattern of misleading and disparaging promotion by Vifor representatives with respect to Monofer; there were a large number of additional points Pharmacosmos could cite, all based on a detailed analysis of the Vifor material.

The relevant briefing document advised representative's that they 'could also project [the SPC comparator tool] from your iPad for use with multiple HCPs at meetings'. This showed the tool was clearly designed to be used at meetings, as the Panel indicated in its ruling, thus it was not for reactive use only. It, furthermore, showed that Vifor briefed its representatives to discuss competitor products, despite the company's promises to the contrary in inter-company dialogue.

The Briefing Document Competitor Update December 2015 clearly identified the Lareb report as a marketing tool. This showed that Vifor's argument that its representatives were not briefed to discuss the Lareb report was not correct.

The Description of Clinical Data Sessions showed that Vifor representatives spent at least 4 hours studying Monofer clinical papers. This confirmed that Vifor had deliberately sought to focus on perceived Monofer shortcomings rather than Ferinject achievements. It, again, showed that Vifor briefed its representatives to discuss competitor products, despite both the absence of comparative data and the company's promises to the contrary in inter-company dialogue.

The Ferinject Differentiation from Monofer Slide Set UK was, by its omissions of key Monofer clinical data and incomplete description of Monofer's clinical proposition, both disparaging and misleading. Examples of this were:

- The name of the job bag for the material: 'Ferinject Differentiation from Monofer Slide Set UK' on the ZINC approval cover page identified Monofer as the target. This undermined and contradicted Vifor's consistent reassurance in inter-company dialogue that its representatives were trained to refer all health professional questions about Monofer to its medical information department.

- In the section entitled 'Breadth of clinical experience', the following key controlled trials on Monofer had been partly or completely omitted although published in peer reviewed journals: Wikstrom *et al* (2011) (nephrology); Hildebrandt *et al* (2010) (cardiology); Reinisch *et al* (2015) (gastroenterology; mentioned in brackets, but not as a separate publication); Birgegard *et al*, 2016 (in oncology) and Dahlerup *et al* (2016) (gasteroenterology).

Pharmacosmos considered that Vifor might argue that its selection criteria (randomised controlled trials) would exclude some of these Monofer trials. However, Wikstrom *et al* and Hildebrandt *et al* were pivotal regulatory Phase 3 trials in the Monofer approval process in Europe and they represented important and relevant studies. Indeed, safety was the primary objective in these two studies and so their absence gave Vifor representatives (and health professionals) a misleading and incomplete picture of Monofer safety data.

Pharmacosmos further noted that in its promotional materials for health professionals, Vifor only presented four Monofer clinical trials but trained its representatives in nine – as evidenced in Description of Clinical Data Sessions. For the studies that had been included, the presentation of study data included several data omissions and/or misleading data representations with respect to Monofer clinical trials publications. The consequence was cherry-picking of data in training and/or misleading promotion.

Pharmacosmos submitted that Vifor might also argue that Wikstrom *et al* and Dahlerup *et al* were published after the document was released in November 2015. However, Vifor was obliged to ensure that documents were revised when new studies were published. It was difficult to imagine that Vifor would delay such revision if a Ferinject study was published.

Pharmacosmos alleged, overall, the above omissions of key Monofer clinical data in the section titled 'Breadth of clinical experience' was misleading. Furthermore, the Monofer clinical data was presented such as to encourage health professionals to draw misleading conclusions on the comparative efficacy and safety of Monofer in the absence of comparative data.

The section titled 'Determination of the cumulative iron dose' suggested that only Ferinject offered simplified dosing for all patients which was not so. The Monofer dose could be determined by either using a simplified dosing table or the Ganzoni formula. The Ganzoni formula was used for particular patient groups where extra caution might be advisable. However, this was a recommendation only, and it remained up to the prescriber's clinical judgement as to whether to determine the dose using the Ganzoni formula or the simplified dosing table.

Pharmacosmos alleged that the information on the slide was structured to imply that 'Monofer equals the Ganzoni formula' and that 'the Ganzoni formula equals inconvenient, prone to error, inconsistently used in clinical practice, and underestimated iron requirements' (repeated on slide 24). Pharmacosmos noted that the phrase 'in other patients simplified dosing can be offered' was Vifor's own wording and not from the Monofer SPC. Pharmacosmos was concerned that Vifor insinuated that appropriate dosing recommendations for specific patient groups implied risk when using Monofer.

The section 'Ferinject and Monofer infusion' contained a call-out box with the subheading 'What does this mean in clinical practice?', which pretended to provide a complete description of the different patient scenarios based on two parameters used for determining iron need, ie the patient's haemoglobin level (Hb) and body weight (kg). However, this presentation was misleading because it failed to recognise the large group of patients with Hb ≥ 10g/dl and 75-100kg, which according to the simplified dosing table required 1,500mg iron. This group was a core component of the simplified dosing table for both products. For these patients Monofer offered treatment in one administration compared with two administrations with Ferinject. Pharmacosmos alleged that it was cherry-picking when clearly pretending to describe relevant scenarios from clinical practice and omitting a patient segment that was common in the UK. Instead, Vifor implied that the only area where Monofer had fewer (one) administrations compared with Ferinject (two) was for patients with a body weight above 100kg. Pharmacosmos was very concerned with the potential serious risks to patients that a misrepresentation of the dosing information of products could pose.

The section 'Undesirable events' underlined the attempt to cast doubt on the safety data for Monofer. The statement about Monofer was accurately quoted from the Monofer SPC, but was unreasonable. When the document was approved in January 2016, Monofer had been studied in more than 1,500 patients across more than 10 clinical studies, and post-marketing data included more than 3 million treatments worldwide. In essence, the slide implied that the risk-benefit profile of Monofer was questionable whereas that of Ferinject was not. This approach was continued on two subsequent slides.

The section 'Contraindications' whilst factually correct, implied that decompensated liver cirrhosis and hepatitis was not a risk factor with Ferinject, despite the fact that the condition was described under Special Precautions in its SPC. Failure to inform health professionals about an important special precaution might pose serious risk to patients.

The 'Medical Update 12 December 2013' Pharmacosmos noted that the section 'SPC Updates' on slides 3-9 informed the representatives of the recent EMA's 'Assessment Report for: Iron containing intravenous (IV) medicines products' ('Article 31 Updates'), which triggered a harmonisation of the SPCs for IV iron product (including Monofer and Ferinject) with regards to the risk of severe hypersensitivity reactions. Pharmacosmos alleged that the statement on slide 7 that 'Insufficient data meant that there was no way of differentiating between any IV iron' was not a fair representation of the situation. In its assessment report, the EMA stated:

> 'As the conclusions of this assessment were mainly drawn from the post-marketing data, differentiation between these iron complexes in terms of hypersensitivity reactions could not be identified. So the CHMP conclusions are applicable to all the iron complexes assessed in this referral.'

Pharmacosmos alleged that the EMA's statement did not imply the data was insufficient as Vifor suggested. The underlying message intended by Vifor was that more data would show favourable difference between Ferinject and other IV iron products.

Pharmacosmos considered that the Panel's ruling also demonstrated that Vifor representatives were being trained on a local audit (subsequently presented as a poster: Grant *et al*). In previous inter-company dialogue in April 2014, Vifor had indicated that its representatives were neither trained in this audit nor discussed it with health professionals. This was clearly not the case. What was even more worrying was Vifor's admission that, despite the commitment in the inter-company dialogue, the audit was included in the nine studies referenced in 'Description of Clinical Data Sessions'. Pharmacosmos submitted that if representatives were trained on this audit during the ITC, there must be a reasonable expectation that they would use the information in promotional discussions.

Pharmacosmos submitted that the above were just some of the several examples of misleading and disparaging promotion that it had identified in the Vifor material provided. Pharmacosmos was particularly concerned that the material appeared to contradict commitments that had been made during inter-company dialogue:

- representatives were being trained to draw attention to the local audit and the Lareb report and they were directing health professionals to perceived concerns about Monofer
- health professional enquiries about Monofer were not being directed to Pharmacosmos' medical information department.

Pharmacosmos noted that it had raised concerns in inter-company dialogue about the consistent and widespread pattern of comments from health professionals indicating that on the balance of probability Vifor representatives had proactively raised the safety profile of Monofer in order to imply differences between the products. Six recent examples formed the basis of inter-company exchanges with Vifor in early 2016 all of which were characterised by health professionals proactively informing Pharmacosmos that Vifor representatives had stated that 'Monofer has a higher rate of adverse drug reactions than Ferinject'. Pharmacosmos also noted Vifor's statement in an inter-company response to Pharmacosmos dated 3 March 2016:

> 'As per your request, a thorough investigation of the incidents mentioned has been conducted by Senior Management. With the available information, no conclusive evidence has been found that the alleged disparaging and misleading claims have been made.'

Pharmacosmos submitted that a review of Vifor's material suggested that Vifor senior management had failed its obligation to adequately investigate, identify and resolve the systematic training in and provision of promotional material, which contained misleading and disparaging information about Monofer's safety profile.

In conclusion Pharmacosmos' stated that its review of the Vifor material supported the Panel's ruling that Vifor's representatives had disparaged Monofer in promotional calls and provided misleading information about Monofer safety. Pharmacosmos was deeply concerned with the evidence and alleged that Vifor representatives were systematically, and in the absence of comparative data, being trained to focus on attacking Monofer rather than promoting Ferinject.

Pharmacosmos alleged that the evidence gave the impression of a company with clear disrespect for the self-regulatory system and the Code; and which seemingly had taken no fundamental learnings from past rulings of serious Code breaches and subsequent audits by the Authority. Based on the review of Vifor's material referenced above, it respectfully urged the PMCPA to again reconsider its decision to set up an external lawyer confidentiality ring. Pharmacosmos submitted that its review above demonstrated that an external lawyer could not feasibly identify the areas where data was presented in a misleading fashion. To identify the issues required specialist technical

knowledge. In fact, even health professionals that specialised in the therapy area might not identify the manner in which key data had been left out or misrepresented; detailed technical knowledge of the product data set was required to identify such shortcomings. Specialists in law would undoubtedly not have the clinical and data-specific knowledge to appropriately assess the balance of evidence and whether or not the presentation of data in Vifor's material was disparaging, misleading or incomplete. Pharmacosmos was very concerned that not allowing it to review and comment on all relevant materials puts at risk the fair and complete resolution of the case and contradicted the general principles of the PMCPA Constitution.

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After referral to, and a decision by, an independent referee Pharmacosmos was provided with redacted versions of the 'Intravenous Iron Differentiator briefing guide' (only slides 1, 2, 21, 22, and 26) and slide 8 of the 'Competitor update at the December Sales Conference'.

Pharmacosmos alleged that whilst this new material further evidenced the consistent pattern of disparaging and misleading claims with respect to the comparative safety of Monofer, it noted that Vifor had tried to stop Pharmacosmos seeing this material, which arguably damaged Monofer the most:

Slide 8 'Competitor update at the December Sales Conference'.

- The briefing to Vifor representatives evidenced a clear intention to undermine confidence in Monofer safety by stating that '5 accounts have switched back to Ferinject from Monofer'
- The briefing evidences that Vifor representatives were trained in the Lareb pharmacovigilance report which contained Monofer safety reports; Lareb was the Netherlands Pharmacovigilance Centre. Vifor failed to recognise that training its representatives in the Lareb pharmacovigilance report represented an inappropriate provision of selective safety data.

The 'Intravenous Iron Differentiator briefing guide', slides 1, 2, 21, 22, and 26:

- Vifor representatives were trained to use the Intravenous Iron Differentiator tool 'proactively in threatened accounts that are considering switching to Monofer and in accounts that have switched to Monofer'. This confirmed that the tool (as also suggested by the compliance job title: 'Ferinject Differentiation from Monofer Slide Set UK') was intended to make comparative claims despite there being no of appropriate head-to-head studies
- Vifor representatives were instructed to ask health professionals 'what sort of adverse events would be expected with Monofer?' This again demonstrated the clear focus on Monofer in the Ferinject campaign despite Vifor's repeated commitments in inter-company dialogue that representatives were instructed not to discuss Monofer safety and instead refer health professionals to its medical information.
- Vifor stated that 'undesirable effects are primarily based on safety data for other IV irons in the Monofer SPC'. Such a statement, without acknowledging that when the document was approved there were 10 clinical trials with more than 1,500 patients treated with Monofer, created a perception which was not representative of the balance of evidence.
- Vifor made various claims with respect to Ferinject under the headline 'Confidence' which implied that health professionals could not have confidence with Monofer.

In conclusion, Pharmacosmos alleged that that the new materials provided further evidence in support of the Panel's ruling.

The independent referee decided that one document should only be provided to Pharmacosmos via an external lawyer confidentiality ring. Pharmacosmos decided not to join a confidentiality ring. This meant that the document 'Questions and Answers Reactive response to competitor messages' could not be provided to Pharmacosmos via a confidentiality ring. It was provided to the Appeal Board.

APPEAL BOARD RULING

The Appeal Board noted that in 2014 Pharmacosmos UK had declined the offer to join the PMCPA list of companies which were not members of the ABPI but had, nonetheless, agreed to comply with the Code; it stated that it no longer wished to accept the jurisdiction of the Authority but that it would continue to be fully committed to the ethical promotion of its products.

The Appeal Board disagreed with Vifor's submission that as Pharmacosmos was neither a member of the ABPI nor a non-member that had agreed to comply with the Code and accept the jurisdiction of the Authority, it was not in a position to be able to complain under the Code. This point had only been raised by Vifor in its appeal. The Appeal Board noted that the Memorandum of Understanding between the ABPI, PMCPA and MHRA did not exhaustively detail who could submit complaints under the Code, referring only to the position of ABPI member companies and non-members that had agreed to comply with the Code. Paragraph 5.1 of the Constitution and Procedure was clear that the complaints procedure could commence once the Director had received information that certain companies might have contravened the Code. Paragraph 5.1 of the Constitution and Procedure only required the *respondent* company to be either an ABPI member or a non-member company which had agreed to comply with the Code and accept the jurisdiction of the Authority. There was thus nothing in the Constitution and Procedure to preclude Pharmacosmos from submitting a complaint; indeed if there were, the Appeal Board considered that such provision might encourage some companies to submit complaints anonymously. In the Appeal Board's view, the Authority had been correct to allow the complaint to proceed.

The Appeal Board noted that Pharmacosmos had made it clear that, if applicable, it would pay any administrative charges due.

The Appeal Board noted Vifor's concerns that it had not seen certain information in relation to anecdotal reports submitted by the complainant until 21 July, after it was advised of the Panel's rulings on 12 July. Vifor was originally provided with the correspondence between Pharmacosmos and the PMCPA relevant to the merits of the case. The relevant detail of the anecdotal reports was included in Pharmacosmos' letter of complaint and Pharmacosmos was clear in that complaint that it was not making specific allegations for each example, rather portraying them as part of the overall picture to give credence to concerns about a pattern of behaviour of misleading and disparaging statements. The Appeal Board considered that it would have been preferable for Vifor to have been provided with the copies of the emails from Pharmacosmos staff before the Panel made its ruling. In any event, the Appeal Board noted that Vifor now had the information and any remedy in it not being provided sooner lay in Vifor's ability to appeal.

The Appeal Board noted that Pharmacosmos had complained about a pattern of behaviour and had cited a number of anecdotal reports to support its allegations that Vifor had disparaged Monofer and misleadingly implied that there was a difference in the safety profiles of Monofer and Ferinject when no head-to-head comparison between the two existed. In addition, Pharmacosmos also provided email evidence from one hospital which it alleged showed that Vifor had misleadingly compared the safety profiles of Monofer and Ferinject.

The Appeal Board noted that a medical update presentation from December 2013 (ref UK/FER/13/0201) included three slides detailing the results of Grant *et al*, a retrospective case note review of patients who had received Monofer at a particular hospital. The third slide detailed the authors' conclusions ie that the use of Monofer had shown a sub-optimal attainment of Hb target and the frequency of adverse reactions was much higher than expected from those reported in the SPC or previous studies in renal patients, and thus they no longer used the medicine. The concluding slide of a competitor update for the December 2015 conference (ref UK/FER/15/0279) headed 'Safety and Tolerability' referred to these properties as being a key factor in choosing an IV iron. The slide named five hospital accounts which had switched back to Ferinject from Monofer. It also drew attention to the Lareb report and included the quotation 'special attention should be given to the comparison of the safety profile of the different intravenous iron-containing medicines and in particular to the safety profile of [Monofer]'. The slide continued by urging representatives to 'Be proactively reactive' and the instruction that if a customer asked about the detailed safety of Ferinject beyond the SPC then they should be referred to medical information for detailed information. No instructions were given on the slide as to what to do if a customer asked for detailed safety information on Monofer or for a comparison of the safety profiles of Monofer and Ferinject.

The Appeal Board noted that Vifor representatives had clearly been briefed about the outcome of Grant *et al* and the conclusion of the Lareb report as it related to Monofer. There was no written briefing about how, if at all, the representatives were to use either paper. In the Appeal Board's view, briefing the field force about the existence of the papers which were highly critical about the safety of the major competitor was not unacceptable *per se* but without any instructions to the contrary it was likely that the representatives would assume that both could be used to support their promotion of Ferinject. The results of neither paper had been put into context. In the Appeal Board's view, the briefing on the Lareb report with the instruction to be 'proactively reactive' would encourage representatives to look for every opportunity to send the paper out. Further, the Appeal Board was concerned to note that there was no standard medical information letter about either Grant *et al* or the Lareb report nor about the comparative safety profile of Monofer and Ferinject. Email evidence from one hospital showed that medical information had sent out the Lareb report to a customer with a very misleading and factually inaccurate covering letter which clearly undermined the reader's confidence with regard to the safety of Monofer.

The Appeal Board noted, overall, the content of the briefing material, the emphasis on and the lack of context given with regard to Grant *et al* and the Lareb report, the absence of clear, unequivocal instructions to the representatives about the use of those two papers, the lack of a defined company position regarding the safety profile of Monofer alone, and vs Ferinject (as standard medical information letters and representatives' briefing material) and the very poor medical information letter sent to a customer with a copy of the Lareb report. Given all of these factors, the Appeal Board considered that, on the balance of probabilities, it was likely that Vifor representatives had disparaged Monofer as alleged. The Panel's ruling of a breach of Clause 8.1 was upheld. The Appeal Board further considered that on the balance of probabilities, it was likely that Vifor representatives had provided misleading information with regard to the safety of Monofer as alleged. The Panel's ruling of a breach of Clause 7.2 was upheld. The appeal was thus unsuccessful.

Complaint received **1 April 2016**

Case completed **7 December 2016**

CASE AUTH/2862/8/16

ANONYMOUS, NON CONTACTABLE v TAKEDA

Engagement of a consultant and his/her training and consultancy company

An anonymous, non-contactable complainant raised concerns about a therapy area specific training and consultancy company and its owner, a health professional who delivered services including practice audits, health professional mentoring, education and classroom based training workshops funded by a number of named pharmaceutical companies including Takeda. These services had been delivered in a number of named clinical commissioning groups (CCGs) in one area. In addition, the health professional was a specialist nurse employed on a contractual basis by a number of NHS organisations including a city based community healthcare organisation (CHO). In his/her role as a nurse within that organisation the health professional had prescribing responsibility and influence within one of the CCGs named by the complainant.

The complainant alleged that the training and consultancy company had conducted industry funded clinical audits in several GP surgeries in the area in question which were identifiable as they had highly irregular use of the sponsoring company's product. The patients of several surgeries in one CCG were either initiated onto or switched to the sponsor's medicine with little consideration given to alternative therapies. Reference was made to Takeda's product. The pattern of disproportionate increases in product sales could be directly linked back to the pharmaceutical company which had funded the training and consultancy company.

The complainant referred to a series of accredited training workshops delivered by the training and consultancy company in partnership with a named CCG which was completely funded by industry. The complainant was concerned about the potential substantial financial support to the training and consultancy company for these workshops due to reservations about the ethics of that organisation and because its owner was directly contracted to the local city based CHO. In the complainant's view industry's financial support for these courses was staggering and could be perceived as an attempt to 'buy the business'.

The complainant alleged that the training and consultancy company had told pharmaceutical companies that if they failed to provide support, their products would not be used in the CCG in which he/she had prescribing responsibility. The complainant stated that his/her company's local representative felt highly pressured to offer funding as he/she had been threatened that if he/she failed to support training events the health professional in question would simply get the money from another pharmaceutical company. The complainant stated that this highly coercive behaviour was completely unacceptable and he/she assumed that similar pressure had been exerted on other pharmaceutical companies. In addition the complainant noted that services provided by industry were in some cases very similar to the offerings developed by the training and consultancy company and alleged that the health professional in question had left individuals in no doubt that if their company attempted to partner in CCGs where he/she wanted to deliver programmes there could be consequences for their sales in the area in which he/she had prescribing responsibility.

The detailed response from Takeda's is given below.

The Panel had no contact details for the complainant and so could not ask him/her for further details. The complainant had the burden of proving his/her complaint on the balance of probabilities; he/she had not provided any evidence in support of the allegations.

The Panel noted that the complainant began by stating that he/she wished to complain about the conduct of the training and consultancy company and subsequently referred to its owner. In this regard the Panel noted that the Code applied solely to the conduct of pharmaceutical companies.

The Panel considered that the scope of the complaint included the engagement of the health professional in question and/or the activities of his/her company with health professionals, whether the company's activities were delivered by its owner or other individuals. However, when considering such matters the totality of a pharmaceutical company's interactions with the health professional in question would nonetheless be relevant.

The Panel noted that the complainant had provided a website address for the training and consultancy company which named the health professional in question as the Director and another health professional as the nurse liaison lead. The Panel noted that the named health professional was contracted by the NHS to work at a number of GP surgeries in addition to his/her role at the city based CHO.

In relation to the audits in a named CCG the Panel noted the allegation that patients were either initiated or switched onto the sponsor's product with little consideration given to other therapies and that surgeries exhibited irregular use of a sponsor's product. Reference was made to abnormally high sales of Takeda's product. The Panel noted the relevant requirements of the Code about switch and therapy review programmes.

The Panel noted Takeda's submission that when it received the complaint it did not know of any funds provided to the named health professional or the training and consultancy company for audits but during the investigation of the complaint it

became aware that the named health professional had delivered two therapy reviews commissioned by clinicians who had received support for those reviews from Takeda in 2015. The Panel noted that Takeda had made a grant to large health centre to run nurse clinics at 11 local practices. Another grant was paid for a similar nurse led clinic at a medical centre based within a different CCG.

The grant request from the medical centre explained that it would work with a company it had previously worked with to deliver the clinics; the company was not named. The service provider and its status was not identified in any of the materials for the medical centre. The Panel noted that according to Takeda in each case the practice had initially raised its need for funding with either the representative and/ or his/her line manager who each advised that an application be made to the company.

The Panel did not accept that Takeda only found out that the named health professional and the training and consultancy company were involved with the audits when it investigated this complaint. Indeed the Panel noted that in relation to the review at the medical centre Takeda paid the monies in October 2015 directly to the training and consultancy company rather than the medical centre. In the Panel's view, at the latest, either on payment to the training and consultancy company (in relation to the medical centre) or when the therapy reviews were taking place, individuals at Takeda were aware of the involvement of the training and consultancy company.

Takeda had stated that it could not comment on any correlation between the training and consultancy company activity and prescribing but noted that its product's use was significant within one of the CCGs where the therapy review took place before the grant request and that the medicine was by a significant margin the least expensive in its class available in the UK.

The Panel first had to consider Takeda's responsibility for the audits. Noting the level of contact between the parties, previous discussions about the need for audits and advice from field-based staff to apply for funding the Panel queried the company's submission that the funding requests were unsolicited. The Panel noted the grant agreements for each therapy review stated that the grant was not an inducement to, or reward for recommending or taking any decisions favourable to Takeda's products or services. The agreements also referred to the NHS body providing a brief report to Takeda on request or as agreed by the parties. The accompanying letters to the practices, however, stated only that Takeda would be extremely interested to hear about the outcomes but that the NHS body was not obliged to provide such details. In addition, the agreement for the health centre stated that it was fully responsible for all aspects of the event; there was no similar statement in the agreement with the medical centre.

The Panel considered that on the available evidence neither audit was a Takeda activity and thus the clause of the Code that applied to the provision of medical and educational goods and services provided by the company did not apply. No breach of the Code was ruled. The Panel noted that the Code described the circumstances in which a medical and educational good and service could be provided as a donation, grant or benefit in kind. The Panel considered that it was beholden on the company to undertake due diligence when making a restricted use grant for a therapy review to a GP practice or group of practices. This was especially important when the restricted use grant was for an audit in an area where the company had a commercial interest. Such due diligence should ensure, *inter alia*, that the arrangements were not and could not be perceived as an inducement to prescribe.

Whilst the Panel had concerns about Takeda's governance of the restricted use grants it nonetheless noted that the complainant bore the burden of proof. The Panel did not consider that the complainant had established that provision of funds and/or the arrangements for the therapy reviews were such that they were a switch service or otherwise an inducement to prescribe as alleged. No breach was ruled.

The Panel noted that Takeda paid for an exhibition stand at a one day clinical awareness course run by the training and consultancy company. Other companies also exhibited. The Panel noted that an email regarding sponsorship from representative 1 to representative 2 referred to the named health professional doing extra clinics in certain cases and helping and supporting representative 1 with [Takeda's product] in a named area by 'convincing GP practices to switch and use the [Takeda's product] family'. The meeting at issue was referred to as one which the named health professional had asked the representatives to support and 'in return [the named health profession] has agreed that he/she will advocate, and help and support us in our cause in primary care with the [Takeda's product] family'. Representative 2 was asked to contact the named health professional. The email in question was copied to the representatives' line manager and the direct report of representative 1, a primary care representative. The Panel noted Takeda's submission that the senior line manager asked representative 1 to refer the proposal to a senior director but failed to recognise that the email suggested a link between the provision of funding and advocacy and support for Takeda's product. Takeda had not stated whether the senior director saw the original email and, if so, what he/she did with the email or who sanctioned the payment. The representatives gave differing accounts of a subsequent meeting with the named health professional to discuss funding of the course at issue. Representative 1 stated that the named health professional made it clear that he/ she would advocate Takeda's product in return for funding. This was denied by representative 2. A customer relations management (CRM) report for a subsequent meeting with the named health

professional stated that he/she agreed to help via speaker meetings to endorse Takeda's product across the region. The Panel also noted Takeda's submission that when it paid for the exhibition stand space, it did not take adequate steps to ensure that it did not exceed fair market value. The Panel considered that given the link between funding and support for Takeda's product as stated in the email, the payment was contrary to the Code and breaches were ruled. The company had failed to maintain high standards and a further breach was ruled.

The Panel was very concerned that despite the senior line manager being copied into the email in question no steps were taken by senior staff to review the initial arrangements or otherwise prevent payment. The level of payment was not assessed to make sure it did not exceed fair market value. In addition, the Panel noted that an inducement to prescribe was listed in the supplementary information to Clause 2 as an example of an activity likely to lead to a breach of the Code. The Panel considered that the impression created by the email brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel noted its rulings of breaches of the Code in relation to the arrangements and impression created by the email. The Panel considered all the circumstances surrounding the meeting with the named health professional very carefully including that the representatives gave differing accounts of that meeting. The Panel also noted that a ruling of a breach of Clause 2 would be the subject of an advertisement in the medical, pharmacy and nursing press. Taking all the circumstances into account, and on balance, the Panel decided not to report Takeda to the Code of Practice Appeal Board on this point for it to consider whether further sanctions were warranted.

The Panel considered that the complainant had not established on the balance of probabilities that there was any evidence to show that the engagement of the named health professional to speak at the two promotional meetings in 2015 was an inducement to prescribe. No breach of the Code was ruled. Nonetheless, the Panel considered that his/her contemporaneous engagement in non-promotional and promotional roles either personally or via the training and consultancy company was not compatible. It did not appear that the company had undertaken any due diligence in this regard. High standards had not been maintained and a breach of the Code was ruled.

The Panel noted that Takeda had also been asked to respond to the requirements of the Code about relationships and contracts with certain organisations: there was no evidence before the Panel that Takeda had engaged in any such activity and thus no breach was ruled.

An anonymous, non-contactable complainant who described themselves as an employee of one of the many manufacturers of therapies in a particular therapy area, complained about the conduct of a therapy area specific training and consultancy company run by a named health professional, that delivered a range of services to, *inter alia*, the NHS including services that were funded by a number of named pharmaceutical companies including Takeda Limited.

COMPLAINT

The complainant stated that the named health professional, in addition to his/her role at his/her company was also a specialist nurse employed on a contractual basis by a number of NHS organisations including a city based community healthcare organisation (CHO). In his/her role as a nurse within that organisation he/she had prescribing responsibility and influence within a named clinical commissioning group (CCG) area. The services offered ranged from in practice audits, health professional mentoring and education, to classroom based training workshops. These offerings had been delivered in a number of named local CCGs. Funding was provided for these initiatives through various mechanisms within the Code ie independent stand meetings.

The complainant stated that he/she had previously raised concerns within his/her organisation in relation the legitimacy of the training and consultancy company business model, in particular how it received funding from the pharmaceutical industry which unfortunately included on-going financial and logistical support from the complainant's own company. The complainant's concerns had been raised internally with management but no action had been taken to rectify the situation and the complainant believed that his/her job would be at risk if his/her confidentiality in raising these issues was not protected.

The complainant explained that the training and consultancy company had conducted industry funded 'clinical audits' in several surgeries across a named part of a city, those practices were very easy for medicines management to identify as they had highly irregular use of the sponsor's product. In several surgeries in a named CCG patients were either initiated onto or switched to the sponsors' medicine with little consideration given to alternative therapies. This situation was particularly obvious when sales data for Takeda's product were assessed. In a named area there was a remarkable correlation between strong product sales and surgeries that had received the training and consultancy company support funded by Takeda. The product was only added to the relevant local formulary in November 2015, yet sales in these surgeries were abnormally high throughout 2015. The pattern of disproportionate increases in product sales could be directly linked back to the pharmaceutical companies' funding support to the training and consultancy company. The complainant explained that unfortunately to protect his/her anonymity, he/she was unable to provide a very detailed narrative but would endeavour to give enough information so that the training and consultancy company and the pharmaceutical companies that used it were held to account.

The complainant stated that at the beginning of 2016 the training and consultancy company started to

deliver a series of training workshops in partnership with a the CCG in which the named health professional had prescribing responsibility which were accredited by the Royal College of General Practitioners (RCGP) and the Royal College of Nursing (RCN). The delivery of the workshops was, and continued to be completely funded by industry. The complainant articulated his/her concerns to his/her line manager regarding the company potentially providing substantial financial support to the training and consultancy company for these workshops due to his/her reservations about the ethics of that organisation and because its owner was directly contracted to the city based CHO.

The complainant stated that the amount of money that industry had pumped into these courses was staggering, and in his/her opinion the risk that the support could be perceived as an attempt to 'buy the business' had led him/her to continuously try to dissuade his/her company from being involved. Unfortunately the concerns the complainant foresaw had materialised into major conflict of interest and anti-competitive issues whereby the training and consultancy company had told potential industry partners that if they failed to provide support, their products would not be used in the CCG in which the complainant stated that the named health professional had prescribing responsibility and influence. The complainant stated that his/her company's local representative felt highly pressured to offer the training and consultancy company funding as the individual had been threatened that if he/she failed to support training events the named health professional would simply get the money from another pharmaceutical company. According to the complainant this was highly coercive behaviour and clearly completely unacceptable and one could only assume that similar pressure had been exerted on all other pharmaceutical companies.

An additional issue that recently came to light was that most of the organisations working in the therapy area provided a range of industry-developed services that were deployed in partnerships with NHS organisations; these services were in some cases very similar to the offerings developed by the training and consultancy company. The named health professional had left individuals in no doubt that if their organisation attempted to partner in CCGs where he/she wanted to deliver the programmes there could be consequences for their sales in the area in which he/she had prescribing responsibility.

In the complainant's view the NHS and industry should be able to collaborate in highly transparent projects that benefited all stakeholders. Having to turn to the PMCPA to whistle-blow on his/her own organisation and the unacceptable behaviour of an organisation that it was actively engaged with was the low point of his/her career in the pharmaceutical industry. The complainant stated that the cavalier attitude of management within his/her own organisation and an inability for him/her to sit on the side-lines as the actions of a few undermined those of many and once again brought the industry into disrepute was too much to stomach. The complainant felt incredibly disillusioned that the industry and his/her company continued to work alongside an organisation that operated in a manner that was simply unacceptable in 2016. Unfortunately, industry was not an innocent party in the affair; all of the companies that had been involved with the training and consultancy company needed to reassess how they conducted business. The complainant appreciated that the evidence given in the complaint might not be detailed enough for the Authority to act but he/she hoped that there was enough information to at least investigate the relationship between the named health professional and a number of pharmaceutical companies. The great shame was that he/she might well be delivering much needed training and support for health professionals, however, the path he/she had decided to follow to extract financial support from industry had sullied what could have otherwise been a noble endeavour. The complainant hoped his/her complaint was seen as a genuine cry for help from the PMCPA as he/she had been ignored by those in positions of power within his/her organisation. The complainant stated that this complaint was motivated by a strong desire to do what was right; he/she was reasonably certain that if the issues outlined were investigated his/her position within his/her company and probably the industry would become untenable.

The complainant provided a website address for the training and consultancy company.

When writing to Takeda, the Authority asked it to consider the requirements of Clauses 2, 9.1, 18.1, 19.1, 19.2, 21 and 23.1 of the Code with regard to the clinical audit and with regard to training workshops delivered in partnership with a named clinical commission group (CCG). The case would be considered under the requirements of the Code relevant to the time the activities took place. The clause numbers cited above were relevant to the 2015 and 2016 Codes.

RESPONSE

Takeda submitted that as a member of the ABPI it strove to abide by the letter and spirit of the Code and maintain high standards in its activities at all times.

Takeda submitted that it had had a number of interactions with the named health professional in his/her capacity as both a health professional and a provider of educational services. Since April 2013 Takeda had knowingly engaged him/her on a fee for service basis on five occasions; Takeda stated the total transfer of value involved.

Takeda submitted that with regard to involvement in audit activity in the relevant area, when it received the complaint it had no knowledge of any funds provided to the named health professional or the training and consultancy company. However, in the course of investigating this complaint Takeda submitted that it had become apparent that the named health professional delivered two therapy review services commissioned by clinicians who had been given donations from Takeda.

Takeda submitted the following information with regard to interactions with the named health professional/the training and consultancy company, including the therapy reviews funded via donations:

- Purchase of exhibition stand space at a training and consultancy company educational meeting, 2014
- Various interactions between Takeda representatives and the named health professional in his/her capacity as a health professional
- The named health professional engaged as a consultant speaker at two Takeda internal training days in 2015
- The named health professional engaged as a consultant speaker at two promotional meetings at two GP practices in 2015. Both practices were in the CCG in which the complainant stated that the health professional had prescribing responsibility
- Request for donation made by the training and consultancy company to fund provision of clinics – declined
- Two therapy reviews indirectly funded by Takeda at two named medical centres in two different CCGs in 2015.

Purchase of exhibition stand space at a the training and consultancy company educational meeting, 2014

Takeda submitted that it paid for a promotional stand at this one-day educational meeting aimed at nurses and healthcare assistants and organised by the training and consultancy company. Takeda's detailed comments about this sponsorship appear below.

Various interactions between Takeda representatives and the named health professional in his capacity as a health professional

Takeda's representatives met with the named health professional on a number of occasions between 2014 and 2016; he/she was an experienced clinician and regarded by Takeda's representatives as a local key opinion leader in specific field. The named health professional worked at a number of local GP practices and therefore was present at a number of sales visits made by the company's representatives. As a regular prescriber of medicines the named health professional was invited along with other health professionals to various promotional events. No fees were paid for any of these activities. All interactions with the named health professional recorded on Takeda's customer relationship management (CRM) system were provided.

Two internal training days in 2015

The named health professional was contracted by Takeda to provide training in the management of a condition at an internal training course for representatives with variable levels of knowledge in the therapeutic area. Payment details were provided which, in Takeda's opinion, represented fair market value for a specialist nurse and were in line with the company's standard rates. The named health professional delivered a PowerPoint presentation certified by Takeda signatories. Takeda considered these engagements a legitimate use of the named health professional's services as a consultant.

Promotional meeting, GP practice, November 2015

The named health professional's services as an expert practitioner were contracted by Takeda for a lunchtime promotional meeting at a GP practice, to discuss the use of its products in suitable patients. The presentation used certified Takeda slide decks. The named health professional was contracted for three hours work including two hours preparation and one hour training. Takeda considered this engagement a legitimate use of the named health professional's services as a consultant.

Promotional meeting, GP practice, December 2015

The named health professional's services as an expert practitioner were contracted by Takeda for a lunchtime meeting at a GP practice, to discuss case studies and recently updated guidelines from the National Institute for Health and Clinical Excellence (NICE). The named health professional's presentation used certified Takeda slide decks. The named health professional was contracted for one and a half hours' work including one hour presentation and half an hour preparation. Takeda considered this engagement a legitimate use of the named health professional's services as a consultant.

Background to Takeda's donations to support therapy review and audit activities

All requests to Takeda for financial support were reviewed by a Grants and Donations Committee, which comprised members of both medical and compliance departments, in accordance with Takeda's standard operating procedures (SOPs). Only unsolicited requests for funding were considered and the judgement of whether an application for financial support was approvable rested entirely with the committee. Takeda stated that all successful requests for funding must be from an institution or organisation and substantiated by a written description of the use to which the requested funds would be applied. The committee took no account of matters concerning the prescribing, purchasing or reimbursement of any Takeda medicine when considering an application. Uplift in sales of any Takeda product following a grant was not monitored.

To avoid creating misplaced perception that funding decisions were contingent on the use of Takeda's medicines, Takeda had previously considered grant requests on the basis of the information provided by the applicant and had not routinely asked for further specific information to be provided. Since the appointment of new senior directors in late 2015, the process had changed to include a greater degree of due diligence. The committee now frequently asked applicants for further information to ensure that grants and donations were only made to support activities with which the company was entirely comfortable.

Request from the training and consultancy company for a donation to fund provision of clinics – declined

In 2014 the named health professional's application for a donation on behalf of the training and

consultancy company to provide fifty clinics in the named area was reviewed and declined by the Grants and Donations Committee.

Therapy review indirectly funded by Takeda at a health centre, 2015

The Grants and Donations Committee received a letter from a GP at a health centre in 2015 requesting funding for clinics in a specified therapeutic area at various local practices. The clinics would be run by specialist nurses in conjunction with local GPs. The health centre stated a local disease prevalence of 9% and aimed to provide the additional clinics to improve the quality of care for these patients. The application did not specify which individual(s) or company would be providing the service. This application was reviewed and approved by Takeda. As per the contractual agreement between Takeda and the health centre, each party acknowledged and agreed that 'the agreement is concluded independently from any business transactions and decisions in relation to the supply or purchase of goods and services from Takeda … and that the provision of the contribution shall not in any way: (i) constitute any inducement to, or reward for, recommending or taking any decisions favourable to any products or service of Takeda …'. Takeda believed that this donation was appropriately reviewed and approved and provided in good faith with the intention of improving patient care. Whilst investigating this complaint, Takeda now understood that the health centre engaged the named health professional to undertake these clinics.

Therapy review indirectly funded by Takeda at a medical centre, 2015

Takeda's committee received a letter requesting funding for additional clinics at a different medical centre. The centre applied for funds to run three weekly surgeries over 26 weeks, including administration costs. The aim was to improve control of the disease in its locality. The application letter did not indicate which individual(s) or company would provide this service, it only stated that it was intended to commission the service from independent specialist nurses. The application was reviewed by the committee on 14 July 2015 and it decided to contribute one third of the sum requested towards the service. As per the contractual agreement between Takeda and the medical centre, each party acknowledged and agreed that 'the agreement is concluded independently from any business transactions and decisions in relation to the supply or purchase of goods and services from Takeda … and that the provision of the contribution shall not in any way: (i) constitute any inducement to, or reward for, recommending or taking any decisions favourable to any products or service of Takeda …'. Takeda believed that this donation was appropriately reviewed and approved and provided in good faith with the intention of improving care for relevant patients. During the course of investigating this complaint, Takeda now understood that the health centre had engaged the named health professional to undertake these clinics.

Takeda denied breaches of the Code in relation to the speaker engagements and grants.

Takeda subsequently submitted that whilst initially investigating this complaint and its sponsorship of an educational meeting in 2014, an email was passed to a senior director which gave cause for concern and resulted in further investigation. Though these investigations were ongoing, Takeda was now able to fully respond to this complaint regarding interactions with the named health professional.

Purchase of exhibition stand space at a the training and consultancy company educational meeting, 2014

Takeda submitted that an email was sent by one regional account director (representative 1) to a colleague (representative 2), copying in their line manager and the direct report of representative 1 (primary care representative). The email alerted representative 2 to the presence of the named health professional as a respected specialist nurse operating across the territories of the two representatives and discussed providing financial support for an awareness course being run by the named health professional. However, the wording of the email raised concerns, specifically:

- '[the named health professional] is … helping and supporting me with [Takeda's product in a named area] i.e. convincing GP practices to switch and use the [product] family.'

- 'In return [for providing financial support for a course being run by the named health professional he/she] has agreed to advocate, and help and support us in our cause in primary care with the [product] family.'

Representative 1 explained that he/she had written the email a few weeks after starting work in the field with Takeda and was, to some extent, showing off to both representative 2 and his/her line manager by overstating the extent of his/her relationship with the named health professional. Representative 1 also stated that when he/she wrote the email, the named health professional had never indicated that he/she would advocate or in any other way support [product] in return for any kind of financial support.

Takeda submitted that representatives 1 and 2 met the named health professional one week after the email was sent, to introduce him/her to representative 2 and to discuss Takeda potentially funding the awareness course which the named health professional was due to run a few days later. The representatives' account of that meeting differed. Representative 1 claimed that the named health professional made it clear that he/she would advocate Takeda's product in exchange for Takeda supporting the awareness course. Representative 2 stated that no such discussion took place and that discussions regarding the course focussed on the educational/scientific value of the course and the mechanisms by which Takeda could fund the course. No minutes of the meeting were available.

Takeda submitted that after meeting with the named health professional, representative 2 committed to procuring stand space at the awareness course meeting which took place in October and the training and consultancy company was subsequently paid. Representative 2 made clear that he/she sponsored this event with the legitimate intent of discussing Takeda's product and developing relationships with primary care specialist nurses, which was a key business tactic at that time. Representative 2 admitted to not giving due consideration as to whether the amount paid for the stand space represented fair value given the scale of the meeting, but agreed to this sum partly on the basis that he/she understood that a competitor had paid the same for a stand at the meeting.

Representative 2 confirmed that the stand was erected in a separate room from the course itself and expressed disappointment that the event attracted only approximately 20 nurses; he/she had expected 30-40 to attend. Following this meeting, representative 2 did not support any further courses arranged by the named health professional/the training and consultancy company.

Meetings with the named health professional in restaurants

As part of the investigation of this complaint, interactions between Takeda personnel and the named health professional were identified from the CRM system. Nine meetings took place in restaurants, including promotional meetings where the named health professional was one of a number of delegates and a 1:1 meeting between the named health professional and the primary care representative. These meetings were all investigated and it was found that:

- Venues were all appropriate for meetings with health professionals
- Amounts paid for subsistence were reasonable and fell within both the £75 limit stipulated by the PMCPA and stricter limits imposed by Takeda's SOPs
- Private rooms were used for promotional meetings, though this was not consistently documented within the CRM system
- Agendas were not available for all promotional meetings, therefore it was not possible to verify that there was always sufficient educational content to justify the provision of food
- Minutes of 1:1 meetings were not kept. However, following interviews with the representatives Takeda believed that these lunchtime meetings incorporated substantial business-related discussions.

Summary

Takeda submitted that given, at times, conflicting accounts from different representatives and a lack of contemporaneous written records of particular meetings, it was not possible to tell whether certain clauses had been breached. However, based on the information available, there appeared to have been breaches of Clauses 9.1, 18.1, 23.1 and 22.1. Takeda denied breaches of Clauses 2, 19.1, 19.2 and 21.

Takeda was disappointed with some of the findings which had arisen from the investigation of this complaint. It had become clear that a number of processes and controls pertaining to the management of the field force required reinforcing. A detailed internal audit of field force activities would be initiated. Once the internal investigation of this complaint was concluded, appropriate disciplinary action would commence.

Takeda remained committed to abiding by both the word and spirit of the Code at all times.

In response to a request for further information, Takeda provided the following:

Product review taking place in a particular geographical area

This reference in the CRM system was to a review of the prescribing of a class of products being undertaken by the local area prescribing committee which operated across 5 CCGs. Takeda was not involved either directly or indirectly with this review. Furthermore, Takeda did not know whether the named health professional was involved in this review. The representative met with the named health professional in his/her capacity as a contracted specialist nurse at a community hospital. The comment made about the ongoing prescribing review simply represented the recording of an important insight which might impact Takeda's business.

Application for donation by the training and consultancy company

The application for funding of therapy reviews was rejected by Takeda since it was submitted by a commercial organisation. Takeda had historically funded grant requests for therapy reviews submitted by NHS bodies, but not by private companies.

The regional account director who covered the relevant geographical area had stated that he/she was not aware of this grant request. Takeda had no reason to believe that this request was discussed with any other members of the sales force.

Named GP Practice

Takeda did not undertake or fund any therapy review at this practice. The representative's comments on the CRM system referred to a review the practice was undertaking, which was evidently being conducted by the named health professional in his/her capacity as a specialist nurse working there.

Clause 19

Takeda was fully aware of the requirements of Clause 19 relating to the provision of therapy review services. As previously described, the therapy reviews referred to above were not supported by Takeda. Therefore CRM entries related to these reviews simply represented the recording of important business insights which might impact Takeda's business. As stated above, Takeda had no reason to believe the grant request from the training

and consultancy company was discussed with any member of the sales force.

Takeda therefore did not believe that Clause 19 had been breached in relation to any of these therapy reviews.

Health centre

During the course of Takeda's investigation, two regional account directors and a representative, who took part in meetings with a GP and the named health professional, were interviewed. Takeda's response was based on these interviews as well as a review of relevant records.

The meeting with the GP at the health centre in March 2015 was a promotional call by the representative to discuss the benefits of a product, specifically in relation to price. No therapy review activities were discussed. The named health professional was at this meeting in his/her capacity as a contract specialist nurse working with the GP.

The meeting in April with the named health professional at a hospital again involved the same representative and discussed the way in which patients at the health centre had their therapy optimised. The representative maintained that potential Takeda-supported therapy reviews were not discussed during this meeting.

The representative stated that he/she separately received a telephone call from the health centre requesting financial support for an audit programme intended to improve the management of patients in a particular therapeutic area across a number of local practices. Specifically, performance in respect of the key processes of care for patients had now apparently fallen well behind NHS performance targets which had resulted in suboptimal care. The representative maintained that he/she advised that it would need to apply for a grant via Takeda's grants and donations process. The representative had no subsequent involvement in this grant application. On the basis of the investigation which had taken place, Takeda believed this grant request was unsolicited. During the course of the investigation, no correspondence which might have prompted the health centre to submit a grant request had been identified.

Once the grant had been made and the audit programme was in operation, the representative became aware that the programme was supported by a grant from Takeda and that the named health professional had been engaged to undertake the audit. He/she could not recall the exact date on which he/she became aware of this.

In the spirit of transparency, Takeda was keen to ensure that whenever a grant or donation was made to support a particular service, this was made clear to relevant parties, including patients who were invited to participate in that service. Therefore, letters sent out to inform applicants that their grant request had been approved included the following: 'We must therefore ask that any material produced in relation to this project contains a prominent declaration stating the nature of the involvement of Takeda UK and that all participants and beneficiaries of the project being supported by the grant are aware of the involvement of Takeda UK'.

When this grant was made, Takeda evaluated grants requested based solely on the information provided by the applicant in his/her application. This was due to a concern that undertaking further due diligence could create the erroneous impression that Takeda looked to evaluate the impact of potential projects on the prescribing of its medicines before it decided whether to approve grant requests. The appointment of new medical and compliance staff had resulted in a change of approach. The Grants and Donations Committee now defined due diligence steps which must be taken in respect of each approved grant, based on factors including the amount requested, the type of applicant (eg GP practice/NHS trust/ individual clinician) and the nature of the request.

The Grants and Donations Committee was responsible for determining whether a particular grant application was approvable based on Takeda's relevant SOP and the Code. Whether or not an 'approvable' grant request could be fulfilled then depended on the availability of sufficient budget within the business. The brand director identified budget to support this request but as he/she had now left the business, Takeda ascertained the factors he/she took into account in deciding to allocate budget to support this request.

Complainant's allegation about a named CCG

Takeda noted the complainant's allegation in relation to the 'sponsor's medicine', which went on to reference its product specifically. The health centre's request for a grant to support a local audit to focus on 'optimising treatment' did not refer to any specific medicine or class of medicines. As described above, Takeda did not request any further information regarding the audit beyond that submitted by the health centre and therefore remained unaware of whatever protocol or guidelines were used to determine any medication changes. Takeda strongly refuted any suggestion that this grant was made with either the expectation or intention of increasing local sales of its product.

Complainant's assertion about a correlation between product sales and sponsored activity

Takeda could not comment on the assertion regarding 'correlation' between the training and consultancy company activity and prescribing of Takeda's product without seeing the data on which the assertion was based. However, it was important to note that use of Takeda's product was significant within the local CCG area before the grant request was received.

In order to provide further context, Takeda stated that its product was supported by an extremely robust value proposition. It was, by a significant margin, the least expensive product in its class available in the UK. This had resulted in strong sales growth across the UK.

Medical centre

During the course of Takeda's investigation of this complaint, the representative responsible for this practice was interviewed. Takeda's response was based on this interview as well as a review of relevant records. A meeting in March 2015 at the medical centre was a small group promotional meeting which discussed improving patient outcomes. Takeda's records indicated that the GP who applied for the grant, the named health professional and two other health professionals attended.

The GP stated during the course of the meeting that he/she would like to engage an independent provider to undertake a therapy review across 3 different practices. He/she was particularly keen to ensure that uncontrolled patients were identified and offered step-up therapy and that newly diagnosed patients were initiated on appropriate treatment. The GP did not identify which provider he/she would look to commission and the representative did not know that it would be the named health professional.

In respect of the proposed therapy review project, the representative referred the GP to his/her line manager who then advised the local GP to apply for funds via the grants and donations process. Neither the representative nor his/her line manager were subsequently involved in this grant application. On the basis of the investigation which had taken place, Takeda believed that this grant request was unsolicited. During the course of the investigation, no correspondence which might have prompted the local GP to submit a grant request had been identified.

Once the grant had been made and the therapy review project was in operation, the representative found out that the review had been supported by a grant from Takeda and that the named health professional had been engaged to undertake the review. He/she could not recall the exact date on which she became aware of this.

As stated above, when this grant was made, Takeda did not undertake due diligence activities with respect to unsolicited requests for grants and donations beyond reviewing materials submitted by the applicant.

The Grants and Donations Committee deemed this grant request to be approvable and so it was necessary to identify whether funds were available to support it. In this instance, the medical team identified funds to partially support this request. A grant of one third of that requested was ultimately approved.

SOPs and Guidance

Takeda provided relevant SOPs and guidance.

Sponsorship of the exhibition stand, 2014

When the senior line manager, who was copied in on this email, received it he/she asked the regional account director to refer the proposal that Takeda fund the attendance of practice nurses at the awareness course to a director. Unfortunately, he/she failed to identify that the email also suggested a link between the provision of funding for the awareness course and advocacy and support for Takeda's product by the named health professional. He/she therefore took no further follow-up action. Takeda believed that this omission represented a failure of oversight and it would take appropriate steps with this individual.

The direct report of the regional account director who wrote this email did not recall having actually read this email when it was sent.

Representative 1, who drafted the email, was relatively new to Takeda and had based his/her statements about how to sponsor nurses to attend the awareness course (incorrectly) on his/her understanding of a previous employer's policy. The assertion that 'we cannot sponsor nurses to attend educational events' was not correct, although an individual representative was not empowered to provide such support.

Takeda supported individual health professionals to attend relevant educational meetings either proactively (eg where the medical department selected individuals to invite to attend a major congress) or reactively, where an individual submitted an unsolicited request for support to attend a particular educational meeting or congress. Representatives were not involved in the decision making process in either scenario.

With the exception of major congresses which Takeda proactively invited health professionals to attend, Takeda did not pay delegate fees to meeting organisers, such as the training and consultancy company. When a health professional approached Takeda to request support to attend a meeting such as the awareness course, they were advised to apply via the Grants and Donations process. If, upon review, the Grants and Donations Committee approved the application, then the health professional was asked to provide confirmation from the meeting organiser that his/her registration had, in fact, been paid. Takeda then reimbursed the health professional's institution (eg NHS trust/university).

The monies which had been paid to the named health professional/the training and consultancy company had not caused concern until this email was brought to Takeda's attention during investigation of this complaint. All other payments made to the named health professional/the training and consultancy company had been reviewed during the course of this investigation and were felt to be appropriate.

This payment for the exhibition stand was approved by a line manager; relevant supporting documentation was provided. When this payment was made, adequate steps to ensure that it did not exceed fair market value were not taken. Given that information relevant to making a fair market value assessment, such as number and expertise of speakers involved in delivering the meeting and the number of delegates attending, was not captured, it was not possible to make a fair market value assessment retrospectively.

Takeda could not therefore determine whether this payment represented fair market value. Takeda recognised that whilst this payment was approved in line with its existing policies, greater scrutiny should be applied to the sponsorship of exhibition stands. As a result of this complaint and subsequent investigation, a number of SOP revisions would be made. These would include the requirement for greater scrutiny in this area.

Pressure to select the named health professional as a speaker

Based on Takeda's investigation, including interviews with representatives in the areas in which the named health professional worked, there was no evidence that any of them had felt pressurised to use him/her.

PANEL RULING

The Panel noted that the anonymous complainant was non contactable and so could not be asked to provide further details. Anonymous complaints were accepted and like all complaints judged on the evidence provided by the parties. The complainant had the burden of proving his/her complaint on the balance of probabilities. The complainant had not provided any evidence in support of the allegations.

The complaint raised concerns about the interactions of certain pharmaceutical companies, including Takeda, and the training and consultancy company run by the named health professional. The complainant stated that the named health professional, a nurse, was employed on a contractual basis by a number of NHS organisations including the named city based CHO. Reference was made to his/her prescribing responsibility and alleged influence in a named CCG area and to the training and consultancy company services provided locally. The training and consultancy company offerings were said to range from practice audits, health professional mentoring and education to classroom based training workshops. More detailed allegations were made in relation to audits and workshops. The complainant alleged that the amount of money that industry had pumped into these courses was 'staggering' and could be perceived as an attempt to 'buy the business'. The complainant also generally referred to the Authority investigating the relationship between the named health professional and certain pharmaceutical companies. In this regard the Panel noted that it could only consider specific matters raised in the complaint.

The Panel noted that the complainant began by stating that he/she wished to complain about the conduct of the training and consultancy company, referred to grave concerns about it and the path which the complainant alleged had been taken by its owner, the named health professional, to extract financial support from the industry including highly coercive behaviour; in this regard the Panel noted that the Code applied solely to the conduct of pharmaceutical companies.

The Panel considered that the complaint was broader than the two matters identified by the case preparation manager, ie audits and specific workshops. The complainant had referred generally to training and support for health professionals delivered by the named health professional but paid for by the pharmaceutical industry. Takeda had, however, responded to all matters raised in the complaint and the Panel ruled accordingly. The Panel considered that the scope of the complaint included the engagement of the named health professional and/or the training and consultancy company activities, with health professionals, whether such activities were delivered by its owner, the named health professional or other individuals. However, when considering such matters the totality of a company's interactions with the named health professional would, nonetheless, be relevant.

The Panel noted that the complainant had provided a website address for the training and consultancy company and this had been provided to all respondent companies. The website listed the named health professional as the Director and another health professional as the nurse liaison lead. The Panel noted that the named health professional was contracted by the NHS to work at a number of surgeries in addition to his/her role at the named city based CHO.

The Panel noted that the complainant had raised concerns in relation to a number of pharmaceutical companies which were taken up with each company individually. Companies made differing submissions about the training and consultancy company and the role and status of the named health professional. Each case was considered on its merits.

In addition, the Panel noted that the case preparation manager had stated that matters would be considered in relation to the requirements of the Code applicable when the matters at issue occurred.

The Panel noted that Takeda's provision of restricted use grants for therapy reviews to two GP practices and the engagement of the named health professional as a speaker at promotional meetings occurred during 2015. There were no significant differences between the relevant requirements of the 2015 and the current 2016 Code and thus these matters were considered under the 2016 Code. The Panel noted that Takeda had sponsored a training and consultancy company meeting in October 2014 by purchasing space for an exhibition stand. The Panel noted that there was a difference between the 2014 and 2016 Codes in the supplementary information to Clause 2 in that the supplementary information to the 2016 Code gave 'unacceptable payments' as an example of a breach of Clause 2. This difference was potentially relevant to the matter at issue and thus all matters pertaining to the October 2014 meeting were ruled under the requirements of the 2014 Code.

In relation to the audits in a named CCG the Panel noted the allegation that patients were either initiated or switched onto the sponsor's product with little consideration given to other therapies and that surgeries exhibited irregular use of a sponsor's product. Reference was made to abnormally high sales of Takeda's product. The Panel noted the

requirements of the 2016 Code set out in Clauses 18 and 19 and the supplementary information to Clause 19.1, Switch and Therapy Review Programmes which stated that Clauses 18.1 and 19.1 prohibited switch services paid for or facilitated directly or indirectly by a pharmaceutical company whereby a company's medicine was simply changed to another without any clinical assessment. It was acceptable for a company to promote a simple switch from one product to another but not to assist the health professional in implementing that switch even if assistance was by means of a third party such as a sponsored nurse or similar. A therapeutic review was different to a switch service: it aimed to ensure that patients received optimal treatment following a clinical assessment and was a legitimate activity for a pharmaceutical company to support and/or assist. Clause 19.2 stated that medical and educational goods and services in the form of donations, grants and benefits in kind to institutions, organisations and associations that were comprised of health professionals and/or, *inter alia*, provided healthcare were only allowed if they complied with Clause 19.1, were documented and kept on record by the company and did not constitute an inducement to, *inter alia*, prescribe.

The Panel noted Takeda's submission that when it received the complaint it did not know of any funds provided to the named health professional or the training and consultancy company for audits but during the investigation of the complaint it became aware that the named health professional had delivered two therapy reviews commissioned by clinicians who had received support for those reviews from Takeda. The Panel noted that in 2015 Takeda's Grants and Donations Committee considered a request from and made a grant to a health centre to run specialist nurse clinics at 11 local practices which would, *inter alia*, identify patients who required medication changes or optimisation or urgent interventions. Payment was made in July 2015. In July 2015 another request was considered from, and a grant paid for a similar nurse led clinic at a medical centre. Monies were paid in October 2015.

The grant request from the medical centre explained that the practice would work with a company it had previously worked with to deliver the clinics; the company was not named. The service provider and its status was not identified in any of the materials for the health centre. The Panel noted that according to Takeda in each case the practice had initially raised its need for funding with either the representative and/or his/her line manager who each advised that an application be made to the company. The Panel noted that in December 2014 the named health professional/training and consultancy company had unsuccessfully applied for a grant to fund clinics in June 2015. CRM entries (November and December 2014) showed that there had been discussions about therapy reviews including how patients would be reviewed with relevant staff including the named health professional at a different medical centre and each November meeting entry referred to the named health professional, who had attended all three meetings in his/her role as a contract nurse, undertaking the reviews. The Panel also noted Takeda's submission that no discussion of Takeda supported therapy reviews took place at meetings with the named health professional and the GP from the health centre which had applied for a grant at the meetings in March and April 2015. In relation to the medical centre which applied for a grant, the Panel noted that at a meeting in March 2015 with the representative and regional account director, the GP at the medical centre had stated that he/she would like to do a clinical therapy review in his 3 surgeries with an independent company. The named health professional was present. When considering references to audits in the CRM entries the Panel noted that the named health professional also undertook local NHS funded clinics and that representatives were aware of these and discussed them with him. The Panel also noted that it had only been provided with CRM entries in relation to contacts with the named health professional and thus did not know what the overall level of contact and discussion had been with other health professionals at the surgeries and whether relevant discussions had occurred in the absence of the named health professional.

The Panel did not accept that Takeda first became aware of the involvement of the named health professional/the training and consultancy company with the audits when investigating the present complaint. Indeed the Panel noted that in relation to the review at the medical centre Takeda paid the monies in October 2015 directly to the training and consultancy company, rather than the surgery. The Panel noted that the representative had met the local GP at the medical centre in March 2015 along with, *inter alia*, the named health professional. The named health professional had been a consultant speaker at a Takeda internal training day two months previously. At that meeting in March the GP at the medical centre had stated he/she would like to engage an independent provider to undertake a therapy review. In the Panel's view, given the services provided by the named health professional's company, it was likely, given his presence at the meeting, that the medical centre was considering engaging the training and consultancy company. In addition Takeda's representative stated that he/she became aware whilst each therapy review was taking place that it was in fact supported by Takeda and that the named health professional was engaged to undertake it. The Panel also noted the overall level of contact between Takeda, its field staff and the named health professional during the relevant period and notes recorded on the CRM system. In addition the named health professional was a speaker at an internal Takeda training day in July 2015 and was engaged as a speaker at a Takeda promotional meeting in November 2015. In the Panel's view, at the latest, either on payment to the training and consultancy company (medical centre) or when the therapy reviews were taking place, individuals at Takeda were aware of the involvement of the training and consultancy company.

Takeda had stated that it could not comment on any correlation between the training and consultancy company activity and prescribing of a class of product but noted that use of its product was

significant within the local CCG before the grant request and that the medicine was by a significant margin the least expensive in its class available in the UK.

The Panel first had to consider Takeda's responsibility for the audits. Noting its comments above, the level of contact between the parties, previous discussions about the need for audits and advice from field-based staff to apply for funding the Panel queried the company's submission that the funding requests were unsolicited. The Panel noted the grant agreements for the therapy reviews each stated that the grant was not an inducement to, or reward for recommending or taking any decisions favourable to products or services of Takeda. The agreements also referred to the NHS body providing a brief report to Takeda on request or as agreed by the parties. The accompanying letters to the practices, however, stated only that Takeda would be extremely interested to hear about the outcomes but that the NHS body was not obliged to provide such details. In addition, Exhibit A to the agreement for the health centre stated that it was fully responsible for all aspects of the event; there was no similar statement in the agreement with the medical centre.

The Panel considered that on the available evidence neither audit was a Takeda activity. Clause 19.1 only applied to the provision of medical and educational goods and services provided by the company and thus in the Panel's view did not apply to the particular circumstances of this case. No breach of Clause 19.1 was ruled. The Panel noted that Clause 19.2 described the circumstances in which a medical and educational good and service could be provided as a donation, grant or benefit in kind. The Panel considered that Clause 19.2 applied to the provision of a restricted use grant for a therapy review to a GP practice or group of practices. The Panel considered that it was beholden on the company to undertake due diligence when making such grants. This was especially important when the restricted use grant was for an audit in an area where the company had a commercial interest. Such due diligence should ensure, *inter alia*, that the arrangements were not and could not be perceived as an inducement to prescribe.

Whilst the Panel had concerns about Takeda's governance of the restricted use grants it nonetheless noted that the complainant bore the burden of proof. The Panel did not consider that the complainant had established that provision of funds and/or the arrangements for the therapy reviews were such that they were a switch service or otherwise an inducement to prescribe as alleged. No breach of Clauses 18.1 and 19.2 was ruled.

The Panel noted the payment for an exhibition stand at a one day course held in October 2014 and run by the training and consultancy company. Other companies also exhibited. The Panel noted that an email sent in October 2014 from representative 1 to representative 2 referred to the named health professional doing extra local clinics and helping and supporting representative 1 with Takeda's product locally 'convincing GP practices to switch and use the [Takeda product] family'. The meeting at issue was referred to as one which the named health professional had asked the representatives to support and 'in return [named health professional] has agreed that [he/she] will advocate, and help and support us in our cause in primary care with the [Takeda product] family'. Representative 2 was asked to contact the named health professional. The email in question was copied to the representatives' line manager who was the sales manager and the direct report of representative 1, a primary care representative. The Panel noted Takeda's submission that the sales manager asked representative 1 to refer the proposal to the compliance director but failed to recognise that the email suggested a link between the provision of funding and advocacy and support for Takeda's product. Takeda had not stated whether the compliance director saw the original email and, if so, what he/she did with the email or who sanctioned the payment. The representatives gave differing accounts of a subsequent meeting with the named health professional in October 2014 to discuss funding of the course at issue. Representative 1 stated that the named health professional made it clear that he/she would advocate Takeda's product in return for funding. This was denied by representative 2. A CRM report for a meeting with the named health professional in October 2014 stated that the named health professional agreed to help via speaker meetings to endorse Takeda's product across the region. The Panel also noted Takeda's submission that when payment was made for the exhibition stand space, it did not take adequate steps to ensure that it did not exceed fair market value. The Panel considered that given the link between funding and support for Takeda's product as stated in the email, the payment was contrary to Clause 18.1 and 18.6 and a breach of those clauses were ruled. The company had failed to maintain high standards and a breach of Clause 9.1 was ruled. These rulings were made under the 2014 Code.

The Panel was very concerned that despite the senior line manager being copied into the email in question no steps were taken by senior staff to review the initial arrangements or otherwise prevent payment. The level of payment was not assessed to make sure it did not exceed fair market value. In addition, the Panel noted that an inducement to prescribe was listed in the supplementary information to Clause 2 as an example of an activity likely to lead to a breach of the Code. The Panel considered that the impression created by the email brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled. This ruling was made under the 2014 Code.

The Panel noted its rulings of breaches of Clauses 18.1, 9.1 and 2 of the 2014 Code in relation to the arrangements and impression created by the email. The Panel considered all the circumstances surrounding the meeting of 25 October very carefully including that the representatives gave differing accounts of their meeting with the named health professional on 21 October. The Panel also noted that a ruling of a breach of Clause 2 would be the subject of an advertisement in the medical, pharmacy and nursing press. Taking all the circumstances into account, and on balance, the Panel decided not to report Takeda to the Code of

Practice Appeal Board on this point for it to consider whether further sanctions were warranted.

The Panel noted that the grants approved by Takeda were paid to the health centre in July 2015 and to the training and consultancy company with regard to the audit at the medical centre in October 2015. The clinics at the health centre would take place over 13 weeks and the services at the medical centre would be provided over 26 weeks. Both projects were sub-contracted to the training and consultancy company/the named health professional. The Panel further noted that in November 2015 and December 2015, thus certainly whilst the medical centre services were knowingly being provided by the training and consultancy company, Takeda engaged the named health professional, its director, as an expert speaker for the two promotional meetings held in a local CCG in 2015. In that regard, the Panel noted that point (vi) of the supplementary information to Clause 19.1, Medical and Educational Goods and Services, stated that sponsored health professionals should not be involved in the promotion of specific products. The Panel considered that the complainant had not established on the balance of probabilities that there was any evidence to show that his engagement to speak at the two promotional meetings was an inducement to prescribe. No breach of Clause 23.1 was ruled. Nonetheless, the Panel considered that his contemporaneous engagement in non-promotional and promotional roles either personally or via the training and consultancy company was not compatible. It did not appear that the company had undertaken any due diligence in this regard. High standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted that Takeda had also been asked to respond to the requirements of Clause 21 of the 2016 Code. There was no evidence before the Panel that Takeda had engaged in any relevant activity and thus no breach of Clause 21 was ruled.

During its consideration of this case, the Panel was concerned about the 9 contacts held with the named health professional in restaurants and the company's submission that private rooms were used for promotional meetings although this was not always documented. Firstly it was entirely unclear what non promotional meetings with health professionals the company thought it could hold in the public part of a restaurant and still comply with the Code. The Panel was also concerned about the company's submission that agendas were not available for all promotional meetings so it was not possible to verify whether there was sufficient educational content to justify the provision of food. The Panel was concerned about the company's poor governance of its representatives and noted that the company was aware that its processes and controls in relation to the field force needed reinforcing and that it would initiate a detailed audit.

The Panel requested that the company be advised of its concerns.

Complaint received **3 August 2016**

Case completed **9 January 2017**

ANONYMOUS, NON CONTACTABLE v LILLY

Engagement of a consultant and his/her training and consultancy company

An anonymous, non-contactable complainant raised concerns about a therapy area specific training and consultancy company and its owner, a health professional who delivered services including practice audits, health professional mentoring, education and classroom based training workshops funded by a number of named pharmaceutical companies including Lilly. These services had been delivered in a number of named clinical commissioning groups (CCGs) in one area. In addition, the health professional was a specialist nurse employed on a contractual basis by a number of NHS organisations including a city based community healthcare organisation (CHO). In his/her role as a nurse within that organisation the health professional had prescribing responsibility and influence within one of the CCGs named by the complainant.

The complainant alleged that the training and consultancy company had conducted industry funded clinical audits in several GP surgeries in the area in question which were identifiable as they had highly irregular use of the sponsoring company's product. The patients of several surgeries in one CCG were either initiated onto or switched to the sponsor's medicine with little consideration given to alternative therapies. The pattern of disproportionate increases in product sales could be directly linked back to the pharmaceutical company which had funded the training and consultancy company.

The complainant referred to a series of accredited training workshops delivered by the training and consultancy company in partnership with a named CCG which was completely funded by industry. The complainant was concerned about the potential substantial financial support to the training and consultancy company for these workshops due to reservations about the ethics of that organisation and because its owner was directly contracted to the local city based CHO. In the complainant's view industry's financial support for these courses was staggering and could be perceived as an attempt to 'buy the business'.

The complainant alleged that the training and consultancy company had told pharmaceutical companies that if they failed to provide support, their products would not be used in the CCG in which he/she had prescribing responsibility. The complainant stated that his/her company's local representative felt highly pressured to offer funding as he/she had been threatened that if he/she failed to support training events the health professional in question would simply get the money from another pharmaceutical company. The complainant stated that this highly coercive behaviour was completely unacceptable and he/she assumed that similar pressure had been exerted on other pharmaceutical companies. In addition the complainant noted that services provided by industry were in some cases very similar to the offerings developed by the training and consultancy company and alleged that the health professional in question had left individuals in no doubt that if their company attempted to partner in CCGs where he/she wanted to deliver programmes there could be consequences for their sales in the area in which he/she had prescribing responsibility.

The detailed response from Lilly is given below.

The Panel had no contact details for the complainant and so could not ask him/her for further details. The complainant had the burden of proving his/her complaint on the balance of probabilities; he/she had not provided any evidence in support of the allegations.

The Panel noted that the complainant began by stating that he/she wished to complain about the conduct of the training and consultancy company and subsequently referred to its owner. In this regard the Panel noted that the Code applied solely to the conduct of pharmaceutical companies.

The Panel considered that the scope of the complaint included the engagement of the health professional in question and/or the activities of his/her company with health professionals, whether the company's activities were delivered by its owner or other individuals. However, when considering such matters the totality of a pharmaceutical company's interactions with the health professional in question would nonetheless be relevant.

The Panel noted that the complainant had provided a website address for the training and consultancy company which named the health professional in question as the Director and another health professional as the nurse liaison lead. The Panel noted that the named health professional was contracted by the NHS to work at a number of GP surgeries in addition to his/her role at the city based CHO.

The Panel noted Lilly's submission that it had sponsored 13 meetings run by the training and consultancy company. Eight of these meetings were for an exhibition stand at two day accredited training courses. The remaining five were for courses at local surgeries and hospitals. The Panel noted that for all 13 meetings the training and consultancy company and the city based CHO's therapy area team lead for specialist nurses and dieticians had full responsibility for the meetings' content and speakers, and for the accredited training courses, selection and registration of attendees from a named CCG. The Panel noted that sponsorship of the accredited training courses varied according to whether Lilly was one of two sponsors or the sole sponsor. In relation to the other 5 courses

run at surgeries and hospitals, the amounts paid in sponsorship again varied according to the duration of the meeting. The Panel noted that there had been 30 contacts between the local representatives and the named health professional between February 2015 and March 2016. No details were provided about the status of the contacts, nonetheless the overall number appeared high. According to Lilly during its internal investigation there was no report or indication that its representatives felt pressurised or obliged to offer support to the training and consultancy company or the named health professional. The Panel noted that the complainant bore the burden of proof and considered that the complainant had not established, on the balance of probabilities, that either the provision of sponsorship or the level of sponsorship for any of the meetings was an inducement to prescribe or otherwise inappropriate in relation to the matters alleged. No breach of the Code was ruled. High standards had been maintained and a further ruling of no breach of the Code was ruled. Nor had the complainant established a breach of Clause 2; no breach of that clause was ruled.

The Panel noted that there was no evidence before the Panel that Lilly had engaged in any relevant activities alleged and the Panel ruled no breach of the Code.

An anonymous, non-contactable complainant who described themselves as an employee of one of the many manufacturers of therapies in a particular therapy area, complained about the conduct of a therapy area specific training and consultancy company run by a named health professional, that delivered a range of services to, *inter alia*, the NHS including services that were funded by a number of pharmaceutical companies including Eli Lilly & Company Limited.

COMPLAINT

The complainant stated that the named health professional, in addition to his/her role at his/her company was also a specialist nurse employed on a contractual basis by a number of NHS organisations including a city based community healthcare organisation (CHO). In his/her role as a nurse within that organisation he/she had prescribing responsibility and influence within a named clinical commissioning group (CCG) area. The services offered ranged from in practice audits, health professional mentoring and education, to classroom based training workshops. These offerings had been delivered in a number of named local CCGs. Funding was provided for these initiatives through various mechanisms within the Code ie independent stand meetings.

The complainant stated that he/she had previously raised concerns within his/her organisation in relation the legitimacy of the training and consultancy company business model, in particular how it received funding from the pharmaceutical industry which unfortunately included on-going financial and logistical support from the complainant's own company. The complainant's concerns had been raised internally with management but no action had been taken to rectify the situation and the complainant believed that his/her job would be at risk if his/her confidentiality in raising these issues was not protected.

The complainant explained that the training and consultancy company had conducted industry funded 'clinical audits' in several surgeries across a named part of a city, those practices were very easy for medicines management to identify as they had highly irregular use of the sponsor's product. In several surgeries in a named CCG patients were either initiated onto or switched to the sponsors' medicine with little consideration given to alternative therapies. The pattern of disproportionate increases in product sales could be directly linked back to the pharmaceutical companies' funding support to the training and consultancy company. The complainant explained that unfortunately to protect his/her anonymity, he/she was unable to provide a very detailed narrative but would endeavour to give enough information so that the training and consultancy company and the pharmaceutical companies that used it were held to account.

The complainant stated that at the beginning of 2016 the training and consultancy company started to deliver a series of training workshops in partnership with the CCG in which the named health professional had prescribing responsibility which were accredited by the Royal College of General Practitioners (RCGP) and the Royal College of Nursing (RCN). The delivery of the workshops was, and continued to be completely funded by industry. The complainant articulated his/her concerns to his/her line manager regarding the company potentially providing substantial financial support to the training and consultancy company for these workshops due to his/her reservations about the ethics of that organisation and because its owner was directly contracted to the city based CHO.

The complainant stated that the amount of money that industry had pumped into these courses was staggering, and in his/her opinion the risk that the support could be perceived as an attempt to 'buy the business' had led him/her to continuously try to dissuade his/her company from being involved. Unfortunately the concerns the complainant foresaw had materialised into major conflict of interest and anti-competitive issues whereby the training and consultancy company had told potential industry partners that if they failed to provide support, their products would not be used in the CCG in which the complainant stated that the named health professional had prescribing responsibility and influence. The complainant stated that his/her company's local representative felt highly pressured to offer the training and consultancy company funding as the individual had been threatened that if he/she failed to support training events the named health professional would simply get the money from another pharmaceutical company. According to the complainant this was highly coercive behaviour and clearly completely unacceptable and one could only assume that similar pressure had been exerted on all other pharmaceutical companies.

An additional issue that recently came to light was that most of the organisations working in the therapy area provided a range of industry-developed services that were deployed in partnerships with NHS organisations; these services were in some cases very similar to the offerings developed by the training and consultancy company. The named health professional had left individuals in no doubt that if their organisation attempted to partner in CCGs where he/she wanted to deliver the programmes there could be consequences for their sales in the area in which he/she had prescribing responsibility.

In the complainant's view the NHS and industry should be able to collaborate in highly transparent projects that benefited all stakeholders. Having to turn to the PMCPA to whistle-blow on his/her own organisation and the unacceptable behaviour of an organisation that it was actively engaged with was the low point of his/her career in the pharmaceutical industry. The complainant stated that the cavalier attitude of management within his/her own organisation and an inability for him/her to sit on the side-lines as the actions of a few undermined those of many and once again brought the industry into disrepute was too much to stomach. The complainant felt incredibly disillusioned that the industry and his/her company continued to work alongside an organisation that operated in a manner that was simply unacceptable in 2016. Unfortunately, industry was not an innocent party in the affair; all of the companies that had been involved with the training and consultancy company needed to reassess how they conducted business. The complainant appreciated that the evidence given in the complaint might not be detailed enough for the Authority to act but he/she hoped that there was enough information to at least investigate the relationship between the named health professional and a number of pharmaceutical companies. The great shame was that he/she might well be delivering much needed training and support for health professionals, however, the path he/she had decided to follow to extract financial support from industry had sullied what could have otherwise been a noble endeavour. The complainant hoped his/her complaint was seen as a genuine cry for help from the PMCPA as he/she had been ignored by those in positions of power within his/her organisation. The complainant stated that this complaint was motivated by a strong desire to do what was right; he/she was reasonably certain that if the issues outlined were investigated, his/her position within his/her company and probably the industry would become untenable.

The complainant provided a website address for the training and consultancy company.

When writing to Lilly, the Authority asked it to consider the requirements of Clauses 2, 9.1, 18.1, 19.1, 19.2, 21 and 23.1 of the Code with regard to the clinical audit and with regard to training workshops delivered in partnership with a named clinical commission group (CCG). The case would be considered under the requirements of the Code relevant to the time the activities took place. The clause numbers cited above were relevant to the 2015 and 2016 Codes.

RESPONSE

Lilly submitted that it took any suggestions of improper conduct extremely seriously and immediately undertook an investigation which was now complete with relevant staff interviewed. Lilly was confident that it had acted appropriately and transparently in all interactions with the training and consultancy company and the named health professional. Lilly therefore refuted all allegations of improper conduct or Code breaches.

Clinical Audit

Lilly submitted that it had not engaged with the training and consultancy company or the named health professional for the purpose of any clinical audit. No clinical audits had been carried out by the training and consultancy company or the named health professional on behalf of Lilly nor had Lilly funded the training and consultancy company or the named health professional to support any clinical audits.

Training Workshop

Lilly submitted that it had sponsored certain meetings conducted by the training and consultancy company for the CCG in which the named health professional had prescribing responsibility. The Sponsoring Independent Meetings for Health Professionals standard operating procedure (SOP) applied to the review and approval of sponsorship of independent meetings. The corresponding form to be completed by field-based staff for approval of meeting sponsorship was also provided as was a copy of the Guidance for Independent Stand Meetings which was referred to in the above SOP. An email template sent to HCOs by Lilly customer meeting services confirming independent meeting sponsorship by Lilly was also provided.

Lilly submitted that during 2015 and 2016, it sponsored 13 meetings organised and run by the training and consultancy company. Lilly paid the training and consultancy company following the Sponsoring Independent Meeting procedure and using the appropriate form. Agenda for these meetings were provided.

Lilly submitted that it was approached by the training and consultancy company in 2015 to sponsor a number of meetings run by it for the CCG in which the named health professional had prescribing responsibility. Lilly was not obliged to sponsor the meetings and nor did it expect or receive any improper benefit for its sponsorship. The sponsorship of these meetings was open to all interested pharmaceutical companies including Lilly. The CCG covered a large area and had a patient population of approximately 39,000 and 62 GP practices. Lilly understood that the team lead for specialist nurses and specialist dieticians at city-based community healthcare organisation had worked with the training and consultancy company to develop a programme of meetings, including the accredited training to educate GPs and practice nurses across the CCG.

The training and consultancy company and the team lead developed the course content and managed all aspects of these meetings including securing sponsorship from pharmaceutical companies for the meetings.

The named health professional had been the point of contact at the training and consultancy company for Lilly when sponsoring these meetings, in addition to the team lead.

Lilly submitted that whilst it had sponsored independent meetings run by the training and consultancy company, it did not have any other commercial relationship and confirmed that all payments made to the training and consultancy company had been in relation to sponsorship of independent meetings organised by the training and consultancy company.

The named health professional confirmed to Lilly that the training and consultancy company was an independent training provider and did not receive any funding from the CCG in which he/she had prescribing responsibilities for its meetings.

Lilly submitted that it was not involved in any aspect of clinical audits carried out by the training and consultancy company and so could not provide any account of arrangements and it had made no associated payments. It was therefore also unable to provide any materials associated with such audit. Lilly confirmed that none of its representatives were involved in the training and consultancy company clinical audits and therefore Lilly was unable to provide any information of surgeries selected and how any subsequent uplift in sales were monitored. Lilly was also unable to provide any information on how medicines were chosen in such audits.

Lilly provided details of the 13 meetings run by the training and consultancy company which it sponsored during 2015 and 2016.

The training and consultancy company and the team lead were responsible for all arrangements of the meetings including the selection and registration of the CCG attendees. The training and consultancy company confirmed that these meetings had 18-24 participants and 4-6 speakers on the programme. The training and consultancy company and the team lead were fully responsible for meeting content and any associated speakers. The training and consultancy company provided a separate room for its sponsors to exhibit and did not permit sponsors to participate in the meeting programme. The training courses were accredited by the RCGP and the RCN and certified by the CPD Certification Service.

The training and consultancy company and the CHO team lead were also fully responsible for the content and any associated speakers for the remaining five the training and consultancy company meetings sponsored by Lilly. The training and consultancy company provided a separate room for its sponsors to exhibit and did not permit sponsors to participate in the meeting programme. Further details of these meetings were provided.

Lilly submitted that it had not supported any other courses in the relevant geographical area but had sponsored a further 11 independent meetings organised by other providers/organisations for health professionals in certain CCGs.

In summary, Lilly submitted that it had appropriately sponsored meetings organised and run by the training and consultancy company and the team lead for the CCG which provided education for health professionals in an effort to improve the care delivered to patients in the CCG. The meetings had clear educational content; were held in appropriate venues conducive to the main purpose of the meeting and provided modest subsistence to attendees who were health professionals within the CCG.

Accordingly, Lilly refuted any breach of Clauses 2, 9.1, 18.1, 19.1, 19.2, 21 or 23.1 with regard to the clinical audit and with regard to the accredited training workshops delivered in partnership with the CCG.

Lilly submitted that it took the matter of its staff being able to 'speak up' very seriously and had initiated an internal investigation to establish if any employee felt he/she could not speak up and report concerns about Lilly's business.

Lilly understood and fully respected the Code and strove to ensure that all activities always complied with the Code.

In response to a request for further information Lilly stated that a senior director who was not part of the UK sales and marketing affiliate had conducted an internal investigation into the company's relationship with the training and consultancy company, to establish if any Lilly employee felt he/she could not speak up and report concerns about Lilly's business. All employees from the relevant geography were interviewed and it was concluded:

- There was no evidence that Lilly had been involved in or funded clinical audits, nurse-led reviews or clinics to assess patients with a particular condition in a named area
- There was also no evidence that Lilly had indirectly paid for the training and consultancy company to conduct clinical audits
- That the training and consultancy company was selected by the CCG in which the named health professional had prescribing responsibility to facilitate CCG educational meetings. The CCG asked Lilly and other sponsors to support the CCG programme by sponsoring the training and consultancy company. The agenda for the meetings was not determined by or influenced in any way by Lilly.

No Lilly employee felt he/she could not speak up and report concerns about Lilly's business.

In response to specific questions raised Lilly responded as follows:

Clinical audits

Lilly confirmed that it had not directly funded a practice or group of practices for it to carry out

an audit/review independently of Lilly. Lilly had not directly or indirectly paid the training and consultancy company to conduct clinical audits. Lilly had not funded any activity provided by the training and consultancy company which might be described as a nurse-led review, a clinic to assess diabetics, or any similar activity.

Meetings

In response to a request to explain the process by which Lilly decided to work with the training and consultancy company Lilly explained that the training and consultancy company was selected by the CCG in which the named health professional had prescribing responsibility to facilitate its education meetings. The CCG asked Lilly and other pharmaceutical companies to sponsor these independent meetings, payment was to be made to the training and consultancy company which would run the meetings on behalf of the CCG. Lilly understood that the team lead for specialist nurses and dieticians at the CHO had worked with the training and consultancy company to develop the programme of meetings, including the accredited training courses, the aims of which were to educate GPs and practice nurses across the CCG.

Lilly did not know if the training and consultancy company was the only regional provider of such services.

Lilly provided details of the sponsorship of each of the 13 meetings including monies paid. Lilly had confirmed to the training and consultancy company and/or the team lead for each meeting that the sponsorship was of an independent stand meeting and was for Lilly to have exhibition/stand space.

The sponsorship of these independent meetings was such that the CCG and the training and consultancy company remained in full control of the agenda, course content, speaker selection and their payment, and registration of delegates.

In response to a question about what factors Lilly took into account in deciding whether the amount paid was reasonable Lilly explained that the Lilly representatives and manager would have known about and followed the guidance in the Lilly job aid 'Guidance for Independent Stand Meetings' (copy provided) when they reviewed and decided whether the sponsorship amount was reasonable. They would have considered the Lilly exhibition/stand space and opportunity in light of the probable hire costs of the venue; the modest subsistence, and the speakers' honoraria required to run such meetings.

In response to a question about how the meetings were approved the Lilly representative received a verbal request to sponsor the meetings from the training and consultancy company/the CCG. The representative completed the Independent Stand Meeting Sponsorship form and submitted it to his/her line manager for approval. The line manager then approved the arrangements for the sponsorship of the meeting. These details were submitted to the Lilly Customer Meeting Services Team (LCMS) which confirmed the sponsorship details with the training and consultancy company/the CCG.

For each meeting Lilly supplied the completed Independent Stand Meeting Sponsorship form, the agenda provided to Lilly, the email of the manager's approval of the meeting, the email sent to the training and consultancy company/the CCG by LCMS confirming the details of the sponsorship and confirmation that the meeting took place and payment being made.

Lilly provided details of contacts entered in the CRM between Lilly representatives and the named health professional for 2015 and 2016.

When asked to comment on the allegation that sponsorship of these meetings could be seen as an attempt to buy business Lilly stated that the sponsorship was not related to the sales of Lilly products either past or anticipated in future. Lilly had appropriately sponsored independent educational meetings developed by team lead and the training and consultancy company that were accredited by the RCGP and the RCN. Lilly was not obliged to sponsor the meetings nor did it expect or receive any improper benefit for its sponsorship. The allegation that such support by Lilly 'could be seen as an attempt to buy business' was unfounded and wrong.

Lilly confirmed that during the thorough internal investigation there was no report or indication that any representative felt pressurised or obliged to support the training and consultancy company and/or the named health professional.

In relation to two day training courses in April and July 2016 which were also sponsored by Boehringer Ingelheim, Lilly confirmed that these were not Boehringer Ingelheim/Lilly Alliance activities. Each company sponsored them separately.

Lilly stated that it understood and fully respected the Code and strove to ensure that all activities were in full in adherence with the Code at all times.

PANEL RULING

The Panel noted that the anonymous complainant was non contactable and so could not be asked to provide further details. Anonymous complaints were accepted and like all complaints judged on the evidence provided by the parties. The complainant had the burden of proving his/her complaint on the balance of probabilities. The complainant had not provided any evidence in support of the allegations.

The complaint raised concerns about the interactions of certain pharmaceutical companies, including Lilly, and the training and consultancy company run by the named health professional. The complainant stated that the named health professional, a nurse, was employed on a contractual basis by a number of NHS organisations including the named city based CHO. Reference was made to his/her prescribing responsibility and alleged influence in a named CCG area and to the training and consultancy company services provided locally. The training and

consultancy company offerings were said to range from practice audits, health professional mentoring and education to classroom based training workshops. More detailed allegations were made in relation to audits and workshops. The complainant alleged that the amount of money that industry had pumped into these courses was 'staggering' and could be perceived as an attempt to 'buy the business'. The complainant also generally referred to the Authority investigating the relationship between the named health professional and certain pharmaceutical companies. In this regard the Panel noted that it could only consider specific matters raised in the complaint.

The Panel noted that the complainant began by stating that he/she wished to complain about the conduct of the training and consultancy company, referred to grave concerns about it and the path which the complainant alleged had been taken by its owner, the named health professional, to extract financial support from the industry including highly coercive behaviour; in this regard the Panel noted that the Code applied solely to the conduct of pharmaceutical companies.

The Panel considered that the complaint was broader than the two matters identified by the case preparation manager, ie audits and specific workshops. The complainant had referred generally to training and support for health professionals delivered by the named health professional but paid for by the pharmaceutical industry. Lilly had, however, responded to all matters raised in the complaint and the Panel ruled accordingly. The Panel considered that the scope of the complaint included the engagement of the named health professional and/or the training and consultancy company activities, with health professionals, whether such activities were delivered by its owner the named health professional or other individuals. However, when considering such matters the totality of a company's interactions with the named health professional would, nonetheless, be relevant.

The Panel noted that the complainant had provided a website address for the training and consultancy company and this had been provided to all respondent companies. The website listed the named health professional as the Director and another health professional as the nurse liaison lead. The Panel noted that the named health professional was contracted by the NHS to work at a number of surgeries in addition to his/her role at the named city based CHO.

The Panel noted that the complainant had raised concerns in relation to a number of pharmaceutical companies which were taken up with each company individually. Companies made differing submissions about the training and consultancy company and the role and status of the named health professional. Each case was considered on its merits.

In addition the Panel noted the case preparation manager's advice that matters would generally be considered in relation to the requirements of the Code applicable when the matters at issue occurred. However, the Panel noted that there were no significant relevant differences between the requirements of the 2016 Code and the requirements of the 2015 Code. The rulings were therefore made under the requirements of the 2016 Code.

The Panel noted Lilly's submission that it had sponsored 13 meetings run by the training and consultancy company between June 2015 and July 2016. Eight of these meetings were for an exhibition stand at two-day accredited training courses. The remaining five were for courses at local surgeries and hospitals and were devised and run by the training and consultancy company. The Panel noted that for all 13 meetings the training and consultancy company and the CHO team lead for specialist nurses and dieticians had full responsibility for the meetings' content and speakers, and for the accredited training courses, selection and registration of the CCG staff. The Panel noted that according to the website for the training and consultancy company, the CHO team lead for specialist nurses also had a role at the training and consultancy company. The Panel noted that the meetings which all had a detailed educational agenda were accredited by the RCN and the RCGP. The Panel noted that sponsorship of these courses varied according to whether Lilly was one of two sponsors or whether it was the sole sponsor. In relation to the other 5 courses run at surgeries and hospitals, amounts paid in sponsorship again varied according to the duration of the meeting. The Panel noted that one of the agendas/invitations for the remaining 5 meetings gave little detail about its educational content. The Panel noted that there had been 30 contacts between the local representatives and the named health professional between February 2015 and March 2016. No details were provided about the status of the contacts, nonetheless the overall number appeared high. According to Lilly during its internal investigation there was no report or indication that its representatives felt pressurised or obliged to offer support to the training and consultancy company or the named health professional. The Panel noted that the complainant bore the burden of proof and considered that the complainant had not established, on the balance of probabilities, that either the provision of sponsorship or the level of sponsorship for any of the meetings was an inducement to prescribe or otherwise inappropriate in relation to the matters alleged. No breach of Clauses 18.1 and 19.2 was ruled. High standards had been maintained; no breach of Clause 9.1 was ruled. Nor had the complainant established a breach of Clause 2; no breach of that clause was ruled.

The Panel noted that Lilly had also been asked to respond to the requirements of Clauses 19.1, 21 and 23.1 of the 2016 Code. There was no evidence before the Panel that Lilly had engaged in any relevant activities and the Panel ruled no breach of Clauses 19.1, 21 and 23.1 accordingly.

Complaint received **3 August 2016**

Case completed **19 December 2016**

CASE AUTH/2864/8/16 *NO BREACH OF THE CODE*

ANONYMOUS, NON CONTACTABLE v BOEHRINGER INGELHEIM

Engagement of a consultant and his/her training and consultancy company

An anonymous, non-contactable complainant raised concerns about a therapy area specific training and consultancy company and its owner, a health professional who delivered services including practice audits, health professional mentoring, education and classroom based training workshops funded by a number of named pharmaceutical companies including Boehringer Ingelheim. These services had been delivered in a number of named clinical commissioning groups (CCGs) in one area. In addition, the health professional was a specialist nurse employed on a contractual basis by a number of NHS organisations including a city based community healthcare organisation (CHO). In his/her role as a nurse within that organisation the health professional had prescribing responsibility and influence within one of the CCGs named by the complainant.

The complainant alleged that the training and consultancy company had conducted industry funded clinical audits in several GP surgeries in the area in question which were identifiable as they had highly irregular use of the sponsoring company's product. The patients of several surgeries in one CCG were either initiated onto or switched to the sponsor's medicine with little consideration given to alternative therapies. The pattern of disproportionate increases in product sales could be directly linked back to the pharmaceutical company which had funded the training and consultancy company.

The complainant referred to a series of accredited training workshops delivered by the training and consultancy company in partnership with a named CCG which was completely funded by industry. The complainant was concerned about the potential substantial financial support to the training and consultancy company for these workshops due to reservations about the ethics of that organisation and because its owner was directly contracted to the local city based CHO. In the complainant's view industry's financial support for these courses was staggering and could be perceived as an attempt to 'buy the business'.

The complainant alleged that the training and consultancy company had told pharmaceutical companies that if they failed to provide support, their products would not be used in the CCG in which he/she had prescribing responsibility. The complainant stated that his/her company's local representative felt highly pressured to offer funding as he/she had been threatened that if he/she failed to support training events the health professional in question would simply get the money from another pharmaceutical company. The complainant stated that this highly coercive behaviour was completely unacceptable and he/she assumed that similar pressure had been exerted on other pharmaceutical companies. In addition the complainant noted that services provided by industry were in some cases very similar to the offerings developed by the training and consultancy company and alleged that the health professional in question had left individuals in no doubt that if their company attempted to partner in CCGs where he/she wanted to deliver programmes there could be consequences for their sales in the area in which he/she had prescribing responsibility.

The detailed response from Boehringer Ingelheim is given below.

The Panel had no contact details for the complainant and so could not ask him/her for further details. The complainant had the burden of proving his/her complaint on the balance of probabilities; he/she had not provided any evidence in support of the allegations.

The Panel noted that the complainant began by stating that he/she wished to complain about the conduct of the training and consultancy company and subsequently referred to its owner. In this regard the Panel noted that the Code applied solely to the conduct of pharmaceutical companies.

The Panel considered that the scope of the complaint included the engagement of the health professional in question and/or the activities of his/her company with health professionals, whether the company's activities were delivered by its owner or other individuals. However, when considering such matters the totality of a pharmaceutical company's interactions with the health professional in question would nonetheless be relevant.

The Panel noted that the complainant had provided a website address for the training and consultancy company which named the health professional in question as the Director and another health professional as the nurse liaison lead. The Panel noted that the named health professional was contracted by the NHS to work at a number of GP surgeries in addition to his/her role at the city based CHO.

The Panel noted that Boehringer Ingelheim's first interaction with the named health professional was in relation to an evening meeting held in 2014 at a GP practice and organised by the CCG in which the health professional had prescribing responsibility. Boehringer Ingelheim submitted that the CCG had decided to use the health professional's services and his/her speaker's fee was paid directly by Boehringer Ingelheim. The Panel noted that the complainant bore the burden of proof and considered that the complainant had not established on the balance of probabilities that there was any evidence to show that the engagement of the health professional was an inducement to prescribe or otherwise inappropriate as alleged. No breach of the Code was ruled, including no breach of Clause 2.

The Panel noted that the same CCG organised two courses, each over two days, using the training and consultancy company. Each course was sponsored by Boehringer Ingelheim and another company. Boehringer Ingelheim subsequently submitted that the courses were organised by the training and consultancy company. At the request of the CCG the contracts for each course were with the training and consultancy company and described it as the organiser. The signature required for the training and consultancy company was that of the named health professional. The Panel noted Boehringer Ingelheim's submission that it was not aware of the relationship between the training and consultancy company and the local CCG/city based CHO. In that regard, however, the Panel noted from the materials provided, Boehringer Ingelheim should have been well aware of the health professional's dual role within the CCG and as the owner of the training and consultancy services company.

The Panel further noted the author of an email from a therapeutic area team lead at the city based CHO to the local representative requesting funding for the courses at issue was also a colleague of the named health professional at the training and consultancy company. In this colleague's role at the CCG in which the health professional had prescribing responsibility, he/she had previously held discussions with Boehringer Ingelheim's representative about supporting training with the named health professional. The company paid for exhibition stands at the two meetings. The Panel noted that the agenda for each course set out a detailed accredited education programme over two days. The Panel noted that the complainant bore the burden of proof and considered that the complainant had not established on the balance of probabilities that either the provision of sponsorship or the level of sponsorship was an inducement to prescribe or otherwise inappropriate in relation to the matters alleged and no breach of the Code was ruled.

The Panel noted Boehringer Ingelheim's submission that it had not funded any clinical audits in this therapeutic area in a named area. It had at the request of the city based CHO funded a meeting to provide training for practices to use a free clinical audit tool which had been developed by a university. The person who requested the funding was linked to the training and consultancy company. Payment was made directly to the university. Boehringer Ingelheim had no role in relation to the development of the tool or its subsequent use. The Panel also noted the company's submission that it did not know whether the named health professional attended the training meeting in July 2016. The Panel noted that there was no evidence that the request for sponsorship and/or the decision to sponsor was linked to the use of Boehringer Ingelheim's medicines. The Panel noted that the complainant bore the burden of proof and considered that the complainant had not established on the balance of probabilities that there was any evidence to show that sponsorship of the training day was an inducement to prescribe or otherwise inappropriate in relation to the matters alleged. No breach of the Code was ruled including no breach of Clause 2.

There was no evidence before the Panel that Boehringer Ingelheim had engaged in any relevant activities in relation to medical and educational goods and services and/or entered into contracts with certain organisations governed by the Code and the Panel ruled no breach of the Code accordingly.

An anonymous, non-contactable complainant who described themselves as an employee of one of the many manufacturers of therapies in a particular therapy area, complained about the conduct of a therapy area specific training and consultancy company run by a named health professional, that delivered a range of services to, *inter alia*, the NHS including services that were funded by named pharmaceutical companies including Boehringer Ingelheim Limited.

COMPLAINT

The complainant stated that the named health professional, in addition to his/her role at his/her company was also a specialist nurse employed on a contractual basis by a number of NHS organisations including a city based community healthcare organisation (CHO). In his/her role as a nurse within that organisation he/she had prescribing responsibility and influence within a named clinical commissioning group (CCG) area. The services offered ranged from in practice audits, health professional mentoring and education, to classroom based training workshops. These offerings had been delivered in a number of named local CCGs. Funding was provided for these initiatives through various mechanisms within the Code ie independent stand meetings.

The complainant stated that he/she had previously raised concerns within his/her organisation in relation the legitimacy of the training and consultancy company business model, in particular how it received funding from the pharmaceutical industry which unfortunately included on-going financial and logistical support from the complainant's own company. The complainant's concerns had been raised internally with management but no action had been taken to rectify the situation and the complainant believed that his/her job would be at risk if his/her confidentiality in raising these issues was not protected.

The complainant explained that the training and consultancy company had conducted industry funded 'clinical audits' in several surgeries across a named part of a city, those practices were very easy for medicines management to identify as they had highly irregular use of the sponsor's product. In several surgeries in a named CCG patients were either initiated onto or switched to the sponsors' medicine with little consideration given to alternative therapies. The pattern of disproportionate increases in product sales could be directly linked back to the pharmaceutical companies' funding support to the training and consultancy company. The complainant explained that unfortunately to protect his/her anonymity, he/she was unable to provide a very detailed narrative but would endeavour to

give enough information so that the training and consultancy company and the pharmaceutical companies that used it were held to account.

The complainant stated that at the beginning of 2016 the training and consultancy company started to deliver a series of training workshops in partnership with the CCG in which the named health professional had prescribing responsibility which were accredited by the Royal College of General Practitioners (RCGP) and the Royal College of Nursing (RCN). The delivery of the workshops was, and continued to be completely funded by industry. The complainant articulated his/her concerns to his/her line manager regarding the company potentially providing substantial financial support to the training and consultancy company for these workshops due to his/her reservations about the ethics of that organisation and because its owner was directly contracted to the city based CHO.

The complainant stated that the amount of money that industry had pumped into these courses was staggering, and in his/her opinion the risk that the support could be perceived as an attempt to 'buy the business' had led him/her to continuously try to dissuade his/her company from being involved. Unfortunately the concerns the complainant foresaw had materialised into major conflict of interest and anti-competitive issues whereby the training and consultancy company had told potential industry partners that if they failed to provide support, their products would not be used in the CCG in which the complainant stated that the named health professional had prescribing responsibility and influence. The complainant stated that his/her company's local representative felt highly pressured to offer the training and consultancy company funding as the individual had been threatened that if he/she failed to support training events the named health professional would simply get the money from another pharmaceutical company. According to the complainant this was highly coercive behaviour and clearly completely unacceptable and one could only assume that similar pressure had been exerted on all other pharmaceutical companies.

An additional issue that recently came to light was that most of the organisations working in the therapy area provided a range of industry-developed services that were deployed in partnerships with NHS organisations; these services were in some cases very similar to the offerings developed by the training and consultancy company. The named health professional had left individuals in no doubt that if their organisation attempted to partner in CCGs where he/she wanted to deliver the programmes there could be consequences for their sales in the area in which he/she had prescribing responsibility.

In the complainant's view the NHS and industry should be able to collaborate in highly transparent projects that benefited all stakeholders. Having to turn to the PMCPA to whistle-blow on his/her own organisation and the unacceptable behaviour of an organisation that it was actively engaged with was the low point of his/her career in the pharmaceutical industry. The complainant stated that the cavalier attitude of management within his/her own organisation and an inability for him/her to sit on the side-lines as the actions of a few undermined those of many and once again brought the industry into disrepute was too much to stomach. The complainant felt incredibly disillusioned that the industry and his/her company continued to work alongside an organisation that operated in a manner that was simply unacceptable in 2016. Unfortunately, industry was not an innocent party in the affair; all of the companies that had been involved with the training and consultancy company needed to reassess how they conducted business. The complainant appreciated that the evidence given in the complaint might not be detailed enough for the Authority to act but he/she hoped that there was enough information to at least investigate the relationship between the named health professional and a number of pharmaceutical companies. The great shame was that he/she might well be delivering much needed training and support for health professionals, however, the path he/she had decided to follow to extract financial support from industry had sullied what could have otherwise been a noble endeavour. The complainant hoped his/her complaint was seen as a genuine cry for help from the PMCPA as he/she had been ignored by those in positions of power within his/her organisation. The complainant stated that this complaint was motivated by a strong desire to do what was right; he/she was reasonably certain that if the issues outlined were investigated, his/her position within his/her company and probably the industry would become untenable.

The complainant provided a website address for the training and consultancy company.

When writing to Boehringer Ingelheim, the Authority asked it to consider the requirements of Clauses 2, 9.1, 18.1, 19.1, 19.2, 21 and 23.1 of the Code with regard to the clinical audit and with regard to training workshops delivered in partnership with a named clinical commission group (CCG). The case would be considered under the requirements of the Code relevant to the time the activities took place. The clause numbers cited above were relevant to the 2015 and 2016 Codes.

RESPONSE

Boehringer Ingelheim submitted that it had worked with the CCG in which the named health professional was stated to have prescribing responsibility and the city based CHO in response to a need identified by them to improve local training in a particular therapy area. At the request of the CCG, the services of the health professional and his/her company had been provided by a contractual agreement between Boehringer Ingelheim and them.

Boehringer Ingelheim submitted that it supported training meetings for general practitioners in 2014 and 2016 and a 'train the trainer' meeting for a medical education goods and service (MEGS) called PRIMIS offered by Boehringer Ingelheim. PRIMIS was a free audit tool developed by a university, for which Boehringer Ingelheim offered funding (via a

MEGS) for training from the university on how to use it. Boehringer Ingelheim's only involvement in delivering the training was in a purely administrative capacity. In addition, Boehringer Ingelheim had supported the named health professional's attendance at a national UK meeting.

Boehringer Ingelheim had not commissioned patient reviews or clinical audits by the CCG or the city based CHO, the training and consultancy company or the named health professional. Boehringer Ingelheim was not aware of the behaviour described by the complainant where the training and consultancy company was alleged to have put improper pressure on pharmaceutical companies to support training events or to refrain from deploying similar services in the area.

Following notification of this complaint, all ongoing and future activity involving the training and consultancy company had been placed on hold and a certified field force briefing had been issued to that effect, a copy was provided. Boehringer Ingelheim provided details of relevant interactions.

Sponsorship of independently organised meeting in 2014

In 2014, the CCG in which the complainant stated that the named health professional had prescribing responsibility and influence organised an evening education meeting for which it used the services of the named health professional in his/her capacity as a nurse educator. The activity was approved via Boehringer Ingelheim's internal approval process and a contract was put in place between Boehringer Ingelheim and the named health professional for the services provided (a copy of the contract and agenda was provided).

Sponsorship of two independently organised meetings in 2016

In 2016, the same CCG organised a two day education and training meeting for which it requested financial support. The training and consultancy company's services were used at this meeting at the CCG's request, contracts were put in place directly between Boehringer Ingelheim and the training and consultancy company to facilitate payment. This was approved by Boehringer Ingelheim's internal approval process.

The same CCG organised a further course sponsored by Boehringer Ingelheim and again at the CCG's request, contracts were put in place directly between Boehringer Ingelheim and the training and consultancy company to facilitate payment. This was approved by Boehringer Ingelheim's internal approval process.

The course was accredited by the RCN and the RCGP and Boehringer Ingelheim's sponsorship was clearly stated on the agenda.

Train-the-trainer PRIMIS training in 2016

In February 2016 an initial introduction to PRIMIS was provided and a subsequent discussion with the named health professional resulted in the city based CHO requesting support to conduct a 'train the trainer' PRIMIS training meeting; a contract was put in place between Boehringer Ingelheim and the city based CHO for financial support for this meeting which was approved by Boehringer Ingelheim's internal approval process.

Sponsorship of the named health professional to a UK national congress

In March 2016, and at his/her request, Boehringer Ingelheim supported the named health professional to attend a national UK congress and this was approved by Boehringer Ingelheim's internal approval process. An agreement was put in place with the named health professional for this activity.

Boehringer Ingelheim addressed each of the clauses cited as follows:

Clause 23.1: The services provided were used to provide training to a city based CHO and a named CCG at their request. The city based CHO and the CCG at which the named health professional had prescribing responsibility identified the need for the services to be delivered and that the named health professional/the training and consultancy company had the required expertise to meet their need. The contract in each case included provisions requiring the obligation to declare support from Boehringer Ingelheim.

Clause 21: The training services provided by the named health professional and the training and consultancy company complied with Clause 19.1 and no inducements to prescribe, supply, administer, recommend, buy or sell any medicine had been made. Boehringer Ingelheim had no input to the training other than to provide requested funding.

Clauses 19.1 and 19.2: The training services provided by the named health professional and the training and consultancy company were provided as a MEGS pursuant to Clause 19.1 to benefit the NHS and enhance patient care by improving health professionals' knowledge of best practice care in a particular therapy area. Boehringer Ingelheim had no input into the training delivered by either the named health professional or the training and consultancy company and had funded this training at the express request of CCG in which the health professional had prescribing responsibility.

The PRIMIS training was delivered by a university and funded by Boehringer Ingelheim as a MEGS to support use of the independently developed PRIMIS audit tool. Boehringer Ingelheim had no input into the PRIMIS training and was not involved in the subsequent use of PRIMIS by the city based CHO. No inducements to prescribe, supply, administer, recommend, buy or sell any medicine had been made. Appropriate contracts had been put in place for all activities and all payments had been, or would be, appropriately disclosed as transfers of value.

Clause 18.1: No gift, pecuniary advantage or benefit had been offered to any health professional in connection with the promotion of medicines or as

an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. Boehringer Ingelheim had had no input or influence over any of the training delivered by the named health professional, the training and consultancy company, the university, or the subsequent use of the PRIMIS tool.

Clauses 9.1 and 2: Given the above, Boehringer Ingelheim submitted that high standards had been maintained and that neither its involvement with the named health professional nor the training and consultancy company had reduced confidence in the pharmaceutical industry or brought discredit upon it. The company thus denied breaches of Clauses 9.1 and 2.

In response to a request for further information, Boehringer Ingelheim submitted the following:

Funding for audits

Boehringer Ingelheim stated that it had not directly supported the training and consultancy company to conduct clinical audits and it was not aware that it had funded any which had been carried out by that company. Boehringer Ingelheim had not funded any relevant clinical audits in the named region. The only service currently supported by Boehringer Ingelheim in relation to relevant clinical audits was funding to a university via a MEGS to train practices to use PRIMIS, a free clinical audit tool developed by the university. The training, developed and provided by the university and Boehringer Ingelheim, was not involved in any aspect of it or the subsequent use of the tool. Boehringer Ingelheim declined a request from the CCG in which the named health professional had prescribing responsibility in July 2016 to fund the remote installation of PRIMIS at 10 practices. This request was subsequently cancelled pending the outcome of this complaint.

Boehringer Ingelheim had not supported or funded the training and consultancy company to conduct anything that might be described as a 'nurse-led review or clinic to assess [relevant patients]'.

Meetings

Boehringer Ingelheim submitted that the CCG in which the named health professional had prescribing responsibility had decided to use the services of his/her training and consultancy company with no input from Boehringer Ingelheim. The local representative had several meetings with the CCG which subsequently led to a request from it to specifically use the named health professional's training and consultancy company to deliver local education meetings in 2016. The two-day training courses were sponsored by Boehringer Ingelheim and this activity was submitted for approval as per Boehringer Ingelheim's processes and procedures and the funds came from a budget for field force funded activities. This was not designated as a joint activity with Lilly.

Boehringer Ingelheim directly funded the named health professional as a speaker at an evening meeting in the same CCG in 2014 and his/her speaker fee was assessed against fair market value. The contracts between Boehringer Ingelheim and the health professional's company for two educational meetings demonstrated that the financial support received by the training and consultancy company was for an exhibition stand. This was assessed as a commercial sponsorship opportunity not as a speaker engagement. Boehringer Ingelheim submitted that as such it was not necessary to assess the cost against fair market value.

The requests for the sponsorship of the educational meetings were placed through the appropriate approval system via representatives. The request for financial support in the same CCG in April and July 2016 came from a health professional at the CCG as did the request for PRIMIS training (copies were provided).

Boehringer Ingelheim provided copies of entries in its customer relationship management (CRM) system for the representatives' interactions with the named health professional. One attachment provided an overview of all 2016 entries involving the named health professional. There were no entries and therefore no interactions for 2015 or any prior year. Details of interactions from February through to July were provided. The two interactions in February and the one in March were to discuss a clinical paper folder, which was not offered, and the PRIMIS offering and to find out information and develop access to the CCG with which he/she was associated. The meeting in June referred to the set-up of a PRIMIS 'train the trainer' session which was held in 2016; there were no call notes for this call.

Boehringer Ingelheim submitted that it disagreed with the complainant's statement that there was a risk that the support by industry of the educational courses run by the training and consultancy company could be perceived as an attempt to 'buy the business' because 'the amount of money that industry has pumped into these courses was staggering'. The CCG associated with the named health professional highlighted in February 2016 that there was a need to improve the level of local education in a specific therapy area and specifically requested support for the educational courses run by that health professional's company. This was documented in the CRM entry with the CCG and opportunities to support relevant training with the named health professional were explored in February 2016. These courses were accredited by the RCGP and the RCN so appeared to be appropriate courses. While in hindsight it would have been more appropriate for the sponsorship contract for these courses to have been between Boehringer Ingelheim and the CCG rather than Boehringer Ingelheim directly paying the named health professional's company, the involvement of the training and consultancy company in these courses was always at the request of the CCG and/or the city based CHO. Boehringer Ingelheim was not aware of the nature of the relationship between the training and consultancy company and the CCG/the city based CHO, however, it was aware that the CCG worked with the training and consultancy company to deliver therapy specific education. The only other payments made by Boehringer Ingelheim to the named health

professional were relatively modest sums for speaking at a meeting in 2014 and travel expenses for attending a national congress in 2016. While a Boehringer Ingelheim representative had discussed the PRIMIS 'train the trainer' session with the named health professional, Boehringer Ingelheim did not know whether he/she attended this training session as it was Boehringer Ingelheim's policy not to attend these sessions. The request for the training session came from the city based CHO.

The company had spoken to the local representative and his/her manager about interactions with the CCG/the city based CHO and the named health professional and there had not been pressure to support relevant education training or the training and consultancy company/the named health professional from any party.

Requests for sponsorship to attend the annual UK congress were placed through the appropriate approval system via a representative. A copy of the named health professional's unsolicited request for support to attend was provided. A copy of the agreement was provided. Boehringer Ingelheim did not routinely request a copy of receipts for attendance at the conference therefore it was not able to supply a receipt for attendance.

PANEL RULING

The Panel noted that the anonymous complainant was non contactable and so could not be asked to provide further details. Anonymous complaints were accepted and like all complaints judged on the evidence provided by the parties. The complainant had the burden of proving his/her complaint on the balance of probabilities. The complainant had not provided any evidence in support of the allegations.

The complaint raised concerns about the interactions of certain pharmaceutical companies, including Boehringer Ingelheim, and the training and consultancy company run by the named health professional. The complainant stated that the named health professional, a nurse, was employed on a contractual basis by a number of NHS organisations including the named city based CHO. Reference was made to his/her prescribing responsibility and alleged influence in a named CCG area and to the training and consultancy company services provided locally. The training and consultancy company offerings were said to range from practice audits, health professional mentoring and education to classroom based training workshops. More detailed allegations were made in relation to audits and workshops. The complainant alleged that the amount of money that industry had pumped into these courses was 'staggering' and could be perceived as an attempt to 'buy the business'. The complainant also generally referred to the Authority investigating the relationship between the named health professional and certain pharmaceutical companies. In this regard the Panel noted that it could only consider specific matters raised in the complaint.

The Panel noted that the complainant began by stating that he/she wished to complain about the conduct of the training and consultancy company, referred to grave concerns about it and the path which the complainant alleged had been taken by its owner, the named health professional, to extract financial support from the industry including highly coercive behaviour; in this regard the Panel noted that the Code applied solely to the conduct of pharmaceutical companies.

The Panel considered that the complaint was broader than the two matters identified by the case preparation manager, ie audits and specific workshops. The complainant had referred generally to training and support for health professionals delivered by the named health professional but paid for by the pharmaceutical industry. Boehringer Ingelheim had, however, responded to all matters raised in the complaint and the Panel ruled accordingly. The Panel considered that the scope of the complaint included the engagement of the named health professional and/or the training and consultancy company activities, with health professionals, whether such activities were delivered by its owner, the named health professional or other individuals. However, when considering such matters the totality of a company's interactions with the named health professional would, nonetheless, be relevant.

The Panel noted that the complainant had provided a website address for the training and consultancy company and this had been provided to all respondent companies. The website listed the named health professional as the Director and another health professional as the nurse liaison lead. The Panel noted that the named health professional was contracted by the NHS to work at a number of surgeries in addition to his/her role at the named city based CHO.

The Panel noted that the complainant had raised concerns in relation to a number of pharmaceutical companies which were taken up with each company individually. Companies made differing submissions about the training and consultancy company and the role and status of the named health professional. Each case was considered on its merits.

In addition, the Panel noted that the case preparation manager had stated that matters would be considered in relation to the requirements of the Code applicable when the matters at issue occurred. In this regard the Panel noted that Boehringer Ingelheim had paid the named health professional to speak at a meeting in October 2014 at a GP practice. The Panel noted that there was a difference between the 2014 and 2016 Codes in the supplementary information to Clause 2 in that the supplementary information to the 2016 Code gave 'unacceptable payments' as an example of a breach of that clause. This difference was potentially relevant to the matter at issue and thus all matters pertaining to the October 2014 meeting were ruled under the requirements of the 2014 Code.

The Panel noted that Boehringer Ingelheim's first interaction with the named health professional appeared to be in relation to an evening meeting

held in June 2014 at a GP practice and organised by the CCG in which the complainant stated that he/she had prescribing responsibility and influence; this was inconsistent with the company's submission that it had not interacted with him/her before 2016. Boehringer Ingelheim had paid the named health professional's speaker fee. The Panel noted that, contrary to the company's submission that the fee had been assessed against fair market value, appendix 2 to the speaker agreement dated the same day as the meeting, a compliance questionnaire which included an assessment of fair market value, had not been completed. Boehringer Ingelheim submitted that the CCG had organised the meeting and decided to use the named health professional's services; the named health professional/the training and consultancy company was paid directly by Boehringer Ingelheim. The Panel noted that the complainant bore the burden of proof and considered that the complainant had not established on the balance of probabilities that there was any evidence to show that the engagement of the named health professional was an inducement to prescribe or otherwise inappropriate as alleged. No breach of Clauses 18.6 and 20.1 of the 2014 Code was ruled. No breach of Clauses 9.1 and 2 of the 2014 Code was also ruled.

The Panel noted that according to Boehringer Ingelheim, the same CCG organised two courses, each over two days, using the training and consultancy company's services, in April and July 2016. Each course was sponsored by Boehringer Ingelheim and another company. Boehringer Ingelheim subsequently submitted that the courses were organised by the training and consultancy company. Boehringer Ingelheim also stated that at the request of the CCG the contracts for each course were with the training and consultancy company. The contracts described the training and consultancy company as the organiser. The signature required for the training and consultancy company was that of the named health professional. The Panel noted Boehringer Ingelheim's submission that it was not aware of the relationship between the training and consultancy company and the CCG/the city based CHO. In that regard, however, the Panel noted in an email from the named health professional in February 2016 to Boehringer Ingelheim requesting sponsorship for his/her attendance at a UK conference, he/she signed him/herself as a therapy area specific specialist nurse from a named hospital. Further, call notes from February and March 2016 showed that discussions with the named health professional had centred around fact finding and developing access with key customers in the CCG with which he/she was associated. It thus appeared that Boehringer Ingelheim should have been well aware of the named health professional's dual role as a health professional within the CCG and the owner of the training and consultancy company.

The Panel further noted an email in March 2016 from the team lead at the community specialist service division at the city based CHO to the local representative requesting funding for the courses at issue. According to the training and consultancy company website, details of which were provided by the complainant, the author of that email was, in addition to his/her NHS role, a colleague of the named health professional at the training and consultancy company and the Panel noted that in his/her role at the CCG associated with the named health professional, he/she had previously held discussions with Boehringer Ingelheim's representative about supporting training with the named health professional. The company paid for exhibition stands at the April and July meetings. The Panel disagreed with Boehringer Ingelheim's submission that as this activity was not a speaker engagement and was assessed as a commercial opportunity it was not necessary to assess the cost against fair market value. The Panel noted that although the fair market value requirement in Clause 23 applied to the company's appointment of consultants, when supporting a healthcare organisation such as the training and consultancy company, the company still had to ensure that the sponsorship arrangements, including the amount of money paid, complied with the Code. In particular, the decision to sponsor an event and the level of funding should not be such that they could be seen as an inducement to prescribe. The Panel noted that the agenda for each course set out a detailed education programme over two days and the course was accredited by the RCN and the RCGP. The Panel noted that the complainant bore the burden of proof and considered that the complainant had not established on the balance of probabilities that either the provision of sponsorship or the level of sponsorship was an inducement to prescribe or otherwise inappropriate in relation to the matters alleged. No breach of Clauses 18.1 and 19.2 was ruled.

The Panel noted Boehringer Ingelheim's submission that it had not funded any relevant clinical audits in a named area. It had at the request of the city based CHO (dated 19 July) funded a meeting on 21 July 2016 to provide training for practices to use PRIMIS, a free clinical audit tool which had been developed by a university. The Panel noted that the person who requested the funding was, according to the training and consultancy company website, linked to the training and consultancy company. Payment was made directly to the university. The company had no role in relation to the development of the tool or its subsequent use. Contacts between the local representative and the named health professional in relation to PRIMIS took place in February and June 2016. A request from the CCG associated with the named health professional to fund the remote installation of PRIMIS in 10 local practices had been declined. The Panel also noted the company's submission that it did not know whether the named health professional attended the training meeting in July 2016. The Panel noted that there was no evidence that the request for sponsorship and/or the decision to sponsor was linked directly or indirectly to the use of Boehringer Ingelheim's medicines. The Panel noted that the complainant bore the burden of proof and considered that the complainant had not established on the balance of probabilities that there was any evidence to show that sponsorship of the training day was an inducement to prescribe or otherwise inappropriate in relation to the matters alleged. No breach of Clauses 18.1 and 19.2 was ruled.

The Panel noted its rulings above and whilst it had some concerns, it did not consider that the complainant had provided any evidence to establish a breach of Clauses 9.1 or 2. No breach of those clauses were ruled.

The Panel noted that Boehringer Ingelheim had also been asked to respond to Clauses 19.1 and 21 of the 2016 Code. There was no evidence before the Panel that Boehringer Ingelheim had engaged in any relevant activities and the Panel ruled no breach of Clauses 19.1 and 21 accordingly.

The Panel considered that Boehringer Ingelheim's sponsorship of the named health professional to attend the UK conference in 2016 was outside the scope of the complaint and the company made no rulings in this regard.

During its consideration of this case, the Panel was concerned about the company's submission that it did not routinely request copies of receipts for attendance at the UK conference and considered that it was vulnerable in this regard. The sponsorship agreement provided was unsigned and referred to sponsorship 'To a maximum of' [figure stated]. This appeared to be based on the named health professional's estimate of his/her expenditure which gave little detail.

Complaint received **3 August 2016**

Case completed **19 December 2016**

ANONYMOUS, NON CONTACTABLE v SANOFI

Engagement of a consultant and his/her training and consultancy company

An anonymous, non-contactable complainant raised concerns about a therapy area specific training and consultancy company and its owner, a health professional who delivered services including practice audits, health professional mentoring, education and classroom based training workshops funded by a number of named pharmaceutical companies including Sanofi. These services had been delivered in a number of named clinical commissioning groups (CCGs) in one area. In addition, the health professional was a specialist nurse employed on a contractual basis by a number of NHS organisations including a city based community healthcare organisation (CHO). In his/her role as a nurse within that organisation the health professional had prescribing responsibility and influence within one of the CCGs named by the complainant.

The complainant alleged that the training and consultancy company had conducted industry funded clinical audits in several GP surgeries in the area in question which were identifiable as they had highly irregular use of the sponsoring company's product. The patients of several surgeries in one CCG were either initiated onto or switched to the sponsor's medicine with little consideration given to alternative therapies. The pattern of disproportionate increases in product sales could be directly linked back to the pharmaceutical company which had funded the training and consultancy company.

The complainant referred to a series of accredited training workshops delivered by the training and consultancy company in partnership with a named CCG which was completely funded by industry. The complainant was concerned about the potential substantial financial support to the training and consultancy company for these workshops due to reservations about the ethics of that organisation and because its owner was directly contracted to the local city based CHO. In the complainant's view industry's financial support for these courses was staggering and could be perceived as an attempt to 'buy the business'.

The complainant alleged that the training and consultancy company had told pharmaceutical companies that if they failed to provide support, their products would not be used in the CCG in which he/she had prescribing responsibility. The complainant stated that his/her company's local representative felt highly pressured to offer funding as he/she had been threatened that if he/she failed to support training events the health professional in question would simply get the money from another pharmaceutical company. The complainant stated that this highly coercive behaviour was completely unacceptable and he/she assumed that similar pressure had been exerted on other pharmaceutical companies. In addition, the complainant noted that services provided by industry were in some cases very similar to the offerings developed by the training and consultancy company and alleged that the health professional in question had left individuals in no doubt that if their company attempted to partner in CCGs where he/she wanted to deliver programmes there could be consequences for their sales in the area in which he/she had prescribing responsibility.

The detailed response from Sanofi is given below.

The Panel had no contact details for the complainant and so could not ask him/her for further details. The complainant had the burden of proving his/her complaint on the balance of probabilities; he/she had not provided any evidence in support of the allegations.

The Panel noted that the complainant began by stating that he/she wished to complain about the conduct of the training and consultancy company and subsequently referred to its owner. In this regard the Panel noted that the Code applied solely to the conduct of pharmaceutical companies.

The Panel considered that the scope of the complaint included the engagement of the health professional in question and/or the activities of his/her company with health professionals, whether the company's activities were delivered by its owner or other individuals. However, when considering such matters the totality of a pharmaceutical company's interactions with the health professional in question would nonetheless be relevant.

The Panel noted that the complainant had provided a website address for the training and consultancy company which named the health professional in question as the Director and another health professional as the nurse liaison lead. The Panel noted that the named health professional was contracted by the NHS to work at a number of GP surgeries in addition to his/her role at the city based CHO.

The Panel noted Sanofi had only worked with the training and consultancy company to provide a patient management and nurse advisor service for patients. The Panel noted that according to the Service Operating Procedure the service was a medical and educational goods and service (MEGS) which included a review of patients' current treatment regimen in line with locally agreed guidance and ran from early 2014 until February 2015.

The Panel noted that although the named health professional originally requested the service and that it be delivered by his/her training and consultancy company, the service was described in the consultancy services agreements as a service to medicine developed by Sanofi. Sanofi was thus

responsible under the Code for it. The agreements stated that the role of the training and consultancy company was to deliver the service and undertake patient assessment clinics.

The Panel noted that according to the service operating procedure the service was to be offered, unrestricted, to local practices upon health care provider request by an NHS outcome manager (NOM) if the practice satisfied certain criteria. If the NOM was satisfied that these criteria were met a Sanofi medical manager would then contact the named health professional who would deliver the service as set out in the service operating procedure via his/her training and consultancy company.

The Panel noted that the objective of the service was to help patients effectively improve control of their condition and reduce their risk of complications. According to the service operating procedure, specialist nurses employed by the training and consultancy company, or the named health professional in question, individually assessed patients and reviewed their treatment in line with locally agreed guidance provided by the practice so that there was clarity on treatment. The locally agreed guidance would include national guidance/treatment pathways. An agreement between the training and consultancy company and each individual practice provided that 'the practice would at all times retain clinical responsibility for the management of patients under its care including but without limitation all prescribing decisions and patient management'.

The Panel noted Sanofi's submission that local sales data showed that the service did not directly affect the uptake of Sanofi products in those practices that received the service. Taking all the circumstances into account the Panel considered that the complainant had not established that the provision and operation of the management and nurse advisor service was an inducement to prescribe or otherwise contrary to the Code as alleged. High standards had been maintained. No breaches of the Code were ruled including no breach of Clause 2.

There was no evidence that Sanofi had employed the named health professional as a consultant. No breach of the Code was ruled.

An anonymous, non-contactable complainant who described themselves as an employee of one of the many manufacturers of therapies in a particular therapy area, complained about the conduct of a therapy area specific training and consultancy company run by a named health professional, that delivered a range of services to, *inter alia*, the NHS including services that were funded by a number of named pharmaceutical companies including Sanofi.

COMPLAINT

The complainant stated that the named health professional, in addition to his/her role at his/her company was also a specialist nurse employed on a contractual basis by a number of NHS organisations including a city based community healthcare organisation (CHO). In his/her role as a nurse within that organisation he/she had prescribing responsibility and influence within a named clinical commissioning group (CCG) area. The services offered ranged from in practice audits, health professional mentoring and education, to classroom based training workshops. These offerings had been delivered in a number of named local CCGs. Funding was provided for these initiatives through various mechanisms within the Code ie independent stand meetings.

The complainant stated that he/she had previously raised concerns within his/her organisation in relation the legitimacy of the training and consultancy company business model, in particular how it received funding from the pharmaceutical industry which unfortunately included on-going financial and logistical support from the complainant's own company. The complainant's concerns had been raised internally with management but no action had been taken to rectify the situation and the complainant believed that his/her job would be at risk if his/her confidentiality in raising these issues was not protected.

The complainant explained that the training and consultancy company had conducted industry funded 'clinical audits' in several surgeries across a named part of a city, those practices were very easy for medicines management to identify as they had highly irregular use of the sponsor's product. In several surgeries in a named CCG patients were either initiated onto or switched to the sponsors' medicine with little consideration given to alternative therapies. The pattern of disproportionate increases in product sales could be directly linked back to the pharmaceutical companies' funding support to the training and consultancy company. The complainant explained that unfortunately to protect his/her anonymity, he/she was unable to provide a very detailed narrative but would endeavour to give enough information so that the training and consultancy company and the pharmaceutical companies that used it were held to account.

The complainant stated that at the beginning of 2016 the training and consultancy company started to deliver a series of training workshops in partnership with the CCG in which the named health professional had prescribing responsibility which were accredited by the Royal College of General Practitioners (RCGP) and the Royal College of Nursing (RCN). The delivery of the workshops was, and continued to be completely funded by industry. The complainant articulated his/her concerns to his/her line manager regarding the company potentially providing substantial financial support to the training and consultancy company for these workshops due to his/her reservations about the ethics of that organisation and because its owner was directly contracted to the city based CHO.

The complainant stated that the amount of money that industry had pumped into these courses was staggering, and in his/her opinion the risk that the support could be perceived as an attempt to 'buy the business' had led him/her to continuously try

to dissuade his/her company from being involved. Unfortunately the concerns the complainant foresaw had materialised into major conflict of interest and anti-competitive issues whereby the training and consultancy company had told potential industry partners that if they failed to provide support, their products would not be used in the CCG in which the complainant stated that the named health professional had prescribing responsibility and influence. The complainant stated that his/her company's local representative felt highly pressured to offer the training and consultancy company funding as the individual had been threatened that if he/she failed to support training events the named health professional would simply get the money from another pharmaceutical company. According to the complainant this was highly coercive behaviour and clearly completely unacceptable and one could only assume that similar pressure had been exerted on all other pharmaceutical companies.

An additional issue that recently came to light was that most of the organisations working in the therapy area provided a range of industry-developed services that were deployed in partnerships with NHS organisations; these services were in some cases very similar to the offerings developed by the training and consultancy company. The named health professional had left individuals in no doubt that if their organisation attempted to partner in CCGs where he/she wanted to deliver the programmes there could be consequences for their sales in the area in which he/she had prescribing responsibility.

In the complainant's view the NHS and industry should be able to collaborate in highly transparent projects that benefited all stakeholders. Having to turn to the PMCPA to whistle-blow on his/her own organisation and the unacceptable behaviour of an organisation that it was actively engaged with was the low point of his/her career in the pharmaceutical industry. The complainant stated that the cavalier attitude of management within his/her own organisation and an inability for him/her to sit on the side-lines as the actions of a few undermined those of many and once again brought the industry into disrepute was too much to stomach. The complainant felt incredibly disillusioned that the industry and his/her company continued to work alongside an organisation that operated in a manner that was simply unacceptable in 2016. Unfortunately, industry was not an innocent party in the affair; all of the companies that had been involved with the training and consultancy company needed to reassess how they conducted business. The complainant appreciated that the evidence given in the complaint might not be detailed enough for the Authority to act but he/she hoped that there was enough information to at least investigate the relationship between the named health professional and a number of pharmaceutical companies. The great shame was that he/she might well be delivering much needed training and support for health professionals, however, the path he/she had decided to follow to extract financial support from industry had sullied what could have otherwise been a noble endeavour. The complainant hoped his/her complaint was seen as a genuine cry for help from the PMCPA as he/she had been ignored by those in positions of power within his/her organisation. The complainant stated that this complaint was motivated by a strong desire to do what was right; he/she was reasonably certain that if the issues outlined were investigated his/her position within his/her company and probably the industry would become untenable.

The complainant provided a website address for the training and consultancy company.

When writing to Sanofi, the Authority asked it to consider the requirements of Clauses 2, 9.1, 18.1, 19.1, 19.2, 21 and 23.1 of the Code with regard to the clinical audit and with regard to training workshops delivered in partnership with a named clinical commission group (CCG). The case would be considered under the requirements of the Code relevant to the time the activities took place. The clause numbers cited above were relevant to the 2015 and 2016 Codes.

RESPONSE

Sanofi confirmed that it had previously worked with the training and consultancy company to provide a patient management and nurse advisor service for relevant patients, but had not worked or funded initiatives with that company to perform either clinical audits in healthcare organisations or to undertake training workshops in the specified therapeutic area.

Sanofi submitted that its relationship with the training and consultancy company was to provide a patient management and nurse advisor service between November 2013 to February 2015 which was delivered as a medical and educational goods and service (MEGS) agreement. Sanofi summarised the history of the MEGS programme using the services of the training and consultancy company which ran in a number of primary care practices in a particular region. Relevant supporting documentation was referred to and provided.

The named health professional first approached Sanofi in late 2013 for his/her training and consultancy company to provide a nurse-led service in selected local GP practices. It was decided in 2013 to contract with the training and consultancy company to run the proposed review in two GP practices and to undertake twelve patient assessment clinics in these practices. The nurse-led service was to be offered as a MEGS programme with the initial contract between Sanofi and the training and consultancy company covering a 2 month period from the end of 2013.

A service operating procedure was created for this service and was certified and approved as a non-promotional item. The Sanofi medical affairs and NHS liaison teams at the time dealt directly with the named health professional and the training and consultancy company in setting up the MEGS agreement and service offering.

The service operating procedure outlined the scope and objectives of the nurse-led service. The objective

of the service was to help patients with a specific condition improve their control and reduce their risk of developing related complications. The training and consultancy company employed specialist nurses to work in primary care alongside the existing practice nurse teams in each organisation. These specialist nurses offered to individually assess patients and to review their current treatment regime in line with locally agreed guidance. The service was to be offered to those healthcare organisations which aimed to improve the healthcare of this group of patients. The service operating procedure outlined that all decisions regarding medicine management following an individual patient assessment review would be based on individual clinical need and in line with local and national guidance. Following a patient review by the training and consultancy company nurse-led team, all decisions regarding medicines would be made by the appropriate health practitioner or the practice's own specialist nurse advisor in strict compliance with a prescribing protocol agreed by the respective healthcare organisation. In addition, Section 5.1 of the signed contract between Sanofi and the training and consultancy company clearly outlined that the MEGS agreement was not an incentive or reward for a person's past, present or future willingness to prescribe, administer, recommend, purchase, consume, use, pay for, reimburse, authorise, approve or supply any product sold or provided by Sanofi.

The initial consultancy agreement and contract between Sanofi and the training and consultancy company was extended and updated in early 2014 and specified that the training and consultancy company would conduct further individual patient assessment clinics in January and February 2014 as detailed. The scope and objectives of the nurse-led service remained identical to that originally agreed.

A new agreement and contract was made with the training and consultancy company to continue the service from 3 March 2014 until the end of 2014. The MEGS service delivery programme was identical to that detailed above and operated according to the previously approved service operating procedure. During 2014, the training and consultancy company carried out between 5 and 15 individual patient assessment clinics per week involving up to fourteen GP practices and community-based hospitals in four CCGs.

Sanofi terminated its agreement with the training and consultancy company on 28 February 2015 following a decision to work with another healthcare company as the provider of a MEGS based programme to provide a nurse advisory service for practices managing such patients nationally. Sanofi had therefore not worked directly with the training and consultancy company and the named health professional since March 2015. However the local Sanofi team that operated in the area still had a relationship with him/her as a *bona fide* NHS customer. However, since March 2015, Sanofi had not contracted any services including nurse-led clinics, clinical audits or training events from him/her or his/her company.

Sanofi submitted that whilst it worked with the training and consultancy company, the relationship between it and the named health professional was managed through the local Sanofi NHS outcome manager (NOM). The NOM would hold a non-promotional discussion with the relevant stakeholders in the local healthcare practices to determine whether there was an unmet need to improve the management of the specific condition in their respective practices. If a particular unmet need was identified, the NOM would complete a referral form to provide key contact details for the practice. This referral for the specialist nurse team programme was then sent to the Sanofi medical manager in head office for review and approval. If considered eligible for the MEGS service, the medical manager would ask the named health professional/the training and consultancy company to contact the relevant practice directly to discuss the nurse-led service in detail. If the practice agreed to participate with the nurse-led service run by the training and consultancy company, then an honorary nurse agreement would be issued and signed by the health professional at the practice and by the named health professional. Once the agreement had been set up the NOM would play no further role in any discussions about the nurse review service at that practice.

Sanofi did not normally track sales against the placement of MEGS programmes. However, as a result of this case, it confirmed that there was no evidence which linked the deployment of the nurse team programme to a disproportionate increase in the sales of relevant Sanofi products. To help validate this Sanofi provided sales growth month by month graphs for September 2013 to December 2015 for the two relevant products which it actively promoted when it supported the training and consultancy company nurse-run service. Each graph illustrated a month by month sales line for the respective product from both a UK perspective and from the three CCGs that received the training and consultancy company service. The graphs illustrated that local sales of those products during November 2013 to February 2015 were overall not markedly dissimilar to that of the UK average sales month by month trend; thus one could surmise that the training and consultancy company nurse service run at the time did not directly impact on the uptake of Sanofi products in those practices that received it.

Sanofi refuted that the nurse-led service that was supported with the training and consultancy company breached the Code and in particular Clauses 2, 9.1, 18.1, 19.1, 19.2, 21 and 23.1 as alleged.

In response to a request for further information regarding its relationship with the training and consultancy company, Sanofi stated that it had attempted to respond with as much information as possible which it held relating to its prior relationship with the training and consultancy company. However, it was unable to supply all the information requested by the Authority as this was a local project within a limited geography, which was set up over 3 years and was run by Sanofi employees who no longer worked for the company. Sanofi had therefore not been able to fully investigate this case because some employees

who were involved were no longer with the company and so could not be interviewed.

The practices which received the training and consultancy company run patient management and nurse advisor service between 2014 and 2015 were based in a particular region. These practices and community clinics were within the three CCGs. Sanofi provided a list of practices and community hospital clinics which received the service from the training and consultancy company.

The NOM employed by Sanofi at the time, was first approached by the named health professional in late 2013 offering the services that his/her training and consultancy company could provide to local primary care and community-based hospital clinics. The training and consultancy company proposal was shared with the head office medical team and it was agreed to commence a pilot project with the training and consultancy company which led to the first contract being created at the end of 2013. No other providers of such services were approached by Sanofi for consideration at that time for this locality.

The NOM at the time would conduct a non-promotional discussion with the relevant stakeholders in the local healthcare practices to determine whether there was an unmet need to improve the management of relevant patients in their respective practices. The NOM followed guidance to only select suitable practices for a discussion on the potential healthcare benefits that the service could provide. As outlined in the document, the service was to only be offered to those healthcare organisations which met the following criteria:

- The individual healthcare organisation must be actively involved in the management of patients with the particular condition
- The health outcomes of patients in the area serviced by the individual healthcare organisation must be 'poor' according to national tools and criteria
- The individual healthcare organisation must be at least a 3-partner medical practice with 5,000 patients; and must be able to identify sufficient patients requiring improved clinical management.

Where the individual healthcare organisation met these criteria, the service was to be offered unrestricted upon request following a discussion with the responsible NOM. The NOM was to thus discuss with the practice such factors as the local prevalence of the condition in the community, whether the practice had hit population targets for control in these patients and how the practice managed its patients such as having specialised clinics for reviewing such patients, etc. If a particular unmet need was identified, the NOM would complete a referral form to provide key contact details for the practice which was then sent to the Sanofi medical manager in head office for review and approval as described above.

No further correspondence was available regarding whether the training and consultancy company made any recommendations in this regard.

Every quarter, the named health professional/the training and consultancy company would send Sanofi a progress report detailing which practices had received its nurse-led service and how many clinics had been delivered by its nurse team at the respective clinics. An example of such a report was provided. As indicated in the service operating procedure, no information regarding the performance of the service was provided apart from the above and no patient level information was shared at such meetings.

The representatives were not involved in the training and consultancy company service apart from the one NOM employee who no longer worked for Sanofi. Sanofi believed that the NOM verbally briefed the local representatives at the time that the service was available to those practices that expressed an interest for the services offered by the training and consultancy company. However, the representatives played no active part in any communication regarding the training and consultancy company services in their practices. There was no documentary evidence about these local discussions between the sales team and the NOM from this time. According to Sanofi's customer relations management (CRM) record system, the named health professional saw its representatives during the time that the training and consultancy company nurse advisor service ran in 2014. Sanofi recorded 14 separate representative visits to the named health professional during this time period which included the one non-promotional strategic discussion with the NOM to discuss the training and consultancy company nurse advisor service. According to Sanofi's CRM records, it did not believe that the other promotional calls made by the representatives with the named health professional discussed the training and consultancy company nurse advisor service.

At the beginning of 2015, Sanofi determined that a nurse-led service was a valuable resource to the NHS nationally and not just within a small region. Hence it was decided to expand the nurse-led service using a provider with a solid reputation and the governance capabilities and resources to run a nationwide service. Therefore, Sanofi decided to create an upgraded nurse-led service using another healthcare organisation to provide the expertise and nursing resource across the country and so the contract with the named health professional and the training and consultancy company was terminated. There was no specific ban but rather there was no need for Sanofi to continue to work with the training and consultancy company locally considering that a replacement service was fully developed and was to be available nationwide.

Sanofi confirmed that from March 2015 it had not worked with the training and consultancy company or carried out any form of activity at exhibition stands in meetings that it had run.

PANEL RULING

The Panel noted that the anonymous complainant was non contactable and so could not be asked to

provide further details. Anonymous complaints were accepted and like all complaints judged on the evidence provided by the parties. The complainant had the burden of proving his/her complaint on the balance of probabilities. The complainant had not provided any evidence in support of the allegations.

The complaint raised concerns about the interactions of certain pharmaceutical companies, including Sanofi, and the training and consultancy company run by the named health professional. The complainant stated that the named health professional, a nurse, was employed on a contractual basis by a number of NHS organisations including the named city based CHO. Reference was made to his/her prescribing responsibility and alleged influence in a named CCG area and to the training and consultancy company services provided locally. The training and consultancy company offerings were said to range from practice audits, health professional mentoring and education to classroom based training workshops. More detailed allegations were made in relation to audits and workshops. The complainant alleged that the amount of money that industry had pumped into these courses was 'staggering' and could be perceived as an attempt to 'buy the business'. The complainant also generally referred to the Authority investigating the relationship between the named health professional and certain pharmaceutical companies. In this regard the Panel noted that it could only consider specific matters raised in the complaint.

The Panel noted that the complainant began by stating that he/she wished to complain about the conduct of the training and consultancy company, referred to grave concerns about it and the path which the complainant alleged had been taken by its owner, the named health professional, to extract financial support from the industry including highly coercive behaviour; in this regard the Panel noted that the Code applied solely to the conduct of pharmaceutical companies.

The Panel considered that the complaint was broader than the two matters identified by the case preparation manager, ie audits and specific workshops. The complainant had referred generally to training and support for health professionals delivered by the named health professional but paid for by the pharmaceutical industry. Sanofi had, however, responded to all matters raised in the complaint and the Panel ruled accordingly. The Panel considered that the scope of the complaint included the engagement of the named health professional and/or the training and consultancy company activities, with health professionals, whether such activities were delivered by its owner the named health professional or other individuals. However, when considering such matters the totality of a company's interactions with the named health professional would, nonetheless, be relevant.

The Panel noted that the complainant had provided a website address for the training and consultancy company and this had been provided to all respondent companies. The website listed the named health professional as the Director and another health professional as the nurse liaison lead. The Panel noted that the named health professional was contracted by the NHS to work at a number of surgeries in addition to his/her role at the named city based CHO.

The Panel noted that the complainant had raised concerns in relation to a number of pharmaceutical companies which were taken up with each company individually. Companies made differing submissions about the training and consultancy company and the role and status of the named health professional. Each case was considered on its merits.

In addition, the Panel noted the case preparation manager's advice that matters would generally be considered in relation to the requirements of the Code applicable when the matters at issue occurred.

The Panel noted Sanofi had only worked with the training and consultancy company to provide a patient management and nurse advisor service. The Panel noted that according to the Patient Management Service Operating Procedure the service was a medical and educational good and service (MEGS) which included a review of patients' current treatment regimen in line with locally agreed guidance. The service ran from early 2014 until 28 February 2015. The relevant requirements for MEGS in the 2014 Code (Clause 18.4), and the 2016 Code (Clause 19.1) were identical. The last two months that the service was offered was within the transition period for the 2015 Code and so that Code did not apply. In addition the Panel noted that the training and consultancy company delivered the MEGS service on behalf of Sanofi as set out in a series of contracts. Such contractual arrangements were covered by Clause 18.7 of the 2014 Code and these relevant requirements were now reproduced in Clause 21 of the 2016 Code. The Panel thus made its rulings under the 2016 Code.

In relation to clinical audits, the Panel noted the allegation that patients were either initiated or switched onto the sponsor's product, little consideration was given to other therapies, and surgeries exhibited irregular use of a sponsor's product. The Panel noted the requirements of the Code set out in Clauses 18 and 19 and the supplementary information to Clause 19.1 Switch and Therapy Review Programmes. The relevant supplementary information stated that Clauses 18.1 and 19.1 prohibited switch services paid for or facilitated directly or indirectly by a pharmaceutical company whereby a company's medicine is simply changed to another. It was acceptable for a company to promote a simple switch from one product to another but not to assist the health professional in implementing that switch even if assistance was by means of a third party such as a sponsored nurse or similar. A therapeutic review was different to a switch service: it aimed to ensure that patients received optimal treatment following a clinical assessment and was a legitimate activity for a pharmaceutical company to support and/or assist. Clause 19.2 stated that medical and educational

goods and services in the form of donations, grants and benefits in kind to institutions, organisations and associations that were, *inter alia*, comprised of health professionals or provided healthcare were only allowed if they complied with Clause 19.1, were documented and kept on record by the company and did not constitute an inducement to prescribe.

The Panel noted that although the named health professional originally requested the service and that it be delivered by his/her training and consultancy company, the service was described in the consultancy services agreements with the training and consultancy company as a service to medicine developed by Sanofi. Sanofi was thus responsible under the Code for it. The agreements stated that the role of the training and consultancy company was to deliver the service and undertake patient assessment clinics.

The Panel noted that according to the service operating procedure the service was to be offered, unrestricted, to local practices upon health care provider request by an NHS outcome manager (NOM) if the practice satisfied the criteria set out in the service operating procedure; namely the size of the practice, its active management of patients with the condition, the health outcomes of relevant patients in the area serviced by the practice must be poor as defined by national tools and finally the practice must be able to identify sufficient patients who needed improvement. If the NOM was satisfied that these criteria were met a Sanofi medical manager would then contact the named health professional who would then deliver the service as set out in the service operating procedure via his/her training and consultancy company.

The Panel noted that his/her objective of the service was to help relevant patients effectively improve control of their condition and reduce their risk of complications. According to the service operating procedure, specialist nurses employed by the training and consultancy company, or the named health professional him/herself, individually assessed patients and reviewed their treatment in line with locally agreed guidance provided by the practice so that there was clarity on treatment. The locally agreed guidance would include national guidance/treatment pathways. An agreement between the training and consultancy company and each individual practice provided that 'the practice would at all times retain clinical responsibility for the management of patients under its care including but without limitation all prescribing decisions and patient management'.

The Panel noted Sanofi's submission that local sales data showed that the service did not directly affect the uptake of Sanofi products in those practices that received the service. Taking all the circumstances into account the Panel considered that the complainant had not established that the provision and operation of the diabetes management and nurse advisor service was an inducement to prescribe or otherwise contrary to the Code as alleged. No breach of Clauses 18.1, 19.1 and 21 of the Code was ruled. High standards had been maintained. No breach of Clause 9.1 was ruled. Nor had the complainant established a breach of Clause 2; no breach of that clause was ruled.

The Panel noted that Sanofi had also been asked to respond to the requirements of Clauses 19.2 and 23.1 of the 2016 Code. There was no evidence before the Panel that Sanofi had engaged in any relevant activities. The Panel ruled no breach of Clauses 19.2 and 23.1 accordingly.

During its consideration of this case, the Panel was concerned to note Sanofi's submission that during 2014 it had recorded 14 separate representative visits with the named health professional, 13 of which it implied were promotional calls. The Panel queried whether such visits complied with Clause 15.4 of the Code. The supplementary information to that clause stated that on average, the number of calls made on a doctor or other prescriber by a representative each year should not normally exceed 3. The Panel noted that the meetings took place at different healthcare venues. The Panel requested that the company be advised of its views.

Complaint received **3 August 2016**

Case completed **19 December 2016**

CASE AUTH/2866/8/16

ANONYMOUS, NON CONTACTABLE v ASTRAZENECA

Engagement of a consultant and his/her training and consultancy company

An anonymous, non-contactable complainant raised concerns about a therapy area specific training and consultancy company and its owner, a health professional who delivered services including practice audits, health professional mentoring, education and classroom based training workshops funded by a number of named pharmaceutical companies including AstraZeneca. These services had been delivered in a number of named clinical commissioning groups (CCGs) in one area. In addition, the health professional was a specialist nurse employed on a contractual basis by a number of NHS organisations including a city based community healthcare organisation (CHO). In his/her role as a nurse within that organisation the health professional had prescribing responsibility and influence within one of the CCGs named by the complainant.

The complainant alleged that the training and consultancy company had conducted industry funded clinical audits in several GP surgeries in the area in question which were identifiable as they had highly irregular use of the sponsoring company's product. The patients of several surgeries in one CCG were either initiated onto or switched to the sponsor's medicine with little consideration given to alternative therapies. The pattern of disproportionate increases in product sales could be directly linked back to the pharmaceutical company which had funded the training and consultancy company.

The complainant referred to a series of accredited training workshops delivered by the training and consultancy company in partnership with a named CCG which was completely funded by industry. The complainant was concerned about the potential substantial financial support to the training and consultancy company for these workshops due to reservations about the ethics of that organisation and because its owner was directly contracted to the local city based CHO. In the complainant's view industry's financial support for these courses was staggering and could be perceived as an attempt to 'buy the business'.

The complainant alleged that the training and consultancy company had told pharmaceutical companies that if they failed to provide support, their products would not be used in the CCG in which he/she had prescribing responsibility. The complainant stated that his/her company's local representative felt highly pressured to offer funding as he/she had been threatened that if he/she failed to support training events the health professional in question would simply get the money from another pharmaceutical company. The complainant stated that this highly coercive behaviour was completely unacceptable and he/she assumed that similar pressure had been exerted on other pharmaceutical companies. In addition the complainant noted that services provided by industry were in some cases very similar to the offerings developed by the training and consultancy company and alleged that the health professional in question had left individuals in no doubt that if their company attempted to partner in CCGs where he/she wanted to deliver programmes there could be consequences for their sales in the area in which he/she had prescribing responsibility.

The detailed response from AstraZeneca is given below.

The Panel had no contact details for the complainant and so could not ask him/her for further details. The complainant had the burden of proving his/her complaint on the balance of probabilities; he/she had not provided any evidence in support of the allegations.

The Panel noted that the complainant began by stating that he/she wished to complain about the conduct of the training and consultancy company and subsequently referred to its owner. In this regard the Panel noted that the Code applied solely to the conduct of pharmaceutical companies.

The Panel considered that the scope of the complaint included the engagement of the health professional in question and/or the activities of his/her company with health professionals, whether the company's activities were delivered by its owner or other individuals. However, when considering such matters the totality of a pharmaceutical company's interactions with the health professional in question would nonetheless be relevant.

The Panel noted that the complainant had provided a website address for the training and consultancy company which named the health professional in question as the Director and another health professional as the nurse liaison lead. The Panel noted that the named health professional was contracted by the NHS to work at a number of GP surgeries in addition to his/her role at the city based CHO.

In addition the Panel noted that matters would be considered in relation to the requirements of the Code applicable when the matters at issue occurred.

The Panel noted that according to AstraZeneca it had sponsored only one, one day meeting run by the training and consultancy company which was held in October 2014. The Panel was very concerned that the form authorising electronic payment to the training and consultancy company for this meeting was signed as approved by the named health professional rather than, as required, by the representative. This was apparently not noted at the time by the representative and/or line manager responsible for overall review and

approval of the meeting. However, the Panel noted that the complainant bore the burden of proof and considered that the complainant had not established on the balance of probabilities that either the provision of sponsorship or the level of sponsorship was an inducement to prescribe or otherwise inappropriate in relation to the matters alleged. No breaches of the Code were ruled including no breach of Clause 2. These rulings were made under the 2014 Code.

The Panel noted that AstraZeneca had engaged the named health professional 54 times between May 2014 and June 2016 as a speaker and twice as a chairman at its lunchtime or evening promotional meetings. In addition, the named health professional had been engaged 5 times between May and November 2015 as a speaker on its Expert on Demand Programme.

The Panel noted that although AstraZeneca referred to the appointment of the named health professional as an individual, the fee for service contracts showed that the fees were in fact paid to the training and consultancy company.

The Panel noted that according to AstraZeneca's standard operating procedure (SOP) written director approval was needed before contracting with a health professional service provider for any further employment over 20 engagements, or over a stated monetary amount, in a 12 month period. There was no evidence before the Panel to show that in relation to the 29 speaker meetings and 5 Expert on Demand engagements in 2016 such approval had been sought. The Panel noted the fees actually paid by AstraZeneca in 2015 and 2016. It appeared to the Panel that particularly for the meetings held at GP practices which comprised one presentation of an hour or less the monies paid exceeded the values in the company's fair market value speaker fees table. There was no evidence before the Panel that there had been written justification and/or signatory approval of the fees as required by the relevant SOP.

The Panel noted AstraZeneca's submission that it had engaged the named health professional because of his/her experience, knowledge and availability, and as he/she was not an NHS employee he/she was available for daytime meetings as he/she was not subject to restrictions on speaking at industry-led promotional daytime meetings. The Panel noted that, nonetheless, he/she had also been engaged to speak at evening meetings.

The Panel noted that according to AstraZeneca its representatives did not feel pressurised to select the named health professional as a speaker and that he/she did not identify practices to receive these meetings. The Panel noted the high level of contact between representatives and the named health professional at various surgeries in addition to contact at the speaker meetings. The customer relations management (CRM) entries did not show whether such contacts were solicited or unsolicited. The CRM entries showed that on occasion such contacts included discussion of educational needs. The Panel noted AstraZeneca's submission that CRM references to 'mapping out practices' and 'further surgeries to consider' referred to the named health professional's availability to speak rather than practice selection.

The Panel noted AstraZeneca's submission that it was not normal practice for the company to engage a speaker 56 times over 2 years within a relatively small geographical area. The named health professional had spoken more than once at a number of GP practices. The company stated that it first became aware of the high use of the named health professional before it was notified of this complaint but did not state what had triggered this.

The Panel noted that paragraph 2 of the fee for service speaker contracts stated that the consultant confirmed that he/she did not interpret the engagement as an incentive or reward for past, present or future willingness to or as an inducement to, *inter alia*, prescribe or recommend AstraZeneca's product or to secure any improper advantage for the company. Paragraph 5 provided that the speaker acknowledged that he/she had been selected to provide the services because of his/her expertise in the relevant subject matter.

In relation to the speaker meetings whilst it had concerns about the company's governance of the activities and materials the Panel considered that the complainant had not established on the balance of probabilities that there was any evidence to show that the engagement of the named health professional/the training and consultancy company was an inducement to prescribe as alleged. No breach of the Code was ruled.

In relation to the Expert on Demand Programme the Panel noted that this was a promotional programme whereby experts delivered 30 minute on line presentations. The named health professional had delivered 5 such meetings in 2015 and had been paid for each. Section 2 of the fee for service contract for the Expert on Demand Programme, dated 28 January 2015 stated that the named health professional did not interpret this engagement as an incentive or reward or an inducement to, *inter alia*, recommend or prescribe any AstraZeneca product. The Panel considered that the complainant had not established on the balance of probabilities that there was any evidence to show that the engagement was an inducement to prescribe. No breach of the Code was ruled.

The Panel noted its comments above regarding the fees paid to the named health professional/ the training and consultancy company. It also noted the number of speaker engagements and considered that when an individual/organisation was so engaged it was beholden upon the company to ensure that all aspects of the arrangements stood up to scrutiny and otherwise complied with the Code. Despite its high use of the named health professional over 2 years, AstraZeneca only became aware of such usage in July 2016, even though such usage was not in accordance with the company's policies and procedures. The impression created both externally and internally by such arrangements

should be borne in mind. The Panel also noted the high number of representative contacts with the named health professional at various local practices. It did not appear that the company had exercised due diligence in its multiple engagements of the named health professional. Such engagements were not in accordance with the relevant SOPs. In this regard, high standards had not been maintained. A breach of the Code was ruled.

The Panel, however, did not consider that the complainant had established a breach of Clause 2 and no breach was ruled accordingly.

In relation to medical and educational goods and services, there was no evidence before the Panel that AstraZeneca had engaged in any relevant activity. No breach of the Code was thus ruled.

An anonymous, non-contactable complainant who described themselves as an employee of one of the many manufacturers of therapies in a particular therapy area, complained about the conduct of a therapy area specific training and consultancy company run by a named health professional, that delivered a range of services to, *inter alia*, the NHS including services that were funded by a number of named pharmaceutical companies including AstraZeneca.

COMPLAINT

The complainant stated that the named health professional, in addition to his/her role at his/her company was also a specialist nurse employed on a contractual basis by a number of NHS organisations including a city based community healthcare organisation (CHO). In his/her role as a nurse within that organisation he/she had prescribing responsibility and influence within a named clinical commissioning group (CCG) area. The services offered ranged from in practice audits, health professional mentoring and education, to classroom based training workshops. These offerings had been delivered in a number of named local CCGs. Funding was provided for these initiatives through various mechanisms within the Code ie independent stand meetings.

The complainant stated that he/she had previously raised concerns within his/her organisation in relation the legitimacy of the training and consultancy company business model, in particular how it received funding from the pharmaceutical industry which unfortunately included on-going financial and logistical support from the complainant's own company. The complainant's concerns had been raised internally with management but no action had been taken to rectify the situation and the complainant believed that his/her job would be at risk if his/her confidentiality in raising these issues was not protected.

The complainant explained that the training and consultancy company had conducted industry funded 'clinical audits' in several surgeries across a named part of a city, those practices were very easy for medicines management to identify as they had highly irregular use of the sponsor's product. In several surgeries in a named CCG patients were either initiated onto or switched to the sponsors' medicine with little consideration given to alternative therapies. The pattern of disproportionate increases in product sales could be directly linked back to the pharmaceutical companies' funding support to the training and consultancy company. The complainant explained that unfortunately to protect his/her anonymity, he/she was unable to provide a very detailed narrative but would endeavour to give enough information so that the training and consultancy company and the pharmaceutical companies that used it were held to account.

The complainant stated that at the beginning of 2016 the training and consultancy company started to deliver a series of training workshops in partnership with the CCG in which the named health professional had prescribing responsibility which were accredited by the Royal College of General Practitioners (RCGP) and the Royal College of Nursing (RCN). The delivery of the workshops was, and continued to be completely funded by industry. The complainant articulated his/her concerns to his/her line manager regarding the company potentially providing substantial financial support to the training and consultancy company for these workshops due to his/her reservations about the ethics of that organisation and because its owner was directly contracted to the city based CHO.

The complainant stated that the amount of money that industry had pumped into these courses was staggering, and in his/her opinion the risk that the support could be perceived as an attempt to 'buy the business' had led him/her to continuously try to dissuade his/her company from being involved. Unfortunately the concerns the complainant foresaw had materialised into major conflict of interest and anti-competitive issues whereby the training and consultancy company had told potential industry partners that if they failed to provide support, their products would not be used in the CCG in which the complainant stated that the named health professional had prescribing responsibility and influence. The complainant stated that his/her company's local representative felt highly pressured to offer the training and consultancy company funding as the individual had been threatened that if he/she failed to support training events the named health professional would simply get the money from another pharmaceutical company. According to the complainant this was highly coercive behaviour and clearly completely unacceptable and one could only assume that similar pressure had been exerted on all other pharmaceutical companies.

An additional issue that recently came to light was that most of the organisations working in the therapy area provided a range of industry-developed services that were deployed in partnerships with NHS organisations; these services were in some cases very similar to the offerings developed by the training and consultancy company. The named health professional had left individuals in no doubt that if their organisation attempted to partner in CCGs where he/she wanted to deliver the programmes there could

be consequences for their sales in the area in which he/she had prescribing responsibility.

In the complainant's view the NHS and industry should be able to collaborate in highly transparent projects that benefited all stakeholders. Having to turn to the PMCPA to whistle-blow on his/her own organisation and the unacceptable behaviour of an organisation that it was actively engaged with was the low point of his/her career in the pharmaceutical industry. The complainant stated that the cavalier attitude of management within his/her own organisation and an inability for him/her to sit on the side-lines as the actions of a few undermined those of many and once again brought the industry into disrepute was too much to stomach. The complainant felt incredibly disillusioned that the industry and his/her company continued to work alongside an organisation that operated in a manner that was simply unacceptable in 2016. Unfortunately, industry was not an innocent party in the affair; all of the companies that had been involved with the training and consultancy company needed to reassess how they conducted business. The complainant appreciated that the evidence given in the complaint might not be detailed enough for the Authority to act but he/she hoped that there was enough information to at least investigate the relationship between the named health professional and a number of pharmaceutical companies. The great shame was that he/she might well be delivering much needed training and support for health professionals, however, the path he/she had decided to follow to extract financial support from industry had sullied what could have otherwise been a noble endeavour. The complainant hoped his/her complaint was seen as a genuine cry for help from the PMCPA as he/she had been ignored by those in positions of power within his/her organisation. The complainant stated that this complaint was motivated by a strong desire to do what was right; he/she was reasonably certain that if the issues outlined were investigated and his/her position within his/her company and probably the industry would become untenable.

The complainant provided a website address for the training and consultancy company.

When writing to AstraZeneca, the Authority asked it to consider the requirements of Clauses 2, 9.1, 18.1, 19.1, 19.2, 21 and 23.1 of the Code with regard to the clinical audit and with regard to training workshops delivered in partnership with a named clinical commission group (CCG). The case would be considered under the requirements of the Code relevant to the time the activities took place. The clause numbers cited above were relevant to the 2015 and 2016 Codes.

RESPONSE

AstraZeneca submitted that it took its obligations to comply with the Code seriously and had investigated the points raised and paid particular attention to its relationship with the training and consultancy company and the named health professional.

AstraZeneca submitted that the scope of its investigation included all AstraZeneca engagements of the named health professional and/or the training and consultancy company which had occurred between 13 May 2014, the date of its first engagement of the named health professional and 3 August 2016 – the date AstraZeneca was notified of this complaint.

Clinical audits

AstraZeneca submitted that it had not provided funding to the training and consultancy company or the named health professional to conduct any clinical audits. Therefore, it denied breaches of Clauses 19.1 or 19.2 of the Code with respect to its involvement with the training and consultancy company.

Accredited training workshops

AstraZeneca submitted that it had not funded any training workshops delivered by the training and consultancy company or the named health professional in partnership with the CCG in which he/she had prescribing responsibility.

AstraZeneca sponsored one workshop delivered by the training and consultancy company at which it had a stand, in October 2014. AstraZeneca understood that two other pharmaceutical companies also sponsored that meeting. A copy of the flyer for the workshop, a copy of the agenda and details of the nature of the funding were provided. AstraZeneca submitted that it did not influence or create the content of the workshop so neither the agenda nor the flyer was certified or examined by AstraZeneca. In compliance with AstraZeneca policies and procedures, the proposed sponsorship was reviewed and approved by the manager of the representative who organised the sponsorship before the workshop occurred.

AstraZeneca's use of the named health professional and the training and consultancy company

AstraZeneca submitted that it engaged the named health professional 56 times between 13 May 2014 and 3 June 2016 at face-to-face AstraZeneca promotional meetings. At fifty-four of the meetings the named health professional provided a speaker service and at two, he/she chaired the meeting.

The named health professional was selected to provide these services due to his/her experience as a specialist nurse in primary care, his/her knowledge of the current management of a particular condition and his/her availability to speak at lunchtime meetings. Representatives interviewed during the investigation stated that while there were other suitable health professional speakers, they were NHS employees and unable to speak during normal business hours due to prohibitions in their NHS contracts. In contrast, while the named health professional provided services to the NHS, he/she was not an NHS employee during the relevant time period and thus, not subject to restrictions on speaking at industry-led promotional lunchtime meetings.

A written contract was agreed with the named health professional before services commenced, which specified the nature and scope of those services and basis for payment. These engagements complied with the requirements of Clause 23.1. The titles and dates of these meetings, as well as the honoraria paid to the named health professional, were provided.

AstraZeneca submitted that the named health professional also spoke five times between 6 May 2015 and 18 November 2015 on its Expert on Demand Programme. This was an AstraZeneca funded promotional programme in which experts delivered thirty minute presentations at virtual meetings via WebEx to health professionals using slides developed and certified by AstraZeneca. They participated in mandatory web conference training which covered the content of the slides before speaking at any meetings. The programme was managed by an external third party which was responsible for scheduling the meetings, arranging the contracts and paying the speakers.

AstraZeneca executed a written contract with the named health professional before services commenced in relation to this programme, which specified the nature, and scope of his services and basis for payment. These engagements complied with the requirements of Clause 23.1. The topics and dates of these meetings, as well as the honoraria paid to the named health professional, were provided. The named health professional was also paid an honoraria for attending a training session on slide content on 12 February 2015.

In the interests of full disclosure, AstraZeneca declared that it had not engaged a named employee of the training and consultancy company, to provide services in any capacity between 1 January 2014 and 3 August 2016.

AstraZeneca had not contracted the training and consultancy company to provide any type of services on its behalf and so Clause 21 was not relevant.

AstraZeneca concluded that it took its compliance with industry Codes of Practice very seriously, and believed that its activities complied with Clauses 2, 9.1, 18.1, 19.1, 19.2, 21 and 23.1.

In response to the Panel's request for further information, AstraZeneca made the following points.

Clinical audits

AstraZeneca stated that it did not directly fund a practice or group of practices to carry out audits/ reviews independently of AstraZeneca in three named CCGs or in a named region between 1 January 2014 to 3 August 2016.

AstraZeneca stated that it had not funded any activity provided by the training and consultancy company which might be described as a nurse-led review or clinic.

Meetings

Copies of contracts with the named health professional were provided and a revised copy of a table listing speaker meetings updated to include meeting numbers and thus allow cross-referencing. Copies of the agendas (showing venues) for meetings conducted by the named health professional were also provided.

Copies of the AstraZeneca Ethical Interactions (EI) standard operating procedure (SOP) and the AstraZeneca Salesforce Meetings Compliance Guide were provided which detailed AstraZeneca's approval and governance processes for such meetings. In brief, the approval process involved:

- Representatives provided their line managers with an agenda, proposed venue, hospitality breakdown, speaker contract and proposed honorarium, as well as slides to be used
- Line managers reviewed this information for compliance with the SOP and other relevant guidance and ensured that representatives made any necessary changes to ensure compliance before they approved the meeting.
- The signatories reviewed any slides to be presented, if they were not all pre-approved. Historically speaker slides were examined by signatories. Following a previous undertaking to the PMCPA in 2016, all speaker slides were now formally certified.

AstraZeneca had in place a suite of governance and monitoring processes around such meetings. Among these, line managers were required to attend at least one promotional meeting each quarter to verify compliance. Any instances of non-compliance were reported to its compliance officer who reviewed them, submitted them to the company's compliance monitoring system, reported on them to the senior management team at quarterly local compliance committee meetings and recommended additional training and/or sanctions, if appropriate. Further, AstraZeneca had a meetings compliance dashboard which summarised compliance data for various types of meetings which were reviewed regularly and disseminated throughout the organisation to enhance compliance and identify training needs. In addition, AstraZeneca's global compliance assurance partner reviewed a sample of promotional meetings annually.

AstraZeneca reiterated that the named health professional was selected to speak at AstraZeneca meetings in a particular region because he/she:

- had broad, relevant experience as a specialist nurse in primary care
- had a comprehensive knowledge of the current management of patients
- was available to speak at daytime meetings. While there were other suitable health professional speakers, they were NHS employees and unable to speak during normal business hours. In contrast, he/she was not an NHS employee and thus not subject to restrictions on speaking at industry led promotional daytime meetings.

AstraZeneca did not normally engage a speaker 56 times over 2 years within a relatively small geographical area. AstraZeneca's SOP described restrictions on the number of occasions an individual might be engaged and the maximum permitted spend per individual.

AstraZeneca was first aware of the high usage of the named health professional on 13 July 2016. On 15 July the sales force was instructed not to plan any further use of the named health professional. Information on the 31 uses of, and the amount paid to, the named health professional was then presented at the local compliance committee at its quarter 2 2016 meeting.

While AstraZeneca recognised that the usage threshold for the named health professional was exceeded on this occasion a clear policy was in place and a communication to prevent further engagements with him/her was issued as soon as this high usage had been identified. Through this investigation the company had identified areas of improvements within its existing procedures including monitoring usage on a more frequent basis so as to identify high frequency engagements earlier and further guidance on geographical distribution of usage with high frequency engagements.

With regard to the number of times a speaker could be engaged under a contract, AstraZeneca's normal practice was to enter into a separate contract for each engagement. The Expert on Demand program, where all multiple engagements were covered by a single contract, was an exception.

The need for meetings was identified locally by representatives based on educational need and level of interest, as expressed by individual practices. Representatives also identified practices using publicly available data on the number of uncontrolled relevant patients under a practice's care. During the course of the investigation into this matter representatives stated that the named health professional did not select or identify practices to receive these educational meetings.

The named health professional was selected to speak for the reasons explained above. During interviews representatives were specifically asked if they had ever felt pressured to select the named health professional as a speaker; in all cases representatives replied that they did not.

Explanations about references in the CRM system were provided. Most related to the named health professional's availability to speak. Furthermore, the three entries in October and November 2015 referring to 'data added tools' and 'an audit tool' related to an Excel spreadsheet made available on request to health professionals to monitor patients' outcomes.

The named health professional correctly signed the authorisation line requiring a signature from a 'member of the meeting organising committee'. The 'approved by' line should have been signed by the representative approving payment for use of exhibition space but was signed by the named health professional in error. This form was then sent to the representative's line manager for approval who appeared not to have noticed this error during his/her review and approval of the meeting.

PANEL RULING

The Panel noted that the anonymous complainant was non contactable and so could not be asked to provide further details. Anonymous complaints were accepted and like all complaints judged on the evidence provided by the parties. The complainant had the burden of proving his/her complaint on the balance of probabilities. The complainant had not provided any evidence in support of the allegations.

The complaint raised concerns about the interactions of certain pharmaceutical companies, including Boehringer Ingelheim, and the training and consultancy company run by the named health professional. The complainant stated that the named health professional, a nurse, was employed on a contractual basis by a number of NHS organisations including the named city based CHO. Reference was made to his/her prescribing responsibility and alleged influence in a named CCG area and to the training and consultancy company services provided locally. The training and consultancy company offerings were said to range from practice audits, health professional mentoring and education to classroom based training workshops. More detailed allegations were made in relation to audits and workshops. The complainant alleged that the amount of money that industry had pumped into these courses was 'staggering' and could be perceived as an attempt to 'buy the business'. The complainant also generally referred to the Authority investigating the relationship between the named health professional and certain pharmaceutical companies. In this regard the Panel noted that it could only consider specific matters raised in the complaint.

The Panel noted that the complainant began by stating that he/she wished to complain about the conduct of the training and consultancy company, referred to grave concerns about it and the path which the complainant alleged had been taken by its owner, the named health professional, to extract financial support from the industry including highly coercive behaviour; in this regard the Panel noted that the Code applied solely to the conduct of pharmaceutical companies.

The Panel considered that the complaint was broader than the two matters identified by the case preparation manager, ie audits and specific workshops. The complainant had referred generally to training and support for health professionals delivered by the named health professional but paid for by the pharmaceutical industry. AstraZeneca had, however, responded to all matters raised in the complaint and the Panel ruled accordingly. The Panel considered that the scope of the complaint included the engagement of the named health professional and/or the training and consultancy company activities, with health professionals, whether such activities were delivered by its owner, the named health professional or other individuals. However, when considering such matters the totality of a company's interactions with the named health professional would, nonetheless, be relevant.

The Panel noted that the complainant had provided a website address for the training and consultancy company and this had been provided to all respondent companies. The website listed the named health professional as the Director and another health professional as the nurse liaison lead. The Panel noted that the named health professional

was contracted by the NHS to work at a number of surgeries in addition to his/her role at the named city based CHO.

The Panel noted that the complainant had raised concerns in relation to a number of pharmaceutical companies which were taken up with each company individually. Companies made differing submissions about the training and consultancy company and the role and status of the named health professional. Each case was considered on its merits.

In addition, the Panel noted that the case preparation manager had stated that matters would be considered in relation to the requirements of the Code applicable when the matters at issue occurred

In addition, the Panel noted the case preparation manager's advice that matters would generally be considered in relation to the requirements of the Code applicable when the matters at issue occurred. However, the Panel noted that AstraZeneca had sponsored a training and consultancy company meeting in October 2014. The Panel noted that there was a relevant difference between the 2014 and 2016 Codes in the supplementary information to Clause 2 in that the supplementary information to the 2016 Code gave 'unacceptable payments' as an example of a breach of Clause 2. This difference was potentially relevant to the matter at issue and thus all matters pertaining to the October 2014 meeting were ruled under the requirements of the 2014 Code.

The Panel noted that in relation to activities that occurred in 2015 in the particular circumstances of this case there were no significant differences between the relevant requirements of the 2015 and the current 2016 Code and thus these matters were considered under the 2016 Code.

The Panel noted that according to AstraZeneca it had sponsored only one meeting run by the training and consultancy company which was held in October 2014. The meeting about a particular condition had a 1 day educational agenda which began at 9.30am. The Panel was very concerned that the form authorising electronic payment to the training and consultancy company was signed as approved by the named health professional rather than, as required, by the representative. This was apparently not noted at the time by the representative and/or line manager responsible for overall review and approval of the meeting. However, the Panel noted that the complainant bore the burden of proof and considered that the complainant had not established on the balance of probabilities that either the provision of sponsorship or the level of sponsorship was an inducement to prescribe or otherwise inappropriate in relation to the matters alleged. No breach of Clauses 18.1 and 18.6 was ruled. Noting this ruling the Panel also ruled no breach of Clauses 9.1 and 2. These rulings were made under the 2014 Code.

The Panel noted that AstraZeneca had engaged the named health professional 54 times between May 2014 and June 2016 to speak and twice to chair its lunchtime or evening promotional meetings. In addition, the named health professional had been engaged 5 times between May and November 2015 as a speaker on its Expert on Demand Programme.

The Panel noted that although AstraZeneca referred to the appointment of the named health professional as an individual the fee for service contracts showed that the fees were in fact paid to the training and consultancy company. The Panel therefore considered this matter under both Clauses 23 and 21.

The Panel noted that the SOP on External Interactions dated May 2012 stated at section 5 that, *inter alia*, the company would only engage health professional service providers where there was a legitimate need for their services, the relevant person was an appropriate candidate and the level of compensation did not have and did not create an impression that the company had undue influence on the individual. Written director approval was needed before contracting with a health professional service provider for any further employment over 20 engagements, or over a set amount, in a 12 month period. There was no evidence before the Panel to show that in relation to the 29 speaker meetings and 5 Expert on Demand engagements in 2016 such approval had been sought. The Panel noted the fair market value speaker fees table. According to the sales force compliance guide there had to be written justification for fees at the top end of the fair market value range and signatory approval for fees outside the fair market value range. The Panel noted the payment to the named health professional/ training and consultancy company for the 29 speaker meetings held in 2016 and most meetings in 2016. It appeared to the Panel that particularly for the meetings held at GP practices which comprised one presentation of an hour or less the monies paid exceeded the values in the fair market value table. The Panel noted that the SOP was dated May 2012 but it was nonetheless provided by the company as a current document. There was no evidence before the Panel that there had been written justification and/or signatory approval of the fees as stated in the relevant SOP.

The Panel noted AstraZeneca's submission that it had engaged the named health professional because of his/her experience, knowledge and availability, and as he/she was not an NHS employee he/she was available for daytime meetings as he/she was not subject to restrictions on speaking at industry-led promotional daytime meetings. The Panel noted that nonetheless he/she had also been engaged to speak at evening meetings.

The Panel noted that according to AstraZeneca its representatives did not feel pressurised to select the named health professional as a speaker and that he/she did not identify practices to receive these meetings. The Panel noted the high level of contact between representatives and the named health professional at various surgeries in addition to contact at the speaker meetings. The customer relations management (CRM) entries did not show whether such contacts were solicited or unsolicited. The CRM entries showed that on occasion such contacts included discussion of educational needs. The Panel noted AstraZeneca's submission that CRM

references to 'mapping out practices' and 'further surgeries to consider' referred to the named health professional's availability to speak rather than practice selection.

The Panel noted AstraZeneca's submission that it did not normally engage a speaker 56 times over 2 years within a relatively small geographical area. The named health professional had spoken more than once at a number of GP practices. The company stated that it first became aware of the high use of the named health professional on 13 July 2016 (ie before it was notified of this complaint) but did not state what had triggered this.

The Panel noted that paragraph 2 of the fee for service speaker contracts stated that the consultant confirmed that he/she did not interpret the engagement as an incentive or reward for past, present or future willingness to or as an inducement to, *inter alia*, prescribe or recommend AstraZeneca's product or to secure any improper advantage for the company. Paragraph 5 provided that the speaker acknowledged that he/she had been selected to provide the services because of his/her relevant expertise.

In relation to the speaker meetings whilst it had concerns about the company's governance of the activities and materials the Panel considered that the complainant had not established on the balance of probabilities that there was any evidence to show that the engagement of the named health professional/the training and consultancy company was an inducement to prescribe as alleged. No breach of Clauses 21 and 23.1 was ruled.

In relation to the Expert on Demand Programme the Panel noted that this was a promotional programme whereby experts delivered 30 minute on line presentations via WebEx. The named health professional had delivered 5 such meetings in 2015 and had been paid the same amount for each. Section 2 of the fee for service contract for the Expert on Demand Programme, dated 28 January 2015 stated that the named health professional did not interpret this engagement as an incentive or reward or an inducement to, *inter alia*, recommend or prescribe any AstraZeneca product. The Panel considered that the complainant had not established on the balance of probabilities that there was any evidence to show that the engagement was an inducement to prescribe. No breach of Clauses 21 and 23.1 was ruled.

The Panel noted its comments above regarding the fees paid to the named health professional/ the training and consultancy company. It also noted the number of speaker engagements and considered that when an individual/organisation was so engaged it was beholden upon the company to ensure that all aspects of the arrangements stood up to scrutiny and otherwise complied with the Code. Despite its frequent engagement of the named health professional over 2 years, AstraZeneca only became aware of the fact in July 2016, even though such frequent engagement was not in accordance with the company's policies and procedures. The impression created both externally and internally by such arrangements should be borne in mind. The Panel also noted the high number of representative contacts with the named health professional at various local practices. It did not appear that the company had exercised due diligence in its multiple engagements of the named health professional. Such engagements were not in accordance with the relevant SOPs. In this regard, high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel, however, did not consider that the complainant had established a breach of Clause 2 and no breach of Clause 2 was ruled accordingly.

The Panel noted that AstraZeneca had also been asked to respond to the requirements of Clause 19.1 of the Code. There was no evidence before the Panel that AstraZeneca had engaged in any relevant activity. No breach of Clause 19.1 was thus ruled.

The Panel noted that AstraZeneca had provided details of monies paid to the named health professional in relation to training he/she received to become an Expert on Demand speaker. The Panel considered that this matter was outside the scope of the complaint and thus made no rulings upon it.

During its consideration of this case the Panel was concerned about the poor control exercised by AstraZeneca over certain activities. In relation to sponsorship of the exhibition stand meeting in October 2014 the Panel was extremely concerned that the representative and his/her line manager had failed to notice that the named health professional had signed the 'approved by' line and thereby approved payment of funds to himself/the training and consultancy company.

The Panel noted that AstraZeneca had identified improvements to its procedures but nonetheless requested that the company be advised of its concerns.

Complaint received **3 August 2016**

Case completed **3 January 2017**

CASE AUTH/2868/8/16

JANSSEN-CILAG v SANOFI GENZYME

Promotion of an unlicensed medicine

Janssen alleged that at The European League Against Rheumatism (EULAR) Congress of Rheumatology held in London, in June 2016, Sanofi Genzyme had promoted its forthcoming interleukin-6 (IL-6) receptor blocker (sarilumab) prior to the grant of its licence.

Janssen noted that Sanofi Genzyme had several activities related to IL-6, these included a large exhibition stand that highlighted its importance in rheumatoid arthritis using claims, interactive videos and handouts, a sponsored symposium which discussed those benefits and included information about sarilumab and posters presenting the results of sarilumab studies. Janssen noted that in January 2016 Sanofi Genzyme announced that the US Food and Drug Administration accepted the licence application for sarilumab for review with a target action date of 30 October 2016; the EU licence application was accepted for review in July 2016.

Janssen considered that this case was an important precedent as it distinguished the difference between legitimate scientific exchange (for example the presentation and discussion of new data at a congress symposium) from the outright promotion of specific scientific activity (such as the promotion of the importance of a specific cytokine such as IL-6, when a company had an unlicensed IL-6 receptor blocker).

Janssen stated that it had not complained about the posters or the symposium *per se*, but that the overall conference activity, focussed specifically on IL-6 and its importance in rheumatoid arthritis, especially the exhibition stand, encouraged attendees to ask questions about sarilumab before the grant of its marketing authorization.

Janssen also alleged a breach for failing to maintain high standards.

The detailed response from Sanofi Genzyme is given below.

The Panel noted that Janssen's complaint was about information about IL-6 presented on Sanofi Genzyme's exhibition stand at the Congress. Although there was no complaint about other activities at the conference, the Panel agreed with Janssen's submission that the materials etc on the exhibition stand had to be viewed in the context of Sanofi Genzyme's other activities about IL-6 at the conference. Sanofi Genzyme's medicine, sarilumab, blocked IL-6 and was being developed as a possible treatment for rheumatoid arthritis. When the EULAR Congress was held, sarilumab did not have a marketing authorization although a licence had been applied for in the US and an EU licence application was about to be made.

The Panel noted that although the Code prohibited the promotion of a medicine prior to the grant of its marketing authorization, the legitimate exchange of medical and scientific information during the development of a medicine was not prohibited provided that this did not constitute promotion which was prohibited by the Code. The PMCPA Guidance about Clause 3 further stated that companies must ensure that such activities constituted a genuine exchange of information and were not promotional. Documents must not have the appearance of promotional material. It should be borne in mind that it would be a breach of the Code if non-promotional information on products or indications that were not licensed was used for a promotional purpose.

Promotion was defined as any activity undertaken by a pharmaceutical company or with its authority which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.

The Panel noted that in addition to having the exhibition stand at the EULAR Congress, Sanofi Genzyme had sponsored a scientific symposium entitled 'IL-6 as a driver of joint destruction in rheumatoid arthritis: translating complex science into patient benefits'; one speaker would give an overview of the management of joint damage in rheumatoid arthritis, including the effectiveness of IL-6 inhibition. The graphics used on the symposium invitation, although different to those used on the exhibition stand, were not wholly dissimilar.

The exhibition stand appeared to be, from the photographs supplied by Janssen and the plans provided by Sanofi Genzyme, typical of those used by pharmaceutical companies at large conferences. One corner of the stand was designated as the medical corner. The statement 'As IL-6 elevates, the effects go beyond the joints' could be seen on what appeared to be the front and the back of the stand. Material on the stand was exclusively about IL-6 and its role in rheumatoid arthritis. One video for use on the stand was entitled 'IL-6 and articular manifestations of rheumatoid arthritis' and concluded that persistently elevated IL-6 might play a central role in the articular manifestations of rheumatoid arthritis, resulting in pain and disability in patients. A second module was entitled 'The role of IL-6 signalling in rheumatoid arthritis' and concluded that elevated IL-6 signalling in rheumatoid arthritis might lead to the disruption of homeostasis in many cell types and physiologic processes. Two key opinion leader videos on IL-6 in rheumatoid arthritis concluded with invitations for the viewer to review the relevant monographs which were available on the stand. Interactive touch screen panels detailed the role of elevated IL-6 levels in the articular and systemic manifestations of rheumatoid arthritis.

Briefing material reminded all staff (none of whom were from sales or marketing) attending the EULAR Congress that sarilumab was an investigational, unlicensed product in Europe and must not be pro-actively discussed with congress attendees. Although the term 'investigational' was not defined, the Panel queried whether a product for which a marketing authorization had been applied for in the US and would, within 5 weeks, be applied for in Europe, could be considered to be an 'investigational molecule' as stated in the briefing material or as being 'in development' as stated by Sanofi Genzyme in its response. In the Panel's view, health professionals were likely to view sarilumab as a pre-licence product. The briefing material continued by stating that if attendees wanted more information about sarilumab or IL-6 inhibitors then they should be referred to scientific advisers (medical scientific liaison (MSLs)) or medical personnel in the medical area of the stand. In the Panel's view, it was reasonable to assume that, on the balance of probabilities, many of the stand visitors would ask about IL-6 inhibition in general and/or Sanofi Genzyme's interest in the area in particular; a virtual reality presentation on the stand invited questions about IL-6 and rheumatoid arthritis. The briefing material had prepared staff for such questions and a discreet area on the stand in which to answer questions about sarilumab had been provided. Through possible US press activity, some visitors to the stand might have already known about Sanofi Genzyme's forthcoming product. The briefing material stated that delegates from every continent would be at the EULAR Congress. The symposium had discussed the effectiveness of IL-6 inhibition in the management of rheumatoid arthritis. In the Panel's view, given the content of the stand and the messages about the role of elevated IL-6 in rheumatoid arthritis, such questions could not take the benefit of personal, unsolicited requests for information referred to at Clause 1.2 of the Code. In the Panel's view the exhibition stand, within the context of Sanofi Genzyme's other activities about IL-6 at the conference, would prepare the market for the introduction of a new medicine for rheumatoid arthritis which would decrease IL-6 levels and solicit questions about the same; Sanofi Genzyme had a commercial interest in one such medicine. Given that that medicine was unlicensed, a breach was ruled. In that regard the Panel considered that high standards had not been maintained and a further breach was ruled. These rulings were upheld on appeal by Sanofi Genzyme.

Janssen alleged that at The European League Against Rheumatism (EULAR) Congress of Rheumatology held in London, in June 2016, Sanofi Genzyme had promoted its forthcoming interleukin-6 (IL-6) receptor blocker (sarilumab) prior to the grant of its licence. Janssen had raised its concerns with Sanofi Genzyme at the congress but inter-company dialogue had failed to resolve the companies' differences.

Sarilumab was developed jointly by Sanofi Genzyme and Regeneron. Regeneron, a US company, had a European head office in Ireland but as far as Janssen was aware did not have a specific UK presence. When advised of the complaint by the Authority, Regeneron declined to join the list of non-member companies that had agreed to comply with the Code and accept the jurisdiction of the Authority.

COMPLAINT

Janssen noted that Sanofi Genzyme had several activities related to IL-6; its importance in rheumatoid arthritis was highlighted by claims on its exhibition stand, interactive videos and handouts. Janssen noted that in January 2016 Sanofi Genzyme announced that the US Food and Drug Administration (FDA) accepted the biologics licence application for sarilumab for review with a target action date of 30 October 2016. The regulatory submission was indicated as being planned in the EU in quarter 3, 2016. Janssen stated that the EU licence application had since been accepted for review. Janssen provided copies of the press release issued by Sanofi Genzyme on 1 August 2016 which confirmed those dates.

Janssen accepted that companies could engage in legitimate scientific exchange; however, it considered that the nature and content of Sanofi Genzyme's congress activities exceeded the boundaries set in the supplementary information to Clause 3.1. Information was provided in such a manner as to promote the importance of IL-6 in rheumatoid arthritis. Janssen noted that in Case AUTH/2651/11/13, Merck Sharp & Dohme highlighted the risks of such linkage and implied that the promotion of the receptor activity for a specific indication/treatment would, in itself, constitute a breach of the Code. Janssen alleged that the nature of the activity at the congress promoted sarilumab and would have encouraged health professionals to ask questions about the product. This was underlined by the fact that the prominent promotion of IL-6 activity coincided with what would otherwise be legitimate scientific exchange about sarilumab (scientific posters and a symposium) but each would have propagated interest in the other.

Janssen explained that Sanofi Genzyme's activity included a large exhibition stand that promoted the benefits of addressing the cytokine IL-6, a sponsored symposium which further discussed those benefits and included information about sarilumab and posters presenting the results of sarilumab studies.

Janssen considered that this case was an important precedent as it distinguished the difference between legitimate scientific exchange (for example the presentation and discussion of new data at a congress symposium) from the outright promotion of specific scientific activity (such as the promotion of the importance of a specific cytokine such as IL-6, when a company had an unlicensed IL-6 receptor blocker).

Janssen stated that it had not complained about the posters or the symposium *per se*, but that the overall conference activity, especially the exhibition stand, encouraged attendees to ask questions about sarilumab before the grant of its marketing authorization. Janssen alleged that this constituted promotion of an unlicensed medicine in breach of Clause 3.1.

Janssen explained that rheumatoid arthritis was a chronic, multisystem, multifactorial autoimmune disease. Although the aetiology was still not clear, it appeared that rheumatoid arthritis had strong correlation with environmental and genetic factors. Cytokines, such as IL-6, carried out many crucial biological processes like cell growth, proliferation, differentiation, inflammation, tissue repair and regulation of the immune response. However, in addition to IL-6, examples of other cytokines were TNF-alpha, IL-1, IL-4, IL-7, IL-10, IL-12, IL-13, IL-17, IL-18, IL-21, IL-23, IL-27, IL-32, IL-33, and IL-35. There were already treatment options to inhibit some of those cytokines and there were others under development.

Janssen submitted that although many pathogenetic elements were responsible for rheumatoid arthritis, it was concerned that all of Sanofi Genzyme's activities at EULAR focused specifically on IL-6 and its importance in rheumatoid arthritis. The exhibition stand was a Sanofi Genzyme and Regeneron branded stand and the two companies had a specific partnership to develop sarilumab. Given the status of the licence applications in the US and EU it was difficult to see it as anything other than the promotion of a forthcoming product prior to the grant of a licence by soliciting enquiries about that product.

As evidence of the pre-licence promotion, Janssen provided images of the large, purpose-built exhibition stand (typical of those at international congresses and measuring approximately 100m^2) and the accompanying video screens and materials that were distributed from it. Janssen clarified that it had not complained about each aspect of the stand individually but the overall nature of the combined activities. Janssen also provided a diagram of the exhibition hall to show the location of the stand.

Janssen noted that the majority of the stand was dedicated to the importance and contribution of IL-6 in the context of rheumatoid arthritis, with bold claims and consistent associated imagery. The stand contained bold statements such as: 'In rheumatoid arthritis (RA), as IL-6 elevates, the effects go beyond the joints'. The statements were in capitals and 'IL-6' and the inference of benefits was in larger font to highlight the benefits of IL-6 inhibition. Further, the claims on IL-6 extended across the entire exhibition stand, even beyond the allocated 'medical corner'. Janssen alleged that this activity would solicit enquiries about sarilumab prior to the grant of its marketing authorization.

Janssen stated that the associated imagery was directly aligned with the claims about the effects of IL-6 in the manner of promotional material, for instance the red inflammation areas on the female model correlated with the colouring of the font in the claims and also extended around the stand linking the video screens and the displays of the 'medical' handouts (educational monographs).

Janssen noted that the interactive videos displayed on the stand bore consistent imagery with that on the stand itself. The content of the videos highlighted the specific importance and contribution of the IL-6 cytokine. The titles of the videos included:

- A Review of the Dual Signalling Mechanism of IL-6
- Contributions of IL-6 to Disease Manifestations of RA
- The Contributions of IL-6 to Bone Resorption in RA
- The Roles For IL-6 in both Innate and Adaptive Immunity.

Janssen further noted that several 'educational monographs' (medical handouts) were available from the stand which was highlighted as part of the stand itself, as in the image provided, and linked with the 'inflammation' graphics. In that context, Janssen alleged that the handouts also promoted the importance and contribution of IL-6. By consistently highlighting the importance of IL-6 in rheumatoid arthritis and indeed the negative consequences of a persistently elevated IL-6 in rheumatoid arthritis, there was an inference on the benefit that inhibiting IL-6 in rheumatoid arthritis would provide. Janssen alleged that this was in a manner that breached Clause 3.1 and would solicit enquiries about the forthcoming Sanofi Genzyme IL-6 receptor blocker.

Photographs of the monographs were provided; their titles were similar to those of the videos listed above.

Janssen alleged that the nature of the exhibition stand (and associated stand materials) in itself constituted promotion of a product prior to the grant of its marketing authorization on the grounds that it was likely to solicit enquires about the associated product, an IL-6 receptor blocker, sarilumab. Janssen's concerns were further increased by Sanofi Genzyme's additional associated activity.

Janssen explained that at the same conference, the Sanofi Genzyme sponsored symposium discussed IL-6 and specifically referred to sarilumab and highlighted the MOBILITY study, one of the key studies cited in Sanofi Genzyme's press releases and pivotal to the sarilumab licence application. Janssen respected the right of companies to engage in legitimate scientific exchange and in that context did not express any particular concerns about the symposium itself. However, the symposium directly linked sarilumab with IL-6, and thus increased the likelihood of questions about the product at the exhibition stand and effectively promoted the product through the stand's focus on the importance of addressing IL-6.

To further underline the link between IL-6 and sarilumab, several posters were presented at the conference which highlighted results with sarilumab. Again, Janssen did not express any particular concerns about the posters directly, but submitted that those posters obviously linked the product and the intense promotion of the importance of the associated IL-6 cytokine in rheumatoid arthritis at the exhibition stand.

Janssen considered that the Sanofi Genzyme exhibition stand was designed to both highlight the importance of IL-6 in rheumatoid arthritis and initiate discussions on it using different mediums and tools. Janssen alleged that the activity would certainly solicit enquiries about sarilumab, a product which was discussed by Sanofi Genzyme

at the same conference, prior to the grant of its marketing authorization.

Janssen alleged that given the nature and content of its material, Sanofi Genzyme had promoted sarilumab prior to the grant of a marketing authorization in breach of Clause 3.1. Janssen also alleged a breach of Clause 9.1 for failing to maintain high standards.

RESPONSE

Sanofi Genzyme submitted that its congress activities included a stand in the exhibition hall on the role of IL-6 in the pathophysiology of rheumatoid arthritis and associated conditions, disease awareness and educational materials on IL-6, available at the exhibition stand, a sponsored symposium entitled 'New findings for IL-6 blockade in Rheumatoid Arthritis', 10 poster presentations relating to rheumatoid arthritis treatment, co-authored with health professionals and 4 peer reviewed abstracts in the conference abstract book.

Sanofi Genzyme submitted that the European Medicines Agency (EMA) accepted the sarilumab marketing authorization application for review on 14 July 2016. EMA records suggested that it would then take an average of 11 months until a marketing authorization was issued but it was too early in the process to offer a realistic estimate as to when it would expect the review of sarilumab to be completed.

Sanofi Genzyme submitted that it and Regeneron were independent companies but had collaborated since 2007 to develop, manufacture and commercialize medicines in a number of therapy areas, including the joint clinical development of sarilumab as a potential treatment for rheumatoid arthritis and other illnesses.

Sanofi Genzyme submitted that the arguments offered by Janssen to support its complaint were not enumerated and did not refer to any specific statements or claims and so it offered a counter-argument and an explanation of its activities.

Sanofi Genzyme corrected two initial factual inaccuracies within Janssen's complaint:

- Sarilumab had no marketing authorization and so Sanofi Genzyme did not market or supply it in the UK as Janssen alleged.
- Sarilumab was still in development so the use of the past tense 'was developed by …' by Janssen was misleading.

Sanofi Genzyme noted that a stand in the exhibition hall at a scientific conference need not necessarily be used for the promotion of specific medicines. Many different companies and organisations used stand space to exhibit a wide variety of products and initiatives. There was, indeed, promotion of specific medicines but there was also corporate promotion, disease awareness projects, promotion of charities and journal subscriptions and promotion of future meetings and events or other related professional organisations and memberships. In reality, in most conference exhibition halls a very wide range of informational, educational and promotional activities took place alongside the promotion of specific medicines. On many pharmaceutical company stands it was not unusual to see the promotion of specific medicines and the provision of medical education or scientific information taking place at different ends of the same stand. Sanofi Genzyme submitted that, therefore, just because an activity took place, or material was made available at an exhibition stand, did not mean that it constituted promotion of a specific medicine.

Clause 1.2 of the Code stated that information related to human health or diseases was excluded from the scope of the Code provided there was no reference, either direct or indirect, to specific medicines.

Sanofi Genzyme submitted that its activities and materials used on its stand consisted of information about a human disease, namely, the role of IL-6 in the pathophysiology of rheumatoid arthritis and did not refer, either directly or indirectly, to a specific medicine. With regard to Janssen's allegation of a breach of Clause 3.1, Sanofi Genzyme noted that no materials used on the stand referred to sarilumab either directly or indirectly, nor was there any mention of the mode of action of sarilumab, nor the mode of action of any potential therapy for rheumatoid arthritis. Claims made in materials and on the exhibition stand were not product claims. Sanofi Genzyme submitted that Janssen appeared to have confused IL-6, a cytokine present naturally in the body, with a pharmaceutical product. No claims were made for sarilumab nor any potential medicine that might target IL-6.

Sanofi Genzyme acknowledged that the materials on its stand focused on IL-6 and submitted that it was a critically important cytokine in the signalling pathway that led to the inflammatory reaction seen in rheumatoid arthritis. Sanofi Genzyme submitted that its collaborative research with Regeneron was focused on IL-6 and its scientific expertise in the area was mainly around the role of IL-6 in the pathophysiology of rheumatoid arthritis and the associated clinical and laboratory signs and symptoms. Sanofi Genzyme considered that it was reasonable to share that scientific expertise and highlight the important role of IL-6 in rheumatoid arthritis with health professionals interested in learning more about the disease. Sanofi Genzyme did not deny that there were components other than IL-6 in the complex pathophysiology of rheumatoid arthritis but nor did the materials used at the stand deny it. Sanofi Genzyme acknowledged that it had a medicine in development that inhibited IL-6 and it submitted that it intentionally focussed its materials and presentations on IL-6 because that was where its interest and expertise lay. Sanofi Genzyme submitted that, however, sharing its knowledge about IL-6 and its role in rheumatoid arthritis and educating health professionals about the importance of IL-6 was not the same as promoting a specific product, either directly or indirectly.

Sanofi Genzyme noted Janssen's reference to Case AUTH/2651/11/13 which highlighted the promotion

of receptor activity for a specific indication or treatment but submitted that it did not promote any receptor activity. IL-6 was not a receptor, it was a cytokine, which was a component part of a complex signalling pathway; it interacted with receptors to cause various physiological and pathological effects. Sanofi Genzyme submitted that those effects were highlighted and explained in the materials on its stand but it did not present anything about the potential for blocking or inhibiting receptors, nor did it present any other mechanistic concepts, such as inhibiting the production of IL-6, nor increasing the metabolism or clearance of IL-6, nor any other potential mode of action for a potential medicine. Sanofi Genzyme submitted that it meticulously avoided mentioning any potential mode of action of a medicine. It also noted that in Case AUTH/2651/11/13, Merck Sharp & Dohme listed its pipeline products by name and ran a satellite symposium at the same conference, yet the Panel ruled no breach of the Code.

Sanofi Genzyme submitted that there were numerous potential methods that might inhibit or reduce the activity of IL-6 and there were several companies, including Janssen, which had medicines in development that targeted IL-6 in various different ways; Roche already marketed tocilizumab that inhibited IL-6. Sarilumab was not unique or exceptional in its mode of action and there were numerous other potential modes of action that could impact IL-6 activity. Sanofi Genzyme submitted therefore, that presenting information about IL-6 in the way that it did, did not solicit questions specifically about sarilumab but was more likely to lead to a discussion about the complexity of the signalling pathways and the multitude of associated pathological effects, as confirmed by the staff who manned the stand.

Sanofi Genzyme noted that Janssen used the term 'promoting' when describing the presentations and materials on its exhibition stand. Sanofi Genzyme submitted that it was difficult to see how it could 'promote' IL-6. IL-6 was not a medicine. Sanofi Genzyme submitted that with high quality and certified materials it had appropriately, and in a considered way, highlighted the importance of IL-6 and the extensive pathophysiological effects it could have. The purpose of the materials and presentations was to educate interested health professionals about the role of IL-6 in rheumatoid arthritis.

Sanofi Genzyme noted that Janssen had not complained about the posters or the symposium but about the overall conference activity and that it was especially concerned about the exhibition stand but even then the complaint was only in the context of the scientific conference and with the background of the scientific presentations on sarilumab. Sanofi Genzyme submitted that Janssen failed to demonstrate any statement or claim made at the stand or in any materials available at the stand that referenced the posters or the sponsored symposium or that could be construed as promotional, for the simple reason that there were no such statements or materials in use.

The scientific posters and symposium were part of the independently organised scientific conference programme, selected independently of Sanofi Genzyme and included data on sarilumab. Sanofi Genzyme noted that the title, theme and branding of the symposium were different and distinct from that of the exhibition stand and the educational and disease awareness materials and were not linked in any way. Janssen did not complain about those activities and they were not raised as a concern nor even mentioned by Janssen during inter-company dialogue. It would thus seem inappropriate to now link them to this complaint. Sanofi Genzyme submitted that if Janssen accepted that the posters and symposium were acceptable in the context of the scientific conference then it should not have to justify them or defend them as part of this response to the complaint. Sanofi Genzyme submitted that a reasonable concern might be if it had shared data on sarilumab at the stand or if it had referenced that data in some way at the stand, but it had not.

Sanofi Genzyme noted Janssen's statement that by consistently highlighting the importance of IL-6 in rheumatoid arthritis and the negative consequences of a persistently elevated IL-6 in rheumatoid arthritis, there was an inference on the benefit that inhibiting IL-6 in rheumatoid arthritis would provide. Sanofi Genzyme presumed that Janssen intended to state that there was an implication rather than an inference, however, either way, the inference that there might be benefit in inhibiting IL-6 could be correct, but there were other inferences that could be taken, such as that reducing the amount of IL-6 could be beneficial or that blocking an IL-6 receptor could be beneficial or that there might be some other effective way of reducing or ameliorating the consequences of elevated levels of IL-6 that might have a therapeutic benefit in rheumatoid arthritis. All of those inferences could be correct but none of them promoted the use a specific product, licensed or unlicensed, and so there was logical *non sequitur* in Janssen's argument. Sanofi Genzyme submitted that by highlighting the importance of IL-6 it did not follow that it had promoted a specific product nor solicited questions about a specific product.

Neither the exhibition stand itself nor the educational monographs or other material available on it, referred directly or indirectly to any unlicensed product. The stand was manned exclusively by members of the medical departments of Sanofi Genzyme and Regeneron.

Sanofi Genzyme noted that Clause 9.1 stated that high standards must be maintained at all times. Review of the copies of the materials, supplied as part of this response, would testify to their high scientific quality. There was nothing trivial, distasteful, irreverent or inappropriate to the intended audience nor to the intended purpose of the materials. Furthermore, each item was reviewed and approved globally and locally by appropriately qualified signatories on behalf of both companies. The approval codes supplied reflected that dual process. Sanofi Genzyme and Regeneron strongly considered that high standards were maintained throughout all activities and materials used at the

2016 EULAR Congress and so complied with Clause 9.1 in both their content and their execution.

Sanofi Genzyme submitted that Janssen's alleged breach of Clause 9.1 showed that it misunderstood the meaning and purpose of that clause which was to ensure high standards of materials and activities, in that they should recognise the special nature of medicines and the professional standing of the audience. Even if its activities and materials were considered to be promotional (which Sanofi Genzyme did not believe they were) they were nonetheless still of a high standard, and so Clause 9.1 was irrelevant to this complaint.

Sanofi Genzyme concluded that it could understand that Janssen did not want health professionals to think of Sanofi Genzyme as a leader in the field of rheumatoid arthritis with expertise in the science of IL-6, as that might impact Janssen's own profile with those health professionals. However, that was not a justifiable reason to try to stop the legitimate exchange of medical and scientific information. Sanofi Genzyme accepted the part of Janssen's conclusions that its stand was designed to highlight the importance of IL-6 in rheumatoid arthritis and to initiate discussion on IL-6 in rheumatoid arthritis using different mediums and tools which was accurate. Sanofi Genzyme disagreed that it followed that it would solicit enquiries on sarilumab. Sanofi Genzyme submitted that the materials on its stand solicited many wide ranging discussions on the role of IL-6 and the pathophysiology of rheumatoid arthritis and the many and varied inflammatory effects of IL-6.

Sanofi Genzyme submitted that Janssen had not given one concrete example of any statement that could be construed as promotional. Janssen had complained about the content of Sanofi Genzyme's material but had not pointed to anything specific that might be considered to even hint at a specific product. Sanofi Genzyme submitted that Janssen's complaint was without foundation and might even reflect a poor understanding of both the spirit and the detail of the Code. Sanofi Genzyme submitted that all of its materials were of a high standard and so it rejected the alleged breach of Clause 9.1. Sanofi Genzyme submitted that all of its material and presentations at the exhibition stand were part of the legitimate exchange of medical and scientific information and so it rejected the alleged breach of Clause 3.1 and considered that there was no real case to answer. Sanofi Genzyme submitted that it wholeheartedly embraced both the principles and the detail of the Code and genuinely believed it had upheld it fully in all its materials and activities at the EULAR 2016 Congress.

PANEL RULING

The Panel noted Sanofi Genzyme's submission that Janssen had not cited any statement that could be construed as promotional and that all of the claims on the exhibition stand were about IL-6 and not about sarilumab. The Panel noted, however, that it was an accepted principle under the Code that a product could be promoted without its name ever being mentioned. Further, the introduction to the Constitution and Procedure stated that a complainant had the burden of proving their complaint on the balance of probabilities.

The Panel noted that Janssen's complaint was about information about IL-6 presented on the Sanofi Genzyme exhibition stand at the EULAR Congress in June 2016. Although there was no complaint about other activities at the conference, the Panel agreed with Janssen's submission that the materials etc on the exhibition stand had to be viewed in the context of Sanofi Genzyme's other activities about IL-6 at the conference. Sanofi Genzyme's medicine, sarilumab, blocked IL-6 and was being developed as a possible treatment for rheumatoid arthritis. When the EULAR Congress was held, sarilumab did not have a marketing authorization although a licence had been applied for in the US and an EU licence application was about to be made; the EU licence application was accepted for review by the EMA on 14 July ie shortly after the EULAR Congress closed.

The Panel noted that although Clause 3 prohibited the promotion of a medicine prior to the grant of its marketing authorization, the Code permitted companies to undertake certain activities with regard to unlicensed medicines. The supplementary information to Clause 3 provided additional details, including a clear statement that the legitimate exchange of medical and scientific information during the development of a medicine was not prohibited provided that this did not constitute promotion which was prohibited by Clause 3 or any other clause. The PMCPA Guidance about Clause 3 further stated that companies must ensure that such activities constituted a genuine exchange of information and were not promotional. Documents must not have the appearance of promotional material. It should be borne in mind that it would be a breach of the Code if non-promotional information on products or indications that were not licensed was used for a promotional purpose.

Clause 1.2 defined promotion as any activity undertaken by a pharmaceutical company or with its authority which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.

The Panel noted that in addition to having the exhibition stand at the EULAR Congress, Sanofi Genzyme had sponsored a scientific symposium entitled 'IL-6 as a driver of joint destruction in rheumatoid arthritis: translating complex science into patient benefits'. It was stated on the invitation that one of the speakers would give an overview of the management of joint damage in rheumatoid arthritis, including the effectiveness of IL-6 inhibition. The graphics used on the invitation, although different to those used on the exhibition stand, were not wholly dissimilar in that joints of the hand were highlighted in red.

The exhibition stand appeared to be, from the photographs supplied by Janssen and the plans provided by Sanofi Genzyme, typical of those used by pharmaceutical companies at large conferences.

One corner of the stand was designated as the medical corner. The statement 'As IL-6 elevates, the effects go beyond the joints' could be seen on what appeared to be the front and the back of the stand. Material on the stand was exclusively about IL-6 and its role in rheumatoid arthritis. One video for use on the stand was entitled 'IL-6 and articular manifestations of rheumatoid arthritis' and concluded that persistently elevated IL-6 might play a central role in the articular manifestations of rheumatoid arthritis, resulting in pain and disability in patients. A second module was entitled 'The role of IL-6 signalling in rheumatoid arthritis' and concluded that elevated IL-6 signalling in rheumatoid arthritis might lead to the disruption of homeostasis in many cell types and physiologic processes. Two key opinion leader videos on IL-6 in rheumatoid arthritis concluded with invitations for the viewer to review the relevant monographs which were available on the stand. Interactive touch screen panels detailed the role of elevated IL-6 levels in the articular and systemic manifestations of rheumatoid arthritis.

Briefing material reminded all Sanofi Genzyme and Regeneron staff (members of the medical departments of both companies) attending the EULAR Congress that sarilumab was an investigational, unlicensed product in Europe and must not be pro-actively discussed with congress attendees. Although the term 'investigational' was not defined, the Panel queried whether a product for which a marketing authorization had been applied for in the US and would, within 5 weeks, be applied for in Europe, could be considered to be an 'investigational molecule' as stated in the briefing material or as being 'in development' as stated by Sanofi Genzyme in its response. In the Panel's view, health professionals were likely to view sarilumab as a pre-licence product. The briefing material continued by stating that if attendees wanted more information about sarilumab or IL-6 inhibitors then they should be referred to scientific advisers (medical scientific liaison (MSLs)) or medical personnel in the medical area of the stand. In the Panel's view, it was reasonable to assume that, on the balance of probabilities, many of the stand visitors would ask about IL-6 inhibition in general and/or Sanofi Genzyme's interest in the area in particular; a virtual reality presentation on the stand invited questions about IL-6 and rheumatoid arthritis. The briefing material had prepared staff for such questions and a discreet area on the stand in which to answer questions about sarilumab had been provided. A press release to accompany the US licence application might have generated interest in the medical press in the early part of the year and so some visitors to the stand might have already known about Sanofi Genzyme's forthcoming product. The briefing material stated that delegates from every continent would be at the EULAR Congress. The symposium had discussed the effectiveness of IL-6 inhibition in the management of rheumatoid arthritis. In the Panel's view, given the content of the stand and the messages about the role of elevated IL-6 in rheumatoid arthritis, such questions could not take the benefit of personal, unsolicited requests for information referred to at Clause 1.2 of the Code. In the Panel's view the exhibition stand, within the context of Sanofi Genzyme's other activities about IL-6 at the conference, would prepare the market for the introduction of a new medicine for rheumatoid arthritis which would decrease IL-6 levels and solicit questions about the same; Sanofi Genzyme had a commercial interest in one such medicine. Given that that medicine was unlicensed, a breach of Clause 3.1 was ruled. In that regard the Panel considered that high standards had not been maintained. A breach of Clause 9.1 was ruled. Both rulings were appealed.

APPEAL BY SANOFI GENZYME

Sanofi Genzyme submitted that both Janssen's complaint, which it received on 5 July 2016, and the subsequent inter-company dialogue, were entirely focused on the activities and materials at its exhibition stand at the EULAR Congress. There was no mention of any concern about Sanofi Genzyme's sponsored symposium at the congress or that its exhibition stand needed to be considered in the context of that symposium. The first indication that the sponsored symposium was part of the complaint was Janssen's complaint to the PMCPA on 11 August 2016. Sanofi Genzyme was therefore not given any opportunity to respond to this aspect of the complaint, or discuss it in inter-company dialogue before it was escalated to the PMCPA.

Sanofi Genzyme submitted that the complaint did not meet the requirements of Paragraph 5.3 of the Constitution and Procedure and that the Panel should not have included that aspect of the complaint in its ruling. Clause 1 stated that the scope of the Code did not include information relating to human health or diseases provided there was no reference, either direct or indirect, to specific medicines. There was no direct or indirect reference to sarilumab in any of the materials or activities at the exhibition stand. In order to infer such a reference to a specific product, a health professional would have had to link the materials at the stand with a poster or a presentation at the symposium or a press release or some other information source, all of which were removed, in varying degrees, in time, location and visual appearance and were distinct and separate from the exhibition stand. The Panel ruling had ignored this clear and overt separation and suggested that any scientific exchange activity might need to be considered as if it were juxtaposed to all other information available, no matter where or when such other information could have been acquired.

Sanofi Genzyme submitted that it appeared from the Authority's letter notifying it of the outcome of the Panel's consideration that insufficient consideration and attention might have been given to the company's arguments in defence of its activities and materials displayed on the exhibition stand. At the outset the Panel noted that Sanofi Genzyme had submitted that Janssen had not cited any statement that could be construed as promotional and that all of the claims on the stand were about IL-6 and not sarilumab. This defence was dismissed in the next sentence. No other points from Sanofi Genzyme's submission were mentioned anywhere

in the letter. In addition, throughout its ruling, the Panel used the terms 'claims' and 'promotion' to describe Sanofi Genzyme's presentation of material on IL-6. These were rather prejudicial terms normally used in relation to promotional activities rather than educational activities or scientific exchange and so it appeared to be some conflation of IL-6 and sarilumab, such that presenting the role of IL-6 was seen as tantamount to promotion of sarilumab.

Sanofi Genzyme submitted that activity at an exhibition stand was not limited to product promotion. The exhibition stand was used for many other purposes including scientific exchange, disease awareness and education activities. Sanofi Genzyme submitted that none of the stand materials mentioned sarilumab or its development and none of them mentioned any potential mode of action of any therapy or potential therapy. The materials were all entirely focused on the effects of the IL-6 cytokine, not the mechanism of blockade of IL-6 or the merits of such blockade.

Sanofi Genzyme submitted that that the Panel assumed that its activities and materials would solicit questions about sarilumab and implied that that was its intention. Actively soliciting enquiries on sarilumab was definitely not Sanofi Genzyme's intention, nor did it happen. Sanofi Genzyme recognised *a priori* that some conference delegates might be aware of sarilumab, and that some might want to enquire about it or other unlicensed therapies which was why a dedicated 'medical corner' was allocated to answer unsolicited questions.

Sanofi Genzyme submitted that the emerging role of IL-6 in the pathophysiology of rheumatoid arthritis was a legitimate topic about which to engage in the exchange of scientific and medical information. IL-6 was one of the major cytokines in the pathophysiology of rheumatoid arthritis and new research findings showed the increasing importance of IL-6 compared with the role of other cytokines.

Sanofi Genzyme noted that the Panel stated that its activities would 'prepare the market for the introduction of a new medicine for rheumatoid arthritis which would decrease IL-6 levels and solicit questions about the same'. Sanofi Genzyme submitted that it was not unreasonable to prepare the market for the introduction of a new product by educating and informing health professionals about scientific advances and new emerging knowledge, as long as it did not promote a specific product or solicit questions about a specific product. If a specific product was subsequently licensed, then a health professional could make a more informed decision about its appropriate use if the underlying science was understood. Educating health professionals about the underlying science could stop well short of suggesting or recommending therapeutic targets or modes of action and was not the same as promoting a product.

Sanofi Genzyme submitted that at the time of the EULAR Congress, no application for a marketing authorization in Europe had been made.

Sanofi Genzyme noted that the Panel had questioned its use of the terms 'investigational' and 'in development' and suggested that sarilumab should be considered 'pre-licence'. Sanofi Genzyme submitted that a reasonable and consistent cut-off point needed to be applied when considering whether legitimate scientific exchange might be construed as promotion simply because a product licence application was being compiled. In previous PMCPA cases periods significantly shorter than a year prior to licence had been deemed sufficient distance to judge an activity not to be pre-licence promotion (Cases AUTH/2651/11/13, AUTH/2479/2/12 and AUTH/2480/2/12). Although the FDA had accepted a sarilumab licence submission for review on 8 January 2016, the product development programme continued and work was ongoing to compile a marketing authorization submission for the EMA. The EULAR Congress was a European event and so it should be the European and UK product licence status that was applicable. As this event took place before a marketing authorization application had been submitted in Europe and more than a year before the potential grant of a European marketing authorization and even longer before potential commercial availability of the product, then it seemed premature and presumptuous to describe the product as 'pre-licence'.

Sanofi Genzyme submitted that the exhibition stand materials and the sponsored symposium materials were completely different from each other.

Sanofi Genzyme noted that the Panel had accepted that the graphics used on the invitation to the sponsored symposium were different to those used on the exhibition stand, yet it went on to state that they were not dissimilar because joints of the hand were highlighted in red. Sanofi Genzyme submitted that they were entirely dissimilar. They were conceived, designed and produced by different teams and while the symposium invitation depicted the redness of inflammation limited to the joints, the stand graphics conveyed the impression of spreading flames using shades of orange and yellow extending beyond the joints to affect other parts of the body. The visual impressions were distinct and there was no suggestion of a link, nor any intent to link the symposium and the stand.

Sanofi Genzyme submitted that sarilumab was only one of several similar IL-6 inhibitors in development at the time of the EULAR Congress and there was one already marketed, so without mentioning any by name, it would not be possible to promote a specific product, even indirectly.

Sanofi Genzyme submitted that the Panel's ruling went beyond previous interpretations of the Code and further restricted what could be considered to be legitimate exchange of scientific and medical information; it moved the UK out of alignment with the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code and its interpretation in most other European countries. This ruling might therefore impact the ability and willingness of organisations to host international medical conferences in the UK and suggested that

it might not be acceptable for a pharmaceutical company to engage with health professionals in the context of a medical conference in the UK in scientific discussion of any pathological process where the company had a research interest.

Sanofi Genzyme noted that the ruling of a breach of Clause 9.1 followed directly from the ruling of a breach of Clause 3.1 and introduced no new material or activities deemed to be in breach and so was simply an additional sanction for the same alleged offence as that ruled on under Clause 3.1.

Sanofi Genzyme recognised that the Panel would rule a breach of Clause 2 in cases deemed to have brought discredit upon, or reduced confidence in, the pharmaceutical industry. A ruling of a breach of Clause 2 was reserved as a sign of particular censure and was applied in addition to rulings of breaches of other clauses. It seemed that, in this case, Janssen and the Panel might have interpreted Clause 9.1 in a similar way, and used it as a milder form of Clause 2, adding an additional penalty for the same alleged breach. Sanofi Genzyme was not aware that this was the purpose of Clause 9.1.

Sanofi Genzyme submitted that as noted in its response and not contested by the complainant, nor in the Panel's ruling, the activities and materials used at its exhibition stand were produced and carried out to a high standard, with quality materials presenting accurate scientific content, reviewed through a rigorous approval process, presented and discussed by highly trained medical staff, fully recognising the professional standing of the audience. Therefore, Sanofi Genzyme submitted it should not be found in breach of Clause 9.1, unless it was intended that Clause 9.1 be used as a form of supplementary penalty to add to another breach.

RESPONSE FROM JANSSEN

Janssen alleged that Sanofi Genzyme's exhibition activities at the EULAR Congress could not benefit from the exemption of the definition of promotion in Clause 1.2. By exclusively highlighting the importance of IL-6 in rheumatoid arthritis and including claims on the stand, interactive videos and handouts, the implications and benefits of IL-6 inhibition in rheumatoid arthritis were clear. Therefore, Sanofi Genzyme had in effect, indirectly promoted sarilumab before its marketing authorization had been granted.

Janssen noted that rheumatoid arthritis was a chronic, multisystem, multifactorial autoimmune disease. Although the aetiology was still not clear, it seemed that rheumatoid arthritis was strongly correlated with environmental and genetic factors. In addition to IL-6, examples of other cytokines involved in the pathogenesis of rheumatoid arthritis were TNF-alpha, IL-1, IL-4, IL-7, IL-10, IL-12, IL-13, IL-17, IL-18, IL-21, IL-23, IL-27, IL-32, IL-33, and IL-35. There were already treatment options to inhibit some of those cytokines and there were others under development. Thus, although there were many pathogenic elements responsible for rheumatoid arthritis, Janssen was concerned that Sanofi Genzyme's activities at the EULAR Congress focused only on IL-6. Janssen reproduced an illustrative example on Cytokines in the pathogenesis of rheumatoid arthritis (McInnes and Schett, 2007).

Furthermore, Janssen noted that the exhibition stand and associated materials were all Sanofi Genzyme and Regeneron branded, and these two companies had a specific partnership to develop sarilumab. Janssen therefore alleged that Sanofi Genzyme was in breach of Clause 3.1 for promoting prior to the grant of a licence and Clause 9.1 for failure to maintain high standards.

Janssen noted that Sanofi Genzyme's activities at the congress included a large exhibition stand which addressed the cytokine IL-6, a sponsored symposium which further discussed the benefits of treating IL-6 and included information about sarilumab and posters which presented the results of sarilumab studies. Janssen recognised the right of companies to engage in legitimate scientific exchange and specifically had not complained about, and did not wish to complain about, the sponsored symposium at the EULAR Congress, nor the posters, hence this was not discussed during inter-company dialogue. Janssen submitted that the point it raised in its complaint was that the nature of the stand activities at the EULAR Congress effectively promoted sarilumab and, in the context of the broader conference activities, would have encouraged health professionals to ask about the product and each activity would have propagated interest in the other. For this reason, Janssen disagreed that the complaint did not meet the requirements of Paragraph 5.3 of the Constitution and Procedure Code and submitted that inter-company dialogue was concluded appropriately.

APPEAL BOARD RULING

The Appeal Board noted that Clause 1.2 defined promotion as any activity undertaken by a pharmaceutical company or with its authority which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines. The supplementary information to Clause 3 stated that the legitimate exchange of medical and scientific information during the development of a medicine was not prohibited provided that this did not constitute promotion which was prohibited by Clause 3 or any other clause.

The Appeal Board considered that although Sanofi Genzyme's activities at the EULAR Congress were geographically separate within the conference venue, ie the poster presentations, the sponsored symposium and the exhibition stand, there was an overarching theme such that they were linked. In the Appeal Board's view, each in their own way would inform health professionals about the importance of IL-6 in the pathophysiology of rheumatoid arthritis. The Appeal Board noted Sanofi Genzyme's submission that it would be more than a year after the conference before sarilumab was commercially available but considered that as there was already one IL-6 blocker on the market, Sanofi Genzyme

would be anxious to ensure that once sarilumab was licensed, it had a rapid uptake.

The Appeal Board considered that the large Sanofi Genzyme/Regeneron exhibition stand appeared to be of the type generally associated with promotion. The Sanofi Genzyme/Regeneron partnership existed specifically for the development of, *inter alia*, sarilumab. The exhibition stand was prominently branded with the two company names, which were illuminated around the top of the stand, and was centrally placed in the exhibition hall. The more-than-life-size depiction of a woman featured on the stand graphics gave the stand a promotional appearance. The open medical corner used to answer unsolicited enquiries faced outwards on a corner of the stand and in that regard it would be possible for passers-by either to hear or join in with conversations taking place there.

The material available on the stand had been certified as non-promotional material but each certificate stated that the product was sarilumab. Sanofi Genzyme's representatives at the appeal stated that whilst the originator of the material was a commercial employee the material was generated by its parent company. The originator had been the contact point who had received the material and entered it into the approval system. He/she had not generated the material. The stand and its material were exclusively focussed on IL-6. The monographs available referred to the clinical consequences of persistently elevated IL-6 levels. The stand was manned by staff from the medical departments of Sanofi Genzyme and Regeneron and included medical science liaison staff. The Sanofi Genzyme representatives at the appeal stated that no questions were asked about sarilumab and the only mention of sarilumab was by a Janssen visitor to the stand.

The Appeal Board disagreed with Sanofi Genzyme's submission that all of its material and presentations at the exhibition stand were part of the legitimate exchange of medical and scientific information. In the Appeal Board's view Sanofi Genzyme's activities at the EULAR Congress were directed at providing information and educating health professionals. The Appeal Board considered, however, that it was difficult for Sanofi Genzyme to provide such specific education about IL-6 and rheumatoid arthritis without promoting the relevant, unlicensed medicine in which it had an interest. The Appeal Board considered that by using a large, promotional-looking stand to raise awareness of only, and very specifically, IL-6 in rheumatoid arthritis, Sanofi Genzyme had indirectly promoted, or prepared the market for sarilumab; the link between IL-6 and sarilumab was too close for this not to be so. The Appeal Board upheld the ruling of a breach of Clause 3.1. In that regard the Appeal Board considered that high standards had not been maintained. A breach of Clause 9.1 was upheld. The appeal on both points was unsuccessful.

Complaint received **11 August 2016**

Case completed **3 February 2017**

CONSULTANT ONCOLOGIST AND A PHARMACIST v LILLY

Oncology handbook

In Case AUTH/2849/6/16 a consultant oncologist and a pharmacist, raised a new matter when asked for further information about their original complaint about the 8th edition of the Handbook of Systemic Treatments for Cancer produced by Eli Lilly & Company. The complainants were advised that the new matter could only be considered if it were the subject of a fresh complaint. The complainants subsequently submitted the present complaint.

The complainants were concerned that the handbook was not up-to-date in relation to newly licensed medicines for the treatment of the cancers referred to in the handbook. For example the omission of, *inter alia*, nivolumab (lung cancer) and ramucirumab (gastric cancer) was misleading and unbalanced and did not therefore reflect the purpose of the handbook, as an authoritative reference text which provided relevant, accurate and up-to-date information on the treatment of various cancers.

The detailed response from Lilly is given below.

The Panel noted that the 8th Edition of the handbook had been withdrawn prior to completion of Case AUTH/2849/6/16.

Turning to this case, the Panel noted that the date of preparation of the handbook, February 2014, was stated on the bottom right hand corner of the even numbered pages. The Panel also noted the disclaimer that the publisher had tried to ensure that the information was accurate and up-to-date at the time of publication and the reference to the need to check the summary of product characteristics (SPC). The disclaimer further reminded the user that the handbook was not a substitute for each product's SPC and went on to provide the user with a link to the electronic medicines compendium. A list of monographs appearing in the handbook was included.

The Panel noted Lilly's submissions regarding the decision to compare cancer agents included in the 7th Edition with those whose launch had been notified to MIMS by the end of November 2013 and that ramucirumab and nivolumab were not approved for use in the UK until 10 and 14 months after that date respectively.

The handbook was clear regarding the date of publication. The intended audience would be aware that it was likely that new medicines would be approved after the publication date.

The Panel did not consider that the omission of ramucirumab and nivolumab from the 8th Edition of the handbook, published months before either were approved, was misleading or unbalanced as alleged. The company had not failed to maintain high standards. The Panel therefore ruled no breaches of the Code including no breach of Clause 2.

In Case AUTH/2849/6/16 the complainants, a consultant oncologist and a pharmacist, raised a new matter when asked for further information about their original complaint which concerned the 8th edition of the Handbook of Systemic Treatments for Cancer 2014 (ref UKONC00326) produced by Eli Lilly & Company Limited. The complainants were advised that the new matter could only be considered if it were the subject of a fresh complaint. The complainants subsequently submitted the present complaint.

In Case AUTH/2849/6/16, the handbook was ruled in breach of Clauses 2, 7.2, 7.4 and 9.1 of the Code as the inclusion of an error, which listed the intramuscular dose of Vitamin B_{12} at 1g instead of 1mg when used before and during treatment with Lilly's Alimta (pemetrexed), meant that the information in the handbook was inaccurate, misleading and not capable of substantiation and high standards had not been maintained. The error reduced confidence in the pharmaceutical industry.

COMPLAINT

The complainants stated that they ceased using the handbook in their hospital unit because they were concerned that it was not up-to-date in relation to other newly licensed medicines available for the treatment of the cancers referred to in the handbook whilst it was being promoted by Eli Lilly. For example, the omission of, *inter alia*, nivolumab (lung cancer) and ramucirumab (gastric cancer) was misleading and unbalanced and did not therefore reflect the purpose of the handbook, as an authoritative reference text which provided relevant, accurate and up-to-date information on the medical treatment of various cancers. The complainants noted that in its response Lilly stated 'The handbook was conceived and published by Lilly to assist health professionals in their day-to-day patient management by providing concise information as guidelines for the administration of medicines commonly used for the treatment of cancer'. To achieve the latter objective would have necessitated inclusion of information pertaining to all cancer medicines that were licensed in the UK whilst the handbook was being 'widely distributed' and promoted by Lilly; this was evidently not the case.

When writing to Lilly, the Authority asked it to consider the requirements of Clauses 2, 7.2 and 9.1.

RESPONSE

Lilly stated that the handbook was a non-promotional educational item as stated on the back. It accepted full responsibility for the handbook and all previous editions.

Lilly submitted that the 8th Edition was published in February 2014, two years after the publication

of the 7th Edition. Lilly had worked with a named hospital to publish the first edition around 20 years earlier. Since then each subsequent edition of the handbook had been produced in consultation with key pharmacy staff at that hospital.

The handbook was conceived and published by Lilly to assist health professionals in their day-to-day patient management by providing concise information and guidelines for the administration of commonly used medicines for the treatment of cancer. Subsequent editions included new anticancer agents as these came to market. In the 7th edition, additional information to support the care of cancer patients was added, including the 'Oncology/ Haematology Helpline Triage Tool' developed by the UK Oncology Nursing Society and endorsed by MacMillan Cancer Support. This information was also included in the 8th Edition.

The handbook was widely distributed by Lilly to cancer-treating institutions in the NHS, with chemotherapy nurses and cancer nurse specialists were the primary users. Consistent feedback confirmed that the handbook in its various editions over the years was a well-regarded and valued resource among health professionals.

As the complexity of information included in the handbook increased, Lilly decided to outsource its production to a third party while maintaining the close association with key pharmacy staff at the hospital. Two of the three authors of the 8th Edition were from the hospital.

Lilly submitted that the publication date was clearly stated on every even page of the handbook, and the disclaimer, which appeared prominently on page 3, stated that the publisher had tried to ensure that the information contained in the handbook was accurate and up-to-date at the date of publication. The disclaimer also stated clearly in bold and underlined text that it was the user's responsibility to ensure that they checked for any variation in the product summary of product characteristics (SPC). The disclaimer further reminded the user that the handbook was not a substitute for each product SPC and went on to provide the user with a link to the electronic medicines compendium (eMC).

The editorial decision taken by the third party when compiling the 8th Edition was to compare those cancer drugs included in the 7th Edition with those whose launch had been notified to MIMS by the end of November 2013. It stood to reason that only medicines approved at that date were included; ramucirumab and nivolumab were not approved for use in the UK until December 2014 and April 2016 respectively. Lilly understood from users of the handbook over the last 20 years; that this was fully understood. Had there been a 9th Edition then any newly licensed anti-cancer agents would have been included.

Lilly referred to the text of the disclaimer:

> 'Welcome to the 8th edition of the Lilly Handbook of Systemic Treatments for Cancer (2014).
>
> The intent of this handbook is to assist healthcare professionals in their day-to-day patient management by providing concise information and guidelines for the administration of commonly used pharmacological agents for the treatment of cancer.
>
> The contents of this handbook have been developed collaboratively by nurse and pharmacist teams at [named hospital and named authors], on behalf of Eli Lilly and Company Ltd ("Lilly") and the publisher, [named].
>
> Lilly's role, as the sponsor of this handbook, has been limited to checking the factual accuracy of information on Lilly products and ensuring compliance with the PMCPA Code of Practice for the Pharmaceutical Industry.
>
> Save for the above, and the compilation of the 'Appendices' section, the updated contents of the handbook have been developed independently by the authors in collaboration with the publisher.
>
> The monographs in this handbook were compiled from manufacturers' summaries of product characteristics (SPCs) and other established resources. Some of the information presented may reflect local practice and the clinical expertise of the healthcare professionals involved.
>
> The monographs of the products contained herein are not intended to be a substitute for the manufacturers' SPCs. Only adverse events deemed to be of particular relevance are included. The publisher has tried to ensure that the information contained in this handbook is accurate and up-to-date at the time of publication. It is the user's responsibility to check for any variation in the product SPC subsequently. These can be found at www.medicines.org.uk/emc. It is important not to use copies of the handbook that are out of date or pass on old editions.
>
> The practice guidance presented in this handbook is offered as recommendations, and does not diminish the requirement for clinical judgment. Readers are strongly advised to check these recommendations against their local protocols and guidelines and to make their own further enquiries of manufacturers or specialists in relation to particular drugs, treatments or advice. Lilly, the publisher and the authors cannot accept liability for errors or omissions, and disclaim any liability arising out of the use of this handbook in practice.'

For the reasons set out above, Lilly denied that it breached Clauses 7.2, 9.1 or 2 in relation to this particular complaint. The date of publication of the handbook was clear, and users would have understood that it contained references to medicines approved at the date of publication.

PANEL RULING

The Panel noted that the 8th Edition of the handbook had been withdrawn prior to completion of the previous case.

Turning to this case, the Panel noted that the date of preparation of the handbook was February 2014 which was stated on the bottom right hand corner of the even numbered pages. The Panel also noted the disclaimer that the publisher had tried to ensure that the information contained in the handbook was accurate and up-to-date at the time of publication and the reference to the need to check the SPC on page 3. The disclaimer further reminded the user that the handbook was not a substitute for each product SPC and went on to provide the user with a link to the eMC. A list of monographs appearing in the handbook was included on page 30 for readers to refer to.

The Panel noted Lilly's submission regarding the decision to compare those cancer agents included in the 7th Edition with those whose launch had been notified to MIMS by the end of November 2013. It also noted Lilly's submission that ramucirumab and nivolumab were not approved for use in the UK until after the cut-off date (December 2014 and April 2016 respectively).

The handbook was clear regarding the date of publication. The intended audience would be aware that it was likely that new medicines would be approved after the publication date.

The Panel did not consider that the omission of ramucirumab and nivolumab from the 8th Edition of the handbook, published 10 months before ramucirumab was approved and 14 months before nivolumab was approved, was misleading or unbalanced as alleged. The Panel therefore ruled no breach of Clause 7.2.

The Panel noted its ruling of no breach of Clause 7.2 and in this regard did not consider that Lilly had failed to maintain high standards in relation to the omission of ramucirumab and nivolumab from the 8th Edition of the handbook and no breach of Clause 9.1 was ruled. The Panel noted its rulings above and ruled no breach of Clause 2.

Complaint received **12 September 2016**

Case completed **9 November 2016**

HEALTH PROFESSIONAL v SHIELD

Promotion of Feraccru

A health professional who until recently worked in the pharmaceutical industry, albeit in a different therapeutic area, alleged that a Feraccru (ferric maltol) journal advertisement issued by Shield Therapeutics UK was misleading and could put patient safety at risk. Feraccru was indicated for the treatment of iron deficiency anaemia in adults with inflammatory bowel disease (IBD).

The complainant noted that the advertisement stated that Feraccru had a safety profile comparable to placebo but the prescribing information stated that it was not suitable for, *inter alia*, children, those who were pregnant or those with severe IBD which was considerably less safe than placebo.

The detailed response from Shield is given below.

The Panel noted the complainant's narrow allegation that to state that Feraccru had a safety profile comparable to placebo when the prescribing information stated that it was not suitable for certain patient groups was misleading and potentially risked patient safety.

The Panel noted that the advertisment stated the licensed indication for Feraccru and further restricted use to a sub-population of patients who had previously failed on oral ferrous products reflecting the inclusion criteria from the pivotal studies. The Panel considered that the advertisement was clear in relation to the use of Feraccru in adults only and that the claims would be read as applying to the intended population rather than the population as a whole.

The Panel noted that according to the prescribing information Feraccru should not be used in patients with IBD flare, IBD patients with Hb (haemoglobin) < 9.5g/dl or children. Given the lack of relevant data, and as a precautionary measure, it was preferable to avoid its use during pregnancy.

The Panel did not consider that the claim 'a safety profile comparable to placebo' was misleading on the narrow ground alleged; that it was not suitable for certain patient groups. The advertisement clearly stated the licensed indication and patient population. The Panel did not consider that the company had failed to maintain high standards or that it had risked patient safety on the narrow ground alleged nor had it brought discredit to or reduced confidence in the pharmaceutical industry. No breaches of the Code were ruled including no breach of Clause 2.

A health professional who until recently worked in the pharmaceutical industry, albeit in a different therapeutic area, complained about a Feraccru (ferric maltol) advertisement (ref UK/FER/2016/004f) issued by Shield Therapeutics UK Limited. The advertisement appeared in Gastrointestinal Nursing, September 2016.

Feraccru was indicated in adults for the treatment of iron deficiency anaemia in patients with inflammatory bowel disease (IBD).

The one page advertisement contained an image of a submarine with the phrase 'Iron doesn't need to be heavy' beneath the submarine image. Under this image were clouds and:

> 'Feraccru (ferric maltol) is a new oral iron alternative for iron deficiency anaemia in adult patients with inflammatory bowel disease, who failed oral ferrous products.
>
> Lighten their load with a significant 2.25g/dl increase in Hb [haemoglobin] at Week 12 and a safety profile comparable to placebo.'

COMPLAINT

The complainant noted that the Feraccru advertisement stated that it had a safety profile comparable to placebo. The complainant noted that the prescribing information stated that it was not suitable for, *inter alia*, children, those who were pregnant or those with severe IBD which was considerably less safe than placebo. The complainant alleged that this was misleading and could put patient safety at risk.

When writing to Shield, the Authority asked it to consider the requirements of Clauses 2, 7.2 and 9.1.

RESPONSE

Shield submitted that the first sentence 'Feraccru (ferric maltol) is a new oral iron alternative for iron deficiency anaemia in adult patients with inflammatory bowel disease, who failed oral ferrous products' was the licensed indication for Feraccru as stated in Section 4.1 of the summary of product characteristics (SPC), but further restricted use to a sub-population who had previously failed on oral ferrous products. This sub-population reflected the inclusion criteria from the pivotal studies.

The second sentence 'Lighten their load with a significant 2.25g/dl increase in Hb at Week 12 and a safety profile comparable to placebo' detailed the top line results from the pivotal studies and provided the primary efficacy outcome, in terms of the haemoglobin rise over 12 weeks of therapy, and the overall safety profile that was seen in the study. This statement was referenced to Gasche *et al*, (2014) and Schmidt *et al* (2016), the two primary reports of the results of the study, and was an accurate reflection of the outcome of the study and the comparative safety profiles seen (although that was not the subject of the complaint).

Shield disagreed with the allegation that the claim '… and a safety profile comparable to placebo' was misleading and would put patients at risk because the prescribing information stated that the medicine was not suitable for, *inter alia*, children, those who were pregnant or those with severe IBD flare. The claim regarding the efficacy and the safety profile accurately reflected the results of the study, supported by the clinical data and publications. Further it was clear that these results related to the licensed indication which was clearly stated in the advertisement and included the restriction to adult patients. The advertisement did not imply that either the efficacy or safety results from the pivotal studies would be applicable outside of the licensed indication, nor in patient groups in whom the medicine was not recommended.

As was common with new therapies, Shield currently had no data on the use of Feraccru in pregnancy, breast-feeding, children (17 years and under) or IBD flare. In line with all advertisements, this lack of data was highlighted in the SPC and the prescribing information to ensure that prescribers could make an informed choice. There was no data to suggest that pregnant women or breast-feeding mothers would have increased risk if exposed to Feraccru, but as a precautionary measure use was not recommended.

There was no data for patients with IBD flare, however as oral ferrous products had been shown to exacerbate IBD, the use of Feraccru was not recommended.

It was evident that the complainant was able to understand from the advertisement that Feraccru should not be used in children, pregnancy or in (severe) IBD flare. In that regard, the advertisement was not misleading and was clear that Feraccru should not be used in those patient groups. There could therefore be no breach of Clauses 7.2 or 9.1. Shield submitted that it provided full information to ensure patient safety and appropriate use of Feraccru where limited or no data existed. In that regard, Shield submitted that it had maintained high standards and therefore had not breached Clauses 9.1 or 2.

PANEL RULING

The Panel noted the complainant's narrow allegation that it was misleading and potentially risked patient safety to state that Feraccru had a safety profile comparable to placebo when the prescribing information stated that it was not suitable for, *inter alia*, children, those who were pregnant and for those with severe IBD flare.

The Panel noted that the advertisment stated the licensed indication ie that Feraccru was for the treatment of iron deficiency anaemia in adult patients with inflammatory bowel disease. The advertisement further restricted use to a sub-population of patients who had previously failed on oral ferrous products. This sub-population reflected the inclusion criteria from the pivotal studies from which the efficacy results were generated. The Panel considered that the advertisement was clear in relation to the use of Feraccru in adults only. The Panel considered that the claims in the advertisement would be read as applying to the intended patient population which was clear rather than the population as a whole. Feraccru was not recommended for use in certain patients.

The Panel noted Shield's submission that the claim 'and a safety profile comparable to placebo' was an accurate reflection of the results of the study, supported by the clinical data and publications. The authors of the initial 12 week study (Gasche *et al*) stated that the low number of recorded adverse events precluded any valid statistical comparison of adverse events between the active and placebo groups. As a result the safety profile was assessed in a descriptive manner. Nevertheless the authors considered it unlikely that the 'differences in incidence of, or instance, constipation' would constitute a statistically significant finding. The extension study (Schmidt *et al*) stated that while Gasche *et al* was adequately powered to discern statistically significant differences, the open label extension had no comparator arm.

The Panel noted that according to the prescribing information, Feraccru should not be used in patients with IBD flare, IBD patients with Hb < 9.5g/dl or children. The Panel further noted that there was no data on the use of Feraccru in pregnant women and as a precautionary measure, it was preferable to avoid its use during pregnancy. Similarly, although ferric maltol was not available systemically and so was unlikely to pass into the mother's milk, as there were no clinical studies available to date it was preferable to avoid the use of Feraccru during breast-feeding.

The Panel did not consider that the claim in question 'a safety profile comparable to placebo' was misleading on the narrow ground alleged; that it was not suitable for certain patient groups. The advertisement made the licensed indication and patient population clear. No breach of Clause 7.2 was ruled.

Given its rulings above the Panel did not consider that the company had failed to maintain high standards or that it had risked patient safety on the narrow ground alleged nor had it brought discredit to or reduced confidence in the pharmaceutical industry. No breach of Clauses 9.1 and 2 was ruled.

Complaint received **21 September 2016**

Case completed **10 November 2016**

CASE AUTH/2875/9/16

HEALTH PROFESSIONAL v RECORDATI

Promotion of Cleen and CitraFleet

A health professional complained about an advertisement for Cleen (sodium dihydrogen phosphate dihydrate and disodium phosphate dodecahydrate) and CitraFleet (sodium picosulphate and magnesium citrate (SPMC)) issued by Recordati Pharmaceuticals. The advertisement appeared in Gastrointestinal Nursing, September 2016.

The advertisement at issue was two pages with the first page split with one half covering Cleen and the other half CitraFleet. The advertisement for Cleen referred to its re-branding; its previous name (Fleet) was replaced by Cleen. The advertisement for CitraFleet highlighted the new approved split dose regime.

Cleen ready to use enema was indicated for use in the relief of occasional constipation and for use where bowel cleansing was required and surgery, delivery and post-partum, and before proctoscopy, sigmoidoscopy or colonoscopy and before radiological examinations of the lower bowel. CitraFleet was indicated for bowel cleansing prior to any diagnostic procedures requiring a clean bowel. The dose was usually administered as one sachet on the evening prior to the procedure and the second in the morning on the day of the procedure. Alternatively, both sachets were administered on the afternoon and evening prior to the procedure. This was more suitable when the procedure was early in the morning.

The complainant stated that the advertisement described the following as 'remarkable events' which seemed inappropriate given the subject matter:

Cleen was claimed to have a 'quick action' but included no comparison. The claim was referenced to the summary of product characteristics (SPC) which did not refer to 'quick'. The complainant alleged that it was an unfair comparison if the reference was supposed to be reference 1 which was a comparison with glycerine suppositories.

The CitraFleet part of the advertisement included the statement 'the approval of the split dosage regime in accordance to the European Guidelines' which the complainant understood to mean that the guidelines supported CitraFleet however, it was not mentioned in the guidelines. The advertisement also stated that 'CitraFleet is the FIRST SPMC [sodium picosulphate with magnesium citrate] in Europe combining split dose regime according to the Guidelines, with the lowest volumen and an effective colon cleansing **'. The explanation for ** was 'than previous-day regimes. SPMC regimens. Split-dose regime approval date: December 2015'. According to the complainant the only SPMC mentioned in the guidelines was Prepopik.

The complainant stated that the guideline listed other products as also having a volume requirement of two litres a day.

The complainant alleged that the claims 'Effective bowel cleansing with low side effects and less impact on daily living' and 'Preferred by patients for its low volume, nice lemon flavour and the free choice of clear liquids' were not clear as to what they were in comparison to.

The complainant also struggled to read the prescribing information because there were more than 100 characters per line.

The detailed response from Recordati is given below.

The Panel noted that the reference to remarkable events appeared as part of a heading across the advertisement that Recordati was committed to improve patients' quality of life and was '… delighted to announce, two remarkable events' and thus, in the Panel's view, applied to the matters described in each part. The Panel noted Recordati's submission that the remarkable events related to developments in its product portfolio. The Panel did not consider that either rebranding a well-established medicine or delivering a split dose regimen in this therapeutic area would be seen as remarkable events. The Panel considered that this exaggerated the developments described in each advertisement and ruled a breach of the Code.

In relation to the claim that Cleen had a 'Quick Action' the Panel considered this could potentially be read as a comparison with other products. It was referenced to the SPC which stated 'Generally 2 to 5 minutes are sufficient to obtain the desired effect. If delayed discontinue further use and consult a physician'. In the Panel's view this might be seen as quick. The Panel did not consider that the complainant had proven on the balance of probabilities that the claim was misleading as alleged or a comparison with glycerine suppositories and that such a comparison would be unfair. The Panel ruled no breach of the Code.

With regard to the claim regarding CitraFleet and split dosing, the Panel noted Recordati's submission that the product was licensed for such use in December 2015 and the competitor was so licensed in June 2016. The Guideline mentioned Picolax and Picoprep in relation to SPMC. There was no mention of CitraFleet. The Panel considered the advertisement gave the impression that the split dose regimen of CitraFleet was mentioned and supported by the Guidelines which was not so. The advertising was misleading as alleged and a breach of the Code was ruled.

The Panel considered that the claim 'CitraFleet is the First SPMC in Europe combining split dose

regime according to the Guidelines, with the lowest volumen and an effective colon cleansing' was a comparative claim as it implied CitraFleet had the lowest volume. The Panel noted Recordati's submission that both CitraFleet and Picolax had the same volume when reconstituted ie 300ml. However, only one product could have the lowest volume and CitraFleet therefore did not have the lowest volume. This use of a superlative was therefore ruled in breach of the Code. Further the Panel considered that the volume related to the whole treatment ie reconstituted medicine plus required clear liquid rather than just the reconstituted medicine. Other products appeared to have lower volume requirements than CitraFleet. The comparator was not clear as alleged. The claim for lowest volume was also misleading and the Panel ruled breaches of the Code.**

The Panel considered that the claim 'Effective bowel cleansing with low side effects and less impact on daily living' implied a comparison with a product that had more impact on daily living. The Panel noted that the advertisement did not mention the comparator polyethylene glycol (PEG) and as this had not been made clear, the Panel considered that this omission rendered the claim misleading. Breaches of the Code were ruled.

The claim 'Preferred by patients for its low volumen, nice lemon flavour and the free choice of clear liquids' was the final bullet point. The Panel considered that the comparator in the claim was not clear and its omission rendered the claim misleading. Breaches of the Code were ruled.

The Panel considered that the line length and spacing between the lines meant that the prescribing information was not clear or legible. A breach of the Code was ruled.

A health professional who until recently worked in the pharmaceutical industry, albeit in a different therapeutic area, complained about an advertisement for Cleen (sodium dihydrogen phosphate dihydrate and disodium phosphate dodecahydrate) and CitraFleet (sodium picosulphate and magnesium citrate (SPMC)) issued by Recordati Pharmaceuticals Ltd. The advertisement appeared in Gastrointestinal Nursing, September 2016.

The advertisement at issue was two pages with the first page split with one half covering Cleen and the other half CitraFleet. The second page had the prescribing information. The advertisement for Cleen referred to its re-branding; its previous name (Fleet) was replaced by Cleen. The advertisement for CitraFleet highlighted the new approved split dose regime.

Cleen ready to use enema was indicated for use in the relief of occasional constipation and for use where bowel cleansing was required, such as before and after lower bowel surgery, delivery and post-partum, and before proctoscopy, sigmoidoscopy or colonoscopy and before radiological examinations of the lower bowel.

CitraFleet was indicated for bowel cleansing prior to any diagnostic procedures requiring a clean bowel eg colonoscopy or x-ray examination in adults (including the elderly) aged 18 years and over. The dose was usually administered as one sachet on the evening prior to the procedure and the second in the morning on the day of the procedure. Alternatively, both sachets were administered on the afternoon and evening prior to the procedure. This was more suitable when the procedure was early in the morning. The time between the sachets should be five hours.

COMPLAINT

The complainant stated that the advertisement described the following as 'remarkable events' which seemed inappropriate given the subject matter:

Cleen was claimed to have a 'quick action' but included no comparison. The claim was referenced to the summary of product characteristics (SPC) which did not refer to 'quick'. The complainant alleged that it was an unfair comparison if the reference was supposed to be reference 1 which was a comparison with glycerine suppositories.

The CitraFleet part of the advertisement included the statement 'the approval of the split dosage regime in accordance to the European Guidelines' which the complainant understood to mean that the guidelines supported CitraFleet but it was not mentioned in the guidelines. The advertisement also stated that 'CitraFleet is the FIRST SPMC [sodium picosulphate with magnesium citrate] in Europe combining split dose regime according to the Guidelines, with the lowest volumen and an effective colon cleansing **'.

The explanation for ** was 'than previous-day regimes. SPMC regimens. Split-dose regime approval date: December 2015'.

According to the complainant the only SPMC mentioned in the guidelines was Prepopik.

The complainant stated that the guideline listed other products as also having a volume requirement of two litres a day.

The complainant alleged that the claims 'Effective bowel cleansing with low side effects and less impact on daily living' and 'Preferred by patients for its low volumen, nice lemon flavour and the free choice of clear liquids' were not clear as to what they were in comparison to.

The complainant also struggled to read the prescribing information because there were more than 100 characters per line.

When writing to Recordati the Authority asked it to consider the requirements of Clauses 4.1, 7.2, 7.3 and 7.10 of the Code.

RESPONSE

Recordati submitted that it took its global corporate compliance responsibility very seriously and was particularly mindful of its overarching obligation

to ensure regulatory compliance of all external communications. Each external communication was subject to rigorous review according to its established process and procedures. Its established review policy took full account of the requirements in law and the Code.

Recordati submitted that the word 'remarkable' was not a superlative; the natural meaning of the expression 'remarkable events' was no more than 'noteworthy events'. In addition, the effect of the word in the context of the advertisement was not to claim anything particular about either product. It related to developments for Recordati as a company in relation to its product portfolio.

For Recordati, the announcement of a brand change to one of the company's oldest products, which had been marketed in the UK for over 20 years, could be characterised as a noteworthy development, and an important one that should be communicated to health professionals to avoid confusion.

In relation to CitraFleet, the approval of the product had taken the company a substantial amount of time and work; obtaining such an approval from the UK authorities for a split-dose mode of administration allowed Recordati to be the first company able to market a product which used a mode of administration that had been recommended by the European Society of Gastrointestinal Endoscopy (ESGE) Guideline ('Guideline') which was a noteworthy development.

Recordati submitted that taking into account the subject matter, use of the word 'remarkable' was not inappropriate in the context. It had no adverse public health consequences and was justified on a factual basis.

Recordati noted that the complainant stated that he/she struggled to read the prescribing information as there were more than 100 characters per line. Recordati submitted that the prescribing information for both products was positioned for ease of reference, and formed part of the advertisement. Supplementary information to Clause 4.1 set out 'recommendations' for the legibility of prescribing information. In line with the supplementary information, the type size used was no less than 1mm in height. There was sufficient space between the lines to facilitate reading, and a clear style of type was used. There was also adequate contrast between the colour of the text and the background (black and white), which, according to the Code, was preferable. In addition, emboldened headings were used at the start of each section of the prescribing information. The Code did not prohibit the use of greater than 100 characters per line; the recommendations, taken as a whole, were a guideline 'to help achieve clarity'. Deviations might occur depending on various factors such as whether a page were in portrait or landscape orientation. The prescribing information contained around 120-130 characters per line. Taking into account its compliance with every other recommendation, the company submitted that the prescribing information was readable, even though like all prescribing information, careful scrutiny was required and the information was not a substitute for consideration of the full SPC, where appropriate (such as where the SPC was relied upon to support a claim). For that reason Recordati considered that fulfilment of seven out of eight of the recommendations was sufficient, and that that part of the complaint was rather vexatious.

Recordati submitted that the reference for the claim for 'quick action' in the Cleen advertisement was the SPC. Section 4.2 (Posology and method of administration) stated that 'generally, 2-5 minutes are sufficient to obtain the desired effect'. Furthermore, Section 4.4 (Precautions for use) stated 'In general, evacuation occurs approximately 5 minutes after Clean Ready-to-Use Enema administration …'. Recordati submitted that in the context of a bowel cleanser, this would ordinarily be accepted to constitute 'quick action'.

Recordati submitted that Clause 7 allowed for comparisons with other products as long as the comparison was not misleading and the medicines were for the same needs or intended for the same purpose. The advertisement for Cleen did not constitute a comparative claim. The language did not suggest that the product was superior in some way to another; the phrase 'quicker action' might imply this, but the advertisement did not use that wording. Recordati had been using the claim that Cleen has 'quick action' for many years, across multiple countries, and without any objection being raised.

Recordati noted that the complainant stated that the inclusion of the phrase 'the approval of the SPLIT DOSE REGIME in accordance to the European Guidelines' in the advertisement for CitraFleet suggested that the Guideline referred to and endorsed the product CitraFleet by name. Recordati submitted that that was not the case and it would seem the health professional had misread the advertisement. The inclusion of the phrase was not misleading; it did not reference the product at all, but instead the type of regime. The recommendation in the Guideline concerned the split-dose regime. 'Split dose regime' was even capitalized in the advertisement, which left little doubt to the preference described in the Guideline for a split dose regime, and not for CitraFleet in particular. Recordati submitted that this part of the complaint was misconceived.

The Guideline recommended the use of this new split dose mode of administration (recently approved for CitraFleet) to ensure better cleansing results. This normally involved administering the dose partly in the evening and partly the following day before the procedure in question. The two products most used in this field were based on polyethylene glycol (PEG) and based on sodium picosulfate with magnesium citrate (SPMC). The Guideline cited a meta-analysis of five random controlled trials which found that, compared with the administration of the full dose of PEG on the day before colonoscopy, a split-dose regimen of PEG significantly improved the percentage of patients with satisfactory colon cleanliness, significantly increased patient compliance, and significantly decreased nausea. The Guideline recommended that regime

regardless of whether a patient was using SPMC or any other bowel evacuant. The Guideline recommended a split regimen of four litres of PEG solution (or a same-day regimen in the case of afternoon colonoscopy) for routine bowel preparation. A split regimen (or same-day regimen in the case of afternoon colonoscopy) of two litres PEG plus ascorbate or of SPMC were said to be valid alternatives.

Recordati submitted that the statement on CitraFleet being the first authorised product, containing SPMC to be administered in a split dose regimen, was a statement of fact. CitraFleet was approved for administration using a split dose regime in December 2015, and the SPC was updated accordingly. In June 2016, six months after CitraFleet obtained its authorisation for the split dose regimen, CitraFleet's competitor product, Picolax, also received approval for that new regimen.

Recordati stated that this part of the complaint was similar to that above but Recordati was not stating that the Guideline referred to CitraFleet as being the first SPMC in Europe combining the split dose regime. It was well known that Guidelines did not contain promotional statements in respect of particular products. The statement was that CitraFleet was the first SPMC in Europe which reflected the split dose regime that was recommended in the Guidelines. It was the regime that was being recommended by the Guideline, not a specific product. The fact that this statement followed the earlier prominent one referring to the concept of the split dose regime proposed by the Guidelines reinforced this overarching message.

Recordati submitted that the asterisk mentioned by the claimant was qualifying the text appearing in the boxed area mentioned above, stating that 'CitraFleet is the FIRST SPMC in Europe combining split dose regime according to the Guidelines with the lowest volumen and an effective colon cleansing'. The text under the asterisk added:

> '(**) than previous-day regimens. SPMC regimens. Split-dose regime approval date: December 2015.'

The reference to 'lowest volumen', in the advertisement did not amount to a comparative claim (ie lower than other products as the claimant argued). It was generally accepted and hardly surprisingly that clinicians looked for a product with the lowest volume compatible with effective cleansing. Therefore, Recordati was entitled to highlight that no other product in the market had a lower volume. CitraFleet had a volume intake of 300ml once reconstituted, which was the same volume intake as the competitor product Picolax. Both, CitraFleet and Picolax had the same low volume. This volume was the lowest compared with the volume intake of the rest of the bowel preparations on the market. Therefore both products had the 'lowest volume'. This fact was supported by CitraFleet's SPC which was referenced.

The volume intake for each bowel preparation on the market appeared in Section 4.2 (Posology and Method of Administration) of the SPCs. These volumes, taking into account the usual dose recommended for adults were: two litres for Moviprep, four litres for Klean Prep and 500ml for Eziclen.

Recordati submitted that the statement in the boxed area concerning effective colon cleansing from a split-dosing regimen was supported by scientific literature such as Prieto-Frias *et al*, 2013 cited as reference 9. This stated that the split-dosing regimen provided higher efficacy than the previous-day regimen as follows:

> 'Background and Aims: It is known that sodium picosulfate–magnesium citrate (SPMC) bowel preparations are effective, well tolerated and safe, and that split-dosing is more effective for colon cleansing than previous-day regimens. (…)'

This statement was further supported by Schulz *et al*, 2016 which concluded that:

> 'A split-dose regimen of SPMC is superior to the AM/PM regimen administered the day before colonoscopy. Split regimen of SPMC should be considered the standard of use.'

Recordati submitted that in relation to the claim of effective bowel cleansing, the advertisement did not claim that SPMC provided more effective bowel cleansing than any other product, and that part of the claim was not a comparative statement. But the statement of effective cleansing was supported by the literature references Choi *et al*, 2014 and Hawkins *et al*, 1996.

With respect to the claim that CitraFleet offered 'low side effects and less impact on daily living', the results of the same studies and also Hamilton *et al*, 1967 showed that SPMC (or MC-SP) provided significantly better cleansing in the right colon, and better acceptability and tolerability profile in patients, compared to that achieved with a two litre PEG + ascorbic acid solution. Both solutions showed a similar level of effectiveness with regard to the overall quality of bowel cleansing.

Recordati submitted that with regard to the preference of patients for CitraFleet's low volume, Mane *et al*, 2013 showed that the better acceptability and tolerability of SPMC was due, among other things, to the amount of volume the patient was required to drink. A comparison between sodium picosulphate PEG for large bowel lavage and sodium picosulphate solution found the latter was more acceptable to patients than PEG and resulted in significantly less nausea and vomiting ($p = 0.0025$) and far fewer consumption difficulties ($p < 0.0001$); the volume intake required for the PEG solution, Klean-Prep was a significant problem. Neither cleansing solution showed a distinct efficacy advantage on the other. However due to the fact that sodium picosulphate was more acceptable to patients, the article stated that sodium picosulphate was the preferred solution for bowel preparation. This acceptability encompassed the taste of the product.

Recordati concluded that it fully appreciated and respected its obligations under the Code and applicable legislation with respect to promotion of its products. However, the complaint was unfounded. The statements made could be justified within the meaning of the Code and applicable legislation.

For the reasons given above, Recordati denied breaches of Clause 4.1, 7.2, 7.3 and 7.10 and stated that the complaint lacked merit.

PANEL RULING

The Panel noted that the reference to remarkable events appeared as part of a heading across the advertisement that Recordati was committed to improve patients' quality of life and was '… delighted to announce, two remarkable events' and thus, in the Panel's view, applied to the matters described in each part. The Panel noted Recordati's submission that the remarkable events related to developments in its product portfolio. The Panel did not accept that 'remarkable' (defined as notably or conspicuously unusual, extraordinary, worthy of notice or attention) would necessarily be interpreted by most readers as closely similar to 'noteworthy' (defined as worthy of notice or attention; notable, remarkable). The word 'remarkable' implied an unusual, extraordinary development. The Panel did not consider that either rebranding a well-established medicine or delivering a split dose regimen in this therapeutic area would be seen as remarkable events. The Panel considered that this exaggerated the developments described in each advertisement and ruled a breach of Clause 7.10.

In relation to the claim that Cleen had a 'Quick Action' the Panel considered this could potentially be read as a comparison with other products. The SPC did not describe the product as having a quick action. The Cleen SPC stated 'Generally 2 to 5 minutes are sufficient to obtain the desired effect. If delayed discontinue further use and consult a physician'. In the Panel's view this might be seen as quick. The Panel noted that the complainant referred to reference 1 which was a comparison of Fleet and glycerin suppositories (Underwood *et al* 2009). However, none of the claims in the advertisement cited reference 1. The study had not been provided by Recordati or by the complainant. The claim in question 'Quick Action' was referenced to the SPC. The Panel did not consider that the complainant had proven on the balance of probabilities that the claim was misleading as alleged or a comparison with glycerine suppositories and that such a comparison would be unfair. The Panel ruled no breach of Clauses 7.2 and 7.3 in this regard.

With regard to the claim regarding CitraFleet and split dosing, the Panel noted Recordati's submission that the product was licensed for such use in December 2015 and the competitor was so licensed in June 2016. The Panel noted that there were three recommendations in the ESGE Guideline, firstly a low fibre diet on the day preceding colonoscopy. Secondly, a split regimen of 4 litres of polyethylene glycol (PEG) solution (or same day regimen in the case of afternoon colonoscopy), a split regimen of 2 litres PEG plus ascorbate or of SPMC might be valid alternatives. Thirdly, advising against the routine use of sodium phosphate. The ESGE Guideline was based on a targeted literature search. The Guideline mentioned Picolax and Picoprep in relation to SPMC. There was no mention of CitraFleet. The Panel noted the claims that 'The Approval of the SPLIT DOSE REGIME in accordance to the European Guidelines' appeared immediately below the brand name and 'CitraFleet is the FIRST SPMC in Europe combining split dose regime according to the Guidelines …'. The Panel considered the advertisement gave the impression that the split dose regimen of CitraFleet was mentioned and supported by the Guidelines which was not so. The advertising was misleading as alleged and a breach of Clause 7.2 was ruled.

The Panel considered that the claim 'CitraFleet is the First SPMC in Europe combining split dose regime according to the Guidelines, with the lowest volumen and an effective colon cleansing**' was a comparative claim as it implied CitraFleet had the lowest volume. The Guidelines referred to magnesium citrate as a low volume bowel preparation in combination with a variety of stimulants including sodium picosulphate (Picolax or Picoprep). The Guideline referred to its combination with 2 litres of PEG. There was no mention of CitraFleet in the Guideline. The Panel noted Recordati's submission that both CitraFleet and Picolax had the same volume when reconstituted ie 300ml. However, only one product could have the lowest volume and CitraFleet therefore did not have the lowest volume. This use of a superlative was therefore ruled in breach of Clause 7.10. Further the Panel considered that the volume related to the whole treatment ie reconstituted medicine plus required clear liquid rather than just the reconstituted medicine. The Panel noted that each CitraFleet sachet was reconstituted in a cup of water and a further 1.5 to 2 litres of clear fluid was to be taken 10 minutes after that. Picolax was reconstituted in a cup of water, approximately 150ml followed by at least five 250ml drinks of clear liquid, ie 1.25 litres. The second sachet was similarly reconstituted and to be followed by at least three 250ml drinks, ie 0.75 litres. Each bottle of Izinova was diluted in water to approximately 0.5 litres followed by one litre of water or clear fluid within 2 hours. Those appeared to be lower volume requirements than CitraFleet. The comparator was not clear as alleged. The claim for lowest volume was also misleading and the Panel ruled breaches of Clauses 7.2 and 7.3.

The Panel considered that the claim 'Effective bowel cleansing with low side effects and less impact on daily living' implied a comparison with a product that had more impact on daily living. Recordati's response referred to studies comparing SPMC with PEG. Choi *et al* compared Coolprep with Picolight (MS-SP). Hawkins *et al* compared Picolax with Klean-Prep, ie SPMC with PEG. Hamilton *et al* was dated 1996 and not 1967 as stated by Recordati in its response. This study compared Picolax with Klean Prep, ie SPMC and PEG. The Panel noted that the advertisement did not mention the comparator (PEG) and as this had not been made clear, the Panel considered that this omission rendered the claim 'Effective bowel cleansing

with low side effects and less impact on daily living' misleading. A breach of Clauses 7.2 and 7.3 was ruled.

The claim 'Preferred by patients for its low volumen, nice lemon flavour and the free choice of clear liquids' was the final bullet point. It was referenced to Manes *et al* 2013 which compared SPMC citrate with low volume PEG plus ascorbic acid. The Panel considered that the comparator in the claim was not clear and its omission rendered the claim 'Preferred by patients for its low volumen, nice lemon flavour and the free choice of clear liquids' misleading. A breach of Clauses 7.2 and 7.3 was ruled.

The supplementary information to Clause 4.1 gave recommendations to assist legibility including, *inter alia*, that lines should be no more than 100 characters in length, including spaces and that sufficient space should be allowed between the lines to facilitate easy reading. The Panel noted the line length used in the prescribing information in the advertisement at issue was longer than 100 characters.

The Panel considered that the line length and spacing between the lines meant that the prescribing information was not clear or legible. A breach of Clause 4.1 was ruled.

Complaint received **21 September 2016**

Case completed **23 November 2016**

HEALTH PROFESSIONAL v ABBVIE

Promotion of Humira

A health professional who until recently worked in the pharmaceutical industry complained about a Humira (adalimumab) journal advertisement issued by AbbVie.

The complainant stated that the two page advertisement included the claim 'Fast symptom relief from week 1 (CD) and week 2 (UC)'. The complainant considered that 'fast' was a relative term and stated that there were other treatments that were as fast or faster as symptoms could be varied. Opiates and antispasmodics could provide symptom relief within hours.

The detailed response from AbbVie is given below.

The Panel noted AbbVie's submission that the claim related solely to the effect of Humira, with no comparisons being made to other treatments. The Panel further noted AbbVie's submission that the promotion of Humira for the treatment of moderately to severely active adult Crohn's disease (CD) and ulcerative colitis (UC) was in accordance with the terms of its marketing authorisation and was not inconsistent with the particulars listed in the summary of product characteristics (SPC). The Panel noted that unlike the advertisement the SPC did not describe the product as providing fast symptom relief from week 1 in Crohn's disease and week 2 in ulcerative colitis. The Humira SPC stated 'Available data in ulcerative colitis suggest that clinical response is usually achieved within 2-8 weeks of treatment.'

The Panel noted that the complainant referred to opiates and antispasmodics but provided no data in support of his/her contention. The Panel noted that AbbVie had not responded in detail with regard to the action of opiates and antispasmodics effects on symptom relief other than to state that these two medicines were not listed as agents with the ability to provide induction of remission for patients with inflammatory bowel disease (IBD) according to NICE or within guidance issued by the British Society of Gastroenterology (BSG). In contrast, NICE referred to biologic agents as therapies which could be used to induce and maintain remission in IBD.

The Panel noted that the complainant was concerned about the alleged comparative nature of the word 'fast'. However, overall and on balance the Panel did not consider that the claim at issue 'Fast symptom relief from week 1 (CD) and week 2 (UC)' within the context of the advertisement was a comparison. Neither the headline nor the visual were comparative. The claims beneath did not refer to other products. None of the three studies referenced included any comparator products although this was not made clear in the advertisement. The Panel did not consider that the complainant had proven on the balance of probabilities that the claim was a comparison with other medicines including opiates or antispasmodics and that such a comparison was unfair and misleading. Based on the very narrow allegation, the Panel ruled no breach of the Code.

Noting its comments above the Panel did not consider that the use of the word 'fast' exaggerated the clinical comparative efficacy of Humira as alleged. No breach of the Code was ruled.

A health professional who until recently worked in the pharmaceutical industry, albeit in a different therapeutic area, complained about an advertisement (ref AXHUG160440b(2)) for Humira (adalimumab) issued by AbbVie Ltd. The advertisement was published in Gastrointestinal Nursing, September 2016.

Humira was indicated, *inter alia*, for the treatment of moderately to severely active Crohn's disease, in adult patients who had not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who were intolerant to or had medical contraindications for such therapies and for the treatment of moderately to severely active ulcerative colitis in adult patients who had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who were intolerant to or had medical contraindications for such therapies.

COMPLAINT

The complainant stated that the two page advertisement included the claim 'Fast symptom relief from week 1 (CD) and week 2 (UC)'. The complainant considered that 'fast' was a relative term and stated that there were other treatments that were as fast or faster as symptoms could be varied. Opiates and antispasmodics could provide symptom relief within hours.

When writing to AbbVie the Authority asked it to respond in relation to the requirements of Clauses 7.2 and 7.10 of the Code.

RESPONSE

AbbVie submitted that the claim in question was fully substantiated using accurate data representing the most up to date published information. The claim related solely to the effect of Humira, with no comparisons being made to other treatments. It was consistent with the use of Humira within the licensed population of patients with moderately to severely active Crohn's disease or ulcerative colitis.

AbbVie explained that Humira was an anti-tumour necrosis factor (TNF) biologic agent with multiple

indications, including inflammatory bowel disease (IBD). AbbVie submitted that moderate to severely active IBD, followed a chronic, relapsing, remitting disease course. According to the National Institute for Health and Care Excellence (NICE) quality standards for IBD, the aim of treatment was 'either to heal the inflammation and so reduce symptoms during a flare-up (inducing remission) or to prevent flare-ups happening in the future (maintaining remission)'.

AbbVie noted that the two medicines mentioned by the complainant, opiates and anti-spasmodics, were not listed as agents with the ability to provide induction of remission for patients with IBD according to NICE or within guidance issued by the British Society of Gastroenterology (BSG). In contrast, NICE referred to biologic agents as therapies which could be used to induce and maintain remission in IBD.

The information contained within the advertisement regarding the promotion of Humira for treatment of moderately to severely active adult Crohn's disease (CD) and ulcerative colitis (UC) was in accordance with the terms of its marketing authorisation and was not inconsistent with the particulars listed in the summary of product characteristics (SPC). It was not inappropriate in promotional material for Humira, to make reference to the time at which symptom relief occurred, as this would be of interest to specialists treating patients with IBD.

A named consultant gastroenterologist described the significance of symptom reduction in this population of patients as:

> 'Adalimumab improves quality of life and reduces rectal bleeding within 2 weeks when used for ulcerative colitis and symptom improvement starts within a week when treating Crohn's disease. This fast onset of action benefits patients who have objective evidence of active inflammation.'

AbbVie therefore submitted that using the term 'fast' to describe a 1-2 week response time to onset of symptom relief was appropriate and fully understood by IBD specialists. Clinical data for Humira focussed on the importance of symptom relief, both from a clinical and patient perspective. The references used to substantiate the claim described both:

1 Time to significant reduction in clinical symptoms, using comprehensive disease-related symptom scores (Crohn's disease activity index (CDAI) for CD and simple clinical colitis activity index (SCCAI) for UC). These clinical symptom scores were used in clinical trials, by the regulatory authorities and were widely recognised by clinicians treating IBD.

2 **Patient-reported symptom relief** using validated questionnaires specific to patients with IBD (inflammatory bowel disease questionnaire (IBDQ) and short IBDQ (SIBDQ) for CD and UC, respectively). These scales were widely used in studies of IBD and recommended by the regulatory authorities.

AbbVie submitted that there was no breach of Clause 7.2, as the term 'fast' was being used in an accurate, objective and qualified manner to reflect the impact of treatment on clinical and patient reported symptoms in the moderately to severely active CD and UC population at early time points. No absolutes such as 'immediate' had been used which ensured the claim was neither misleading, nor a hanging comparison.

AbbVie denied a breach of Clause 7.10 as the claim did not exaggerate the properties of Humira, as the relevant timings (ie week 1 and week 2) were clearly stated and all information was fully substantiated within the references provided. The claim also did not use any superlatives, such as 'faster' or 'fastest'.

AbbVie concluded that it had not breached Clauses 7.2 or 7.10. The advertisement was accurate and clearly substantiated, describing the outcomes of using Humira when considering the rational use in the licensed populations of patients with moderately to severely active Crohn's disease and ulcerative colitis.

AbbVie confirmed that the advertisement was displayed across two adjacent pages of the journal and when viewed was similar in size to A3.

PANEL RULING

The Panel noted the complainant's concern that the word 'fast', which appeared in the claim 'Fast symptom relief from week 1 (CD) and week 2 (UC)' within the Humira advertisement, was a relative term. According to the complainant there were other treatments that were as fast or faster as symptoms could be varied. The complainant stated that opiates and antispasmodics could provide symptom relief within hours.

The Panel noted AbbVie's submission that the claim related solely to the effect of Humira, with no comparisons being made to other treatments. The Panel further noted AbbVie's submission that the promotion of Humira for the treatment of moderately to severely active adult Crohn's disease (CD) and ulcerative colitis (UC) was in accordance with the terms of its marketing authorisation and was not inconsistent with the particulars listed in the SPC. The Panel noted that unlike the advertisement the SPC did not describe the product as providing fast symptom relief from week 1 in Crohn's disease and week 2 in ulcerative colitis. The Humira SPC stated 'Available data in ulcerative colitis suggest that clinical response is usually achieved within 2-8 weeks of treatment.'

The Panel noted that Crohn's disease and ulcerative colitis were the 2 main forms of inflammatory bowel disease. The NICE Quality Standard on inflammatory bowel disease stated that in Crohn's disease, inflammation of the digestive system led to diarrhoea, abdominal pain, tiredness and weight loss. Symptoms of active disease or relapse of ulcerative colitis included bloody diarrhoea, an urgent need to defecate and abdominal pain. According to NICE the aim when treating

inflammatory bowel disease was either to heal the inflammation and so reduce symptoms during a flare-up (inducing remission) or to prevent flare-ups happening in the future (maintaining remission).

The Panel noted that 'fast' might be considered by some to be a relative term and thus the claim could potentially be read as a comparison with other products. The Panel noted that the complainant referred to opiates and antispasmodics but had provided no data in support of his/her contention. The Panel noted that AbbVie had not responded in detail with regard to the action of opiates and antispasmodics effects on symptom relief other than to state that the two medicines mentioned by the complainant were not listed as agents with the ability to provide induction of remission for patients with IBD according to NICE or within guidance issued by the British Society of Gastroenterology (BSG). In contrast, NICE referred to biologic agents as therapies which could be used to induce and maintain remission in IBD. The claim in question referred to symptom relief from weeks 1 and 2 and was referenced to Hanauer *et al* 2006 and Sandborn *et al* 2007 with regard to Crohn's disease and Travis *et al* 2016 with regard to ulcerative colitis.

Hanauer *et al* was a randomized, double-blind, placebo-controlled, dose-ranging trial to evaluate the efficacy of adalimumab induction therapy in patients with moderated to severe Crohn's disease naïve to anti-TNF therapy. The primary endpoint was demonstration of a significant difference in the rates of remission at week 4. The rates of remission at week 4 in the SPC recommended 80mg/40mg adalimumab dose group was 24% (p=0.06). The Panel noted that the study stated that significant responses compared with placebo were demonstrated as early as week 1 in this dose group; patients in the 80mg/40mg treatment group (75 patients) had significantly lower mean Crohn's disease activity index (CDAI) scores and higher mean inflammatory bowel disease questionnaire (IBDQ) total scores than patients in the placebo group. The study authors acknowledged that it was a short 4-week trial and there was insufficient data to determine whether an 80mg loading dose followed by 40mg every other week would be effective for induction and maintenance of remission in patients with Crohn's disease.

Sandborn *et al*, was also a 4 week, randomized, double-blind, placebo-controlled trial in which patients were randomly assigned to receive induction doses of adalimumab, 160mg and 80mg, at weeks 0 and 2, respectively or placebo at the same time points. The primary end point was induction of remission at week 4. At week 4, 21% of patients in the adalimumab group compared with 7% of patients in the placebo group achieved remission (p<0.001) whilst patients in the adalimumab group had statistically significantly lower mean CDAI total scores at weeks 1, 2 and 4 than did patients in the placebo group. The Panel noted that the Humira SPC stated that the recommended dose for adult patients with moderately to severely active Crohn's disease was 80mg at week 0 followed by 40mg at week 2. The SPC further stated that if there was a need for a more rapid response to therapy then 160mg at week 0 and 80mg at week 2 could be used with the awareness that the risk for adverse events was higher during induction. After induction treatment, the recommended dose was 40mg every other week via subcutaneous injection.

Travis *et al* was a poster presented at the European Crohn's and Colitis Organisation (ECCO) in March 2016 which detailed a single-arm, multi-country, open-label study that evaluated the effect of adalimumab on clinical outcomes, health-related quality of life (HRQoL), and costs of clinical care in patients with ulcerative colitis treated according to usual clinical pratice. Patients received 160mg/80mg adalimumab at week 0/2 followed by 40mg every other week at week 4 through week 26. Data from 461 patients were analysed and at week 2, 74% achieved Simple Clinical Colitis Activity Index (SSCAI) response, defined as a decrease of ≥ 2 points compared to baseline, at week 2 and 27% achieved SCCAI remission.

The recommended Humira induction dose regimen for adult patients with moderate to severe ulcerative colitis was 160mg at week 0 and 80mg at week 2. After induction treatment, the recommended dose was 40mg every other week via subcutaneous injection.

The Panel noted that the complainant was concerned about the alleged comparative nature of the word 'fast'. However, overall and on balance the Panel did not consider that the claim at issue 'Fast symptom relief from week 1 (CD) and week 2 (UC)' within the context of the advertisement was a comparison. Neither the headline nor the visual were comparative. The claims beneath did not refer to other products. None of the three studies referenced included any comparator products although this was not made clear in the advertisement. The Panel did not consider that the complainant had proven on the balance of probabilities that the claim was a comparison with other medicines including opiates or antispasmodics and that such a comparison was unfair and misleading. Based on the very narrow allegation, the Panel ruled no breach of Clause 7.2.

Noting its comments above the Panel did not consider that the use of the word 'fast' exaggerated the clinical comparative efficacy of Humira as alleged. No breach of Clause 7.10 was ruled.

Complaint received **21 September 2016**

Case completed **10 January 2017**

MEMBER OF THE PUBLIC v MEDA

Alleged promotion to the public

A member of the public complained about an EpiPen (adrenaline auto injector) Facebook post by the mother of a child with life-threatening allergies. It consisted of a photograph of two EpiPens followed by the statement 'This petition supports the #carrytwocampaign. We ask the British Society for Allergy and Clinical Immunology BSACI to reverse its recommendation of one auto injector pen, back to two'. This was followed by a link to the petition.

The complainant objected to the advertising of only one of three available adrenaline pens to 50,000 individuals. The complainant did not know if the person who posted the petition had received any gratuity and regardless of whether she did it was still advertising a prescription only medicine to the public.

The complainant stated that had all three options been included there would have at least been equal bias but either way she considered that Facebook should not be a platform for advertising prescription only medicines to the public.

The detailed response from Meda is given below.

The Panel noted Meda's submission that it had had no involvement with the petition or the Facebook post and it had not had any contact directly or indirectly with the person involved or provided the photograph. The Panel considered that on the information before it, Meda had had no involvement with the petition or Facebook post and thus it could not be in breach of the Code. The Panel ruled no breach of the Code including Clause 2.

A member of the public complained about an EpiPen (adrenaline auto injector) advertisement placed on Facebook. The Facebook post was from the mother of a child with life-threatening allergies who was concerned that the British Society for Allergy and Clinical Immunology (BSACI) had recommended that prescriptions for adrenaline auto injector pens should be changed from a minimum of two pens to one.

The Facebook post consisted of a photograph of two EpiPens followed by the statement 'This petition supports the #carrytwocampaign. We ask the BSACI to reverse its recommendation of one auto injector pen, back to two'. This was followed by a link to the petition.

COMPLAINT

The complainant stated that she did not object to the sentiment of the petition but rather to the advertising of only one of three available adrenaline pens to 50,000 individuals. The complainant did not know if the person who posted the petition had received any gratuity for it but considered that it was possible and regardless of whether she did it was still advertising a prescription only medicine to the public.

The complainant stated that had the advertisement been presented with all three options there would have at least been equal bias but either way she considered that Facebook should not be a platform for advertising prescription only medicines to the public.

When writing to Meda the Authority asked it to respond in relation to the requirements of Clauses 26.1, 9.1 and 2.

RESPONSE

Meda stated that it had no involvement in the carry two Facebook petition and was unaware of it until notified of the complaint. It was unaware of the mother who posted the petition and had never had any contact directly or indirectly with her. Meda submitted that it did not provide the EpiPen photograph in question nor had it paid any gratuity or provided any benefits for the publication of the photograph. Meda stated that photographs of all adrenaline auto injectors were easily accessible via the Internet. Meda concluded that it had no involvement with the petition on Facebook and was committed to abiding by the Code at all times.

PANEL RULING

The Panel noted Meda's submission that it had had no involvement with the petition or the Facebook post. The Panel further noted Meda's submission that it had not had any contact directly or indirectly with the person involved nor had it provided the photograph. The Panel considered that on the information before it, Meda had had no involvement with the petition or Facebook post and thus it could not be in breach of the Code. The Panel ruled no breach of Clauses 2, 9.1 and 26.1.

Complaint received **28 October 2016**

Case completed **16 November 2016**

ANONYMOUS, NON CONTACTABLE v BRISTOL-MYERS SQUIBB

Orencia patient support service

An anonymous non-contactable member of public alleged that his/her mother had a distressing experience when a nurse from a third party paid for by Bristol-Myers Squibb allegedly attempted to call at her house unannounced.

The complainant explained that his/her mother had severe rheumatoid arthritis and was prescribed Orencia (abatacept) in 2014. The complainant stated that the situation had upset his/her mother and another patient who was too scared to say anything.

The complainant stated that after being started on Orencia in 2014, his/her mother suddenly had someone calling at her house to show her how to use the injection. She refused to open the door as no one had warned her that anyone was going to visit. The person explained she was from a named third party and that the doctor had sent her.

Upon enquiry to the hospital, the complainant was told that this was part of the service from the NHS and he/she wondered why no one had communicated this and why his/her permission had not been sought to visit his/her mother at home.

The complainant usually attended most of his/her mother's hospital appointments and was puzzled when the nurse showed him/her a blank form and stated that the doctor would have signed the consent form on his/her mother's behalf. The complainant was shocked as he/she was not aware that doctors could make decisions for patients without their relatives being informed.

The situation caused the complainant's mother distress especially seeing as she had not asked for the visits. The complainant did not trust pharmaceutical companies and was upset to find that Bristol-Myers Squibb was paying for the nurse.

The complainant queried how it was possible that someone could visit an old woman's house without any permission and without telling him/her. The complainant stated that according to the citizens advice bureau it was not a legal action for the doctor to sign for his/her mother to be visited by Bristol-Myers Squibb or its third party.

The detailed response from Bristol-Myers Squibb is given below.

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints would be accepted, but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. The Panel noted that extreme dissatisfaction was usually required on the part of an individual before he or she was moved to complain. All complaints were judged on the evidence provided by the parties. The complainant had not provided sufficient information so that the particular circumstances could be identified. The complainant could not be contacted for more information.

Notwithstanding its comments about the consent forms the Panel did not consider that the complainant had provided sufficient information to demonstrate on the balance of probabilities that Bristol-Myers Squibb's arrangements were inadequate in relation to the complaint's mother or had not been followed. No breach of the Code including Clause 2 was ruled.

An anonymous non-contactable member of the public alleged that his/her mother had a distressing experience when a nurse from a third party allegedly attempted to call at her house unannounced.

The complainant explained that his/her mother had severe rheumatoid arthritis and was prescribed Orencia in 2014. The complainant stated that his/her mother's doctors and nurses were generally very nice but this situation upset her and another patient who was too scared to say anything. The complainant wished to remain anonymous due to fear that his/her mother would be victimised and treated badly.

Bristol-Myers Squibb Pharmaceuticals Limited's product Orencia (abatacept) in combination with methotrexate was indicated for use in rheumatoid arthritis.

COMPLAINT

The complainant stated that after being started on Orencia in 2014, his/her mother suddenly had someone calling at her house to show her how to use the injection. She refused to open the door as no one had warned her that anyone was going to visit and there had recently been burglaries in the area. The person explained that she was from the third party and that the doctor had sent her. The patient called the complainant but by the time he/she arrived at his/her mother's house the caller had gone.

Upon enquiry to the hospital, the complainant was told that this was part of the service from the NHS and he/she wondered why no one had communicated this and why his/her permission had not been sought to visit his/her mother at home.

The complainant knew how frightened his/her mother was of visitors and he/she had been advised to apply for power of attorney to manager her affairs as she was getting older.

The complainant usually attended most of his/her mother's hospital appointments and was puzzled when the nurse showed him/her a blank form and stated that the doctor would have signed the consent form on his/her mother's behalf. The complainant was shocked as he/she was not aware that doctors could make decisions for patients without their relatives being informed.

The situation caused the complainant's mother distress especially seeing as she had not asked for visits. The complainant did not trust pharmaceutical companies and was upset to find that Bristol-Myers Squibb was paying for the nurse.

The complainant queried how it was possible that someone could visit an old woman's house without any permission and without telling him/her. The complainant stated that according to the citizens advice bureau it was not a legal action for the doctor to sign for his/her mother to be visited by Bristol-Myers Squibb or the third party.

The complainant decided to submit this complaint after all that time as he/she has heard that it happened to another lady at the same hospital. The complainant stated that the nurses and doctors at the hospital were very nice to his/her mother and hoped that it could be looked into to stop other patients from having the same experience.

When writing to Bristol-Myers Squibb the Authority asked it to consider the requirements of Clauses 2, 9.1, 18.1 and 18.4 of the 2014 Code.

RESPONSE

Bristol-Myers Squibb submitted that it strove to ensure that the homecare service provided for patients treated with Orencia (abatacept), was of a high quality and met the needs of its health professionals and patients. Bristol-Myers Squibb was therefore concerned to hear of the alleged incident.

Bristol-Myers Squibb submitted that the anonymous nature of the complaint made it difficult to provide specific commentary and response, however it provided details of the standard operating procedure followed once a patient had been prescribed subcutaneous Orencia and had consented to receive the service.

Given the comprehensive procedures and protocols which were in place, Bristol-Myers Squibb was confident that prior consent to receive the homecare service would have been obtained from the patient and that this alleged nurse visit could only have taken place by directly booking an appointment with the patient.

Bristol-Myers Squibb therefore refuted the allegations and breaches of Clauses 2, 9.1, 18.1 and 18.4.

Bristol-Myers Squibb explained that Orencia was a biologic Disease Modifying Anti Rheumatic Drug (bDMARD) and as with most other bDMARDs, Orencia was administered via infusion and/or subcutaneously. Orencia was marketed subcutaneously via a pre-filled syringe and since June 2015 as a pre-filled pen device (ClickJect). It was also available as an intravenous formulation which was outside the scope of the homecare service. Orencia required cold chain storage and distribution between 2°C and 8°C.

As the complaint related to the 2014 period Bristol-Myers Squibb included the relevant summary of product characteristics (SPC) for the pre-filled syringe as it was the only formulation in scope of the homecare service.

Rheumatoid arthritis (RA) was an autoimmune disease which impacted the joints of patients who commonly presented with swollen or tender joints in the hands, wrists and feet. Patients could become severely disabled by rheumatoid arthritis in its advanced stages and many patients had effects on the hands where there were deformities of the digits, including deviation of metacarpophalangeal joints and swan-neck deformity of the fingers. This could lead to some patients with rheumatoid arthritis being unable to grasp objects properly and made it difficult for them to carry out daily tasks of living, such as impacting their ability to use a pen or to administer injections properly.

As these medicines could be administered subcutaneously at home without the support of a health professional, there was a requirement to provide training to patients on how to safely administer their medication. For that reason, it was common practice for suppliers of subcutaneous biologic therapies, within the rheumatology field, to offer homecare services to their patients due to the long term nature of the condition and the requirement for regular treatment.

Bristol-Myers Squibb engaged a named third party to provide cold chain medicine delivery as well as nurse training and support to patients prescribed subcutaneous Orencia. The third party worked in partnership with the NHS, the pharmaceutical industry and private medical insurers to support patients with a range of conditions.

The purpose of the homecare service for Orencia was:

- To ensure that the patient received a continual supply of the cold chain medicine, without interruption, except when specifically requested by their clinician.

- To provide patients with nurse training in their own home once they had received delivery of Orencia. The training was provided to ensure that the patient was familiar with their medication and understood how to safely administer the injection. The nurse also educated the patient on when it might not be safe to administer and how to report any issues they might have with their treatment. In some instances where the patient was unable to safely administer their own medication the nurse might be required to do this on their behalf. Additionally the nurse would ensure that the patient understood the requirements for storage of their treatment and sharps disposal.

The nurse visit would only take place once the delivery of Orencia had been arranged with and delivered to the patient.

Bristol-Myers Squibb submitted that the service was part of a package deal made available to patients who had been prescribed Orencia and who consented to the homecare service. Only NHS trusts that entered into a service level agreement with the third party could take advantage of the service.

When a health professional, in conjunction with the patient/carer, made a decision to prescribe subcutaneous Orencia a number of steps were required before patients could receive the homecare service.

Following the initial discussion with the health professional there were multiple processes and safeguards in place to ensure that patients had consented to the homecare service and were able to safely receive, store and administer their medication. Details were provided.

If the health professional believed that the patient/carer would also benefit from receiving the homecare service, a discussion took place between the health professional and the patient/carer. At the end of this conversation if, and only if, the patient consented to receive the service, the health professional was required to complete the 'Abatacept SC Patient Registration' form.

Both the health professional and the patient/carer must sign the form to confirm that consent had taken place. If, for any reason the patient was unable to sign the consent section, (eg where a patient had rheumatoid arthritis related complications of the hand joints and had difficulty in using a pen), it was possible that the health professional could sign on the patient's behalf to confirm that the service had been discussed and that consent had been obtained from the patient to receive this service.

The 'Patient Registration' form was updated in 2014. As the complaint letter did not refer to a specific date within 2014 when the alleged event took place, Bristol-Myers Squibb provided the two versions of the form that spanned that period, Version 1 available from January 2013 and Version 2 available from June 2014.

Bristol-Myers Squibb noted that there were some differences between the two versions of the form. Mainly, these were minor text changes in the initial sections. There were also changes made to the 'patient consent' and 'referring physician' sections, further details were provided below.

Both forms required the following information to be completed:

- Patient details
- Referring trust
- GP details
- Patient adverse event reporting consent
- Invoicing details
  Prescriber adverse event reporting consent
  Information required prior to dispensing
  Patient consent
  Referring clinician declaration.

Bristol-Myers Squibb noted that there was one NHS trust that used a slightly different patient registration form. However, the core content and declarations were similar to the main registration form provided.

Bristol-Myers Squibb drew attention to the section 'Information required prior to dispensing' on both versions of the forms. In that section there was a requirement for the clinician to tick whether the patient required training by the nursing service. This should only be ticked after the clinician had had a detailed discussion with the patient to determine if they required the nurse training service and were in agreement to provide their consent for the training to be delivered by nurses from the third party.

The two versions of the forms had relevant declarations in the 'Patient consent' sections for the patient to receive the service. Version 1 required the patient/parent/guardian to sign to give consent. The declaration had wording pertaining to the provision of the … Service:

> 'I confirm my agreement for … to hold, update and use my information for the purpose of providing, monitoring and improving a home delivery service.'

Additionally, the 'referring clinician' had to sign the document which had the following declaration:

> 'I have fully explained and discussed the homecare service with the patient and he/she has given their explicit informed consent to receive this service from …. The patient understands and consents to his/her personal and health information being passed to and processed by …, under the provisions of the Data Protection Act 1998, in order for the homecare service to be provided to them.'

Version 1 could be signed by the patient, parent or guardian. Version 2, made available in June 2014, had slightly different declarations. Version 2 was amended to remove the option for the parent/guardian to sign on the patient's behalf. There was an accompanying amendment to the 'referring physician' section also such that consent was 'to be completed by the referring clinician/Trust representative (if the patient is unable to sign)'.

Version 2 was introduced in response to clinician feedback that patients often had physical difficulty in signing the document due to their disease. To support the patient the form was therefore modified so that the onus was on the referring physician/trust representative to obtain explicit consent before signing the form and thus confirming that such consent had been obtained from the patient. It had been, and still was, a requirement that the patient should be able to comprehend and consent to the service before either version of the form was signed. Both forms had clear information stating: 'This registration form will not be processed … unless it is completed in full and accompanied by a valid prescription'.

Once the form had all relevant sections completed, it was faxed to the third party. In order to initiate

the service, the third party had multiple processes and safeguards in place to ensure that patients had consented to the service and were able to safely receive, store and administer their medication.

Once the registration form and a valid prescription had been received a patient services co-ordinator was required to telephone the patient (installation call) to confirm, *inter alia*, whether the patient had been informed of and consented to the service. There would be an additional explanation of the service and the patient would be given the opportunity to ask questions throughout the call. A script was provided.

- If a patient did not consent to receiving the service in the installation call, they would stop the call and refer the patient back to the hospital.
- If the patient had consented to receive the service the co-ordinator would organise a delivery slot for the patient to receive their medicine and sharps bin.

If the 'training required' tick box had been selected on the 'patient registration' form, an additional telephone call to the patient was made by a nurse co-ordinator to organise a nurse visit. The purpose of the nurse training visit was to teach the patient and/or carer how to administer their medicine safely. As mentioned previously the nurse also educated the patient on when it might not be safe to administer their medication and how to report any issues they might have with their treatment. This visit was always scheduled post-delivery of their medication.

The details of the call made by the nurse co-ordinator was summarised in work instruction. A 'Patient Information Form and Environmental Risk Assessment – Injections' form – SP-NUR-508** was filled in to record vital information needed for the nurse to carry out the visit.

Once the visit date and time had been agreed, one of the team would contact the referring hospital via telephone to inform them of the appointment so that any follow up appointments required could be arranged by the trust.

Following the initial call, if a patient had consented to receiving the service, information packs would be sent to the patient. The information packs provided further details about the service, what to expect and the planned nurse visit (if applicable). This pack was posted to ensure it arrived prior to the first scheduled delivery of the medicine. The welcome information packs included the following documents:

- Patient Information Guide: Sometimes home is the best place to be.
- There was an insert included with this 'Information For Patients Receiving Subcutaneous Orencia (Abatacep)'.

Bristol-Myers Squibb noted the relevant content of the documents were as follows:

a) 'Patient Information Guide: Sometimes home is the best place to be'

Bristol-Myers Squibb stated that the purpose of the 'Patient Information Guide' document was to inform the patient about the patient services co-ordinator as well as information on the service, practical information about packaging and sharps bin, nursing and clinical services available, holiday information, data protection and information about how to complain if the services were not of a good standard. The third party confirmed that it had received no related complaints.

The document provided the following information about what the service entailed:

Why is … providing a service to me at home?

> 'The clinical team responsible for your care in hospital has arranged for us to continue to support your healthcare needs while you are at home. Depending upon your requirements and the service agreed with your consultant, we may provide you with: medicines delivered at regular scheduled intervals, all necessary equipment and ancillaries, comprehensive nursing training, nursing care and support from fully qualified professionals, if required, clinical waste collection (at point of delivery) and disposal.'

The document made it clear that a patient services co-ordinator would have already contacted the patient to make arrangements for the first and subsequent deliveries.

The document stated that the third party took patient security and confidentiality very seriously. All delivery drivers wore a uniform and carried photo ID which could be produced upon request.

The nursing service was also highlighted in this document. It gave information about how the service was set up and delivered to the patient. The document stated that the nursing care was provided in accordance with the procedures and protocols approved by the referring unit (ie the patient's hospital).

The document stated that all nurses were qualified and registered with the Nursing and Midwifery Council and adhered to their code of professional conduct.

The Patient Information Guide gave the following additional information about the nurse visit:

> 'Nursing requests are normally co-ordinated during office hours, Monday to Friday, with nursing care being delivered at the designated time and date arranged on an individual basis.'

There were details of the complaints process. The third party was registered and regulated by the Care Quality Commission (CQC) and the Social Care and Social Work Improvement Scotland (SCSWIS). The Patient Information Guide provided information on what the patient could do if they were unhappy with the service - in the first instance to contact the patient services co-ordinator, customer services manager and lastly the CQC.

b) Information For Patients Receiving Subcutaneous Orencia (Abatacept))

This document provided the patient with further information about abatacept treatment and the nurse visit:

> 'Your consultant or GP may decide that a nurse training visit is necessary for you to be able to self-administer. If this is the case, your co-ordinator will schedule the nurse training visit(s) in conjunction with your first homecare delivery. This training can also be provided to anyone who will help you with your injections. You should not attempt to inject your medication until you have received this training and feel confident about the procedure.'

In addition to the protocols and work instructions in place, the third party explicitly confirmed to Bristol-Myers Squibb, via email, that it would never send a nurse to an address without prior consent or arrangement with the patient or carer or if the patient had not received their first delivery of Orencia. This was to avoid any confusion or distress to the patient, to ensure the security of the patient, avoid wasted/ failed visits for the nurse and even more importantly to ensure that it was honouring its health & safety at work obligations to its nurses. This ensured that the safety and welfare of its nurses was maintained.

The nurses wore a company logo, as well and carried photo ID.

Additionally, there was a service level agreement with every hospital which included a summary of the service to be provided to patients who required the delivery and nursing service.

The relevant sections with regard to patient consent, communication and visits included:

Section 1 Patient Consent/Registration:

> 'Patient consent must be received from all patients/carers prior to the patient record being created and treatment supplied. At the commencement of the service, patients will be registered on the Provider's system and patient consent will be received in the form of a signed patient registration form. This will be the responsibility of the Referrer.'

Section 4 Communication:

> 'The patient co-ordinator will contact the patient prior to their first delivery to explain the service and to ensure that all the information/ requirements are correct. A maximum of 3 attempts will be made to contact new patients. If no contact has been made after this time, a letter will be sent to the patient and the Referrer will be notified. The Provider's patient co-ordinator will await further instructions from the Referrer.'
>
> 'All new patients will receive a letter of introduction and a patient information pack (attachments 10, 11, 12); this will provide an outline of the Provider's service together with details of the patient's delivery schedule in the form of a delivery calendar and all relevant contact details.'

Section 7 Nursing Services:

> 'At all times the Provider's nurses will work and be managed in strict accordance with the established protocols and procedures of the Referrer. The Provider's nurses are employed by the Provider, and may work in a full or part-time capacity.'
>
> 'Where the Referrer is training the patient in medication administration it is necessary to provide the Referrer's scheduled date of training on the registration form. The provision of this information will allow the Provider's patient co-ordinator to ensure that the patient receives the delivery of medications prior to this planned training.
>
> The Provider's nurse will visit the patient at an agreed, convenient time to train the patient (and/ or carer if required) to administer the drug.
>
> The Provider's nurse will contact patients prior to their visit. This allows the nurse to:
>
> - Confirm that the patient has received their installation delivery
> - Agree a convenient date and time for the training.
>
> Training will be initiated within the appropriate timescale of the installation delivery being made, provided this is acceptable to the patient.'

Consent during a nurse visit at a patient's home

In addition to the consent sought in the 'Patient Registration' Form and verbal consent during the installation call, when the nurse visited the patient's home, the nurse would also gain further written consent from the patient. This consent confirmed that the patient had understood and accepted the terms of the service and wanted to receive nursing support prior to commencing the administration training.

The nurse went through all of the documentation provided to the patient in relation to the service. The nurse would also carry out an environmental check to ensure that the patient had all relevant facilities required, in order to successfully store and administer their medicine, and would then train the patient on how to administer the medicine safely. In some instances where the patient was unable to safely administer their own medication the homecare service nurse might be required to do this on their behalf.

Documentation that was relevant for the referring trust to retain would be sent back to the trust following a nurse visit to the patient's home.

Bristol-Myers Squibb submitted that there were multiple steps and layers of processes and procedures in place to speak to and inform the patient about the service and to gain and confirm consent.

- Patient Registration form: The prescribing physician explained the service and gained consent from the patient. The patient and the physician had to sign the form, unless the patient could not physically sign the form. In this instance, the patient was still required to consent and the physician would sign the declaration stating that the patient consented to receiving the service.
- Installation call: A co-ordinator would telephone every patient before initiating any elements of the service. At the beginning of the call the patient was required to provide consent to the service or the call was closed and the patient referred back to the trust.
- Patient Information Packs were sent to the patient prior to the initial first visit with the nurse. As described above, information was provided within the pack about the service and also about nurse visits ie any such visit (if required) would be organised on a designated date and time which was agreed with the patient on an individual basis.
- Nurse co-ordinator call: If a patient had also consented to the nurse training element of the service then a second call would be placed to the patient by the nurse co-ordinator. This was to organise a suitable time for the nurse to visit, as well as to elicit relevant information for the nurse to have prior to the visit.
- In addition to the patient consent to receive the service obtained by the health professional after the health professional had decided to prescribe Orencia in agreement with the patient, further written patient consent was obtained by the nurse at the initial nurse visit: prior to initiation of the service by the nurse.

Given the above, and in addition to the documentation provided to the patient, Bristol-Myers Squibb submitted that it was extremely unlikely, if not impossible, that a nurse would visit a patient without their prior knowledge or arrangement.

The process required the nurse to arrange a time slot with the patient/carer prior to the nurse visit. Bristol-Myers Squibb therefore refuted any breaches of the Code.

In summary, Bristol-Myers Squibb submitted that there were multiple processes and safeguards in place to ensure that a nurse could not call on the patient unsolicited, or without gaining appropriate and relevant consent.

Bristol-Myers Squibb provided screenshots of the approvals/certificates and copies of the relevant material and the list of Bristol-Myers Squibb signatories and their qualifications.

To summarise Bristol-Myers Squibb submitted that it strove to ensure that the service that it provided for patients treated with Orencia, was of high quality and met the needs of its health professionals and patients. Bristol-Myers Squibb worked closely with the NHS and the third party to ensure that patients were appropriately trained to administer injections safely.

Given the comprehensive procedures and protocols which were in place both in the hospital and within the third party, Bristol-Myers Squibb was confident that prior consent to receive the service would have been obtained and that the alleged nurse visit could only have taken place by directly booking an appointment with the patient or their carer.

Based on the information provided Bristol-Myers Squibb submitted that it was unable to find a way that the events described and alleged by the complainant in the anonymous letter to the PMCPA, could have occurred.

Bristol-Myers Squibb was confident that there had not been any breaches of Clause 18.4, Cause 18.1, Clause 9.1 or Clause 2 and it therefore refuted the allegations.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints would be accepted, but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. The Panel noted that extreme dissatisfaction was usually required on the part of an individual before he or she was moved to complain. All complaints were judged on the evidence provided by the parties. The complainant had not provided sufficient information so that the particular circumstances could be identified. The complainant could not be contacted for more information.

The Panel noted that Bristol-Myers Squibb had provided information about the general arrangements for the provision of the homecare service and the procedures in place to ensure consent was obtained prior to delivery of the service. In that regard the Panel noted that the Patient Registration forms provided by Bristol-Myers Squibb were Versions 1 and 3 not Versions 1 and 2 as submitted by the company. Version 2 had not been provided. The section to be signed by the patient/parent/guardian on Version 1 was headed 'patient consent' and referred to the provisions of the Data Protection Act and consent to keep patient details on the third party computer system. It was consent to hold the data rather than consent to receive the service. The referring clinician section contained two elements: firstly a statement that the clinician had fully explained and discussed the homecare service with the patient and that the patient had given explicit informed consent to receive the homecare service and secondly that the patient understood and consented to his/her information being passed to and processed by the third party under the provisions of the Data Protection Act in order for the homecare service to be provided. Version 3 of the form had different wording for the patient section but still referred to the use of information and the Data Protection Act and this section was no longer to be signed by the 'parent/guardian'. The second part was also different, it was now headed 'to be completed by the referring clinician/Trust representative (if the patient is unable to sign)'. The content which followed this heading was similar to Version 1 other than amendments to reflect that it could be signed by either the clinician or a trust representative. The Panel considered it could have been clearer on Version 1 and

Version 3 that the patient when signing (or the parent/guardian on Version 1) was consenting to the provision of the service. The option for the parent/guardian to sign on the patient's behalf had been removed. In the Panel's view it was preferable for either the patient or someone on their behalf (other than the referring clinician or trust representative) to also sign the form.

Notwithstanding its comments above the Panel did not consider that the complainant had provided sufficient information to demonstrate on the balance of probabilities that Bristol-Myers Squibb's arrangements were inadequate in relation to the complainant's mother or had not been followed. No breach of Clauses 18.1, 18.4, 9.1 and 2 were ruled.

Complaint received **11 October 2016**

Case completed **4 January 2017**

ANONYMOUS, NON-CONTACTABLE v BRISTOL-MYERS SQUIBB

Alleged pre-licence promotion of Opdivo

An anonymous non-contactable complainant complained about the conduct of Bristol-Myers Squibb Pharmaceuticals in relation to Opdivo (nivolumab). The complainant stated that he/she was a consultant oncologist and haematologist working in the UK and referred to two incidents.

Opdivo was licensed for the treatment of certain cancers, these being melanoma, non-small cell lung cancer (NSCLC) and renal cell carcinoma.

The detailed response from Bristol-Myers Squibb is given below.

1 Treatment for non-Hodgkin lymphoma

The complainant stated that he/she was visited by the husband of a recently diagnosed patient with non-Hodgkin lymphoma (NHL). Mr X was a member of parliament (MP) and gave the impression that the complainant had not explored all the possible treatments with his wife. Mr X was adamant that a member of the Bristol-Myers Squibb access team had informed him that nivolumab was a good treatment and he was concerned that the complainant was not offering it for his wife.

The complainant understood that nivolumab did not have a licence for NHL. It was available for Hodgkin patients under the early access to medicines scheme (EAMS). This scheme did not mean that the medicine had been declared safe in that its benefits outweighed its side effects, otherwise it would already have a licence and be freely available.

The fact that an MP had been actively informed of this medication even before it had a licence surely showed an issue with how medicines were licensed and how the medical profession were involved and informed.

As a clinician the complainant queried why he/she should be subjected to an MP who was not a health professional questioning his/her professional advice.

The complainant believed that with nivolumab, even for its now licensed indications, MPs were prior to licence, presented with data and medical information and briefed on treatment pathways, etc.

The complainant stated that he/she was informed by the MP that they were regularly 'entertained' by Bristol-Myers Squibb to ensure that if there was ever an issue with formularies that they might step in and influence patient treatment pathways to ensure that a medicine was prescribed.

The complainant stated that he/she was not aware of how MPs influenced prescribing habits, and if they didn't actually have any impact on his/her ability to ensure that patients received the best medication possible, the complainant concluded that Bristol-Myers Squibb was actually promoting a prescription only medicine to members of the public.

This was in itself an insult to the medical profession. It was certainly not appropriate to be approached by a MP who had no specialist knowledge and be exposed to the out of context information that they had received from a pharmaceutical company.

The Panel considered that it was not necessarily unreasonable for pharmaceutical companies to discuss health care and treatments with a variety of audiences including MPs. Companies had to ensure that such activities were in line with the Code including the prohibition of advertising prescription only medicines to the public. The Panel considered that such discussions and activities were more likely to be about the general treatment of a particular disease than the use of a specific medicine for that disease. Companies should be confident that such discussions were only with people whose need for, or interest in, it could reasonably be assumed. The Panel also noted that MPs might be covered by the definition of other relevant decision makers which included those, particularly with an NHS role, who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who were not health professionals. There would inevitably be instances where the provision of appropriate information to MPs might overlap with their own health or that of their friends and families. It was of concern that a health professional had considered that an MP had questioned his/her professional advice based on information allegedly provided by a pharmaceutical company employee. The Code was clear that requests from individual members of the public for advice on personal medical matters had to be refused and the enquirer recommended to consult his or her own doctor or other prescriber or health professional.

The Panel noted Bristol-Myers Squibb's submission that the national policy and access manager for its haemato-oncology role was non-promotional. The job description listed the function as market access with one of the key accountabilities to prepare, champion and execute national policy and access programmes to deliver access in key disease areas. This would surely include use of Bristol-Myers Squibb's products. It was difficult to see how this and other aspects of the role were not within the broad definition of promotion as an activity undertaken by a pharmaceutical company or with its authority which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.

In this regard, the Panel noted that the file notes of meetings the Bristol-Myers Squibb national policy and access manager had had with various MPs and the follow-up emails to those MPs included references to specific Bristol-Myers Squibb medicines and to the MPs submitting parliamentary questions to raise issues Bristol-Myers Squibb considered were relevant. There was discussion with at least one MP about what was referred to as the access challenges for cancer medicines in general and Opdivo specifically in renal cell carcinoma. Mention was made of the likelihood of Bristol-Myers Squibb using political support to ensure patients were able to access a different Bristol-Myers Squibb medicine, dasatinib, if a National Institute for Health and Care Excellence (NICE) decision was negative. Reference was made to a roundtable parliamentary discussion in November 2016, which was after the date of the complaint, looking at access to treatments for lymphoma and treatment of Hodgkin lymphoma patients who had failed to respond to or relapsed on other therapies. Mention was made of Bristol-Myers Squibb negotiations with NHS England regarding discounts for dasatinib. Discussions also covered the size of the clinical trial for Bristol-Myers Squibb's medicine for Hodgkin lymphoma; that the clinical trial data was positive and the medicine was suitable for patients who had failed chemotherapy and a stem cell transplant so would not have further treatment options.

The Panel considered that the national policy and access manager's work as shown by the email and file notes promoted specific medicines. Involving politicians and others in activities to increase access to Bristol-Myers Squibb medicines by a Bristol-Myers Squibb employee could not be anything other than promotion. In the Panel's view, certain aspects of the national policy and access manager's role would satisfy that of a representative.

The Panel noted that there were a number of ways that companies could provide information about medicines or indications that were not licensed. Such activity was referred to in the Code, as well as in the PMCPA Guidance on Clause 3. If companies were holding meetings for MPs and other non-health professionals then such meetings should follow the requirements of the Code. The Panel considered that specific decisions on formularies and treatment pathways were for health care providers rather than for individual MPs although of course MPs and local council members might be involved as part of a broader decision making group. Whether such individuals would qualify as other relevant decision makers would depend on their individual circumstances including the role of any decision making group.

Although the Panel had some concerns about the meetings organised/sponsored by Bristol-Myers Squibb in relation to the points outlined above, it noted the information provided by the parties and that there appeared to be a difference of opinion. It noted that the complainant had not provided evidence to support his/her complaint and in the Panel's view had not proved on the balance of probabilities that Bristol-Myers Squibb had promoted its medicine for unlicensed indications to MPs as alleged. It was not clear whether the complainant was concerned about the provision of information to MPs prior to the licensing of Opdivo for any of its indications (according to its summary of product characteristics Opdivo was first authorized in June 2015) or for NHL. The Panel ruled no breaches of the Code including Clause 2.

The Panel did not consider that the complainant had established that Bristol-Myers Squibb's activities with MPs amounted to promotion of prescription-only medicines to the public. Insufficient detail had been provided. Although it was concerned about the detail, it did not consider that the complainant had shown, on the balance of probabilities, that the information was not factual nor presented in a balanced way. The Panel ruled no breaches of the Code.

The Panel noted that the MPs had been provided with limited subsistence at meetings. It did not consider that the complainant had shown, on the balance of probabilities, that gifts, pecuniary advantages or benefits-in-kind had been provided in connection with promotion or as an inducement to recommend any medicine. Nor had the complainant established that MPs had been entertained as alleged. No breaches of the Code were ruled.

2 Meeting in the Republic of Ireland

The complainant stated he/she was even more surprised to hear that in September 2016 Bristol-Myers Squibb had invited a colleague from the UK to a meeting on the use of nivolumab in Hodgkin lymphoma. The meeting was held in the Republic of Ireland. The complainant gave details of the meeting.

The Panel noted that the meeting was held in the Republic of Ireland for health professionals in Eire. There were no UK health professional delegates. The meeting content therefore did not come under the scope of the Code and no breach was ruled in that regard.

As there was a UK health professional speaker the Code applied in relation to the arrangements for him/her. The cost of subsistence, travel and accommodation were not unreasonable in relation to the requirements of the Code and therefore the Panel ruled no breach of the Code.

An anonymous non-contactable complainant submitted a complaint about the conduct of Bristol-Myers Squibb Pharmaceuticals Limited in relation to Opdivo (nivolumab). The complainant stated that he/she was a consultant oncologist and haematologist working in the UK.

Opdivo was licensed for the treatment of certain cancers, these being melanoma, non-small cell lung cancer (NSCLC) and renal cell carcinoma.

COMPLAINT

The complainant was concerned about the behaviour Bristol-Myers Squibb which made nivolumab (Opdivo). The complainant referred to two incidents.

1 Treatment for non-Hodgkin lymphoma

The complainant stated that he/she was visited by the husband of a recently diagnosed patient with non-Hodgkin lymphoma (NHL). Mr X was a member of parliament (MP) and gave the impression that the complainant had not explored all the possible treatments with his wife. Mr X was quite adamant that a member of the Bristol-Myers Squibb access team had informed him that nivolumab was a good treatment and was now available and he was concerned that the complainant was not offering the treatment to his wife.

The complainant's understanding was that nivolumab was already licensed for other indications but did not have a licence for NHL. It was also available for Hodgkin patients under the early access to medicines scheme (EAMS). This scheme did not mean that the medicine had been declared safe in that its benefits outweighed its side effects, otherwise it would already have a licence and be freely available.

The fact that a member of parliament had been actively informed of this medication even before it had a licence surely showed an issue with how medicines were licensed and how the medical profession who actually treated these patients were involved and informed.

As a clinician the complainant queried why he/she should be subjected to a member of parliament who was not a health professional questioning his/her professional advice.

The complainant believed that with nivolumab, even for its now licensed indications, MPs were presented with data and medical information and briefed on treatment pathways, etc, even before the medicine received an official licence from the regulatory authorities.

The complainant stated that he/she was informed by the MP that they were regularly 'entertained' by Bristol-Myers Squibb to ensure that if there was ever an issue with formularies that they might step in and influence patient treatment pathways to ensure that a medicine was prescribed. Whether this actually was a reality or not was beyond the complainant's remit as MPs, unless specialist health professionals in their own right, knew nothing of specialised healthcare medications.

The complainant stated that he/she was not aware of how they influenced prescribing habits, and if they didn't actually have any impact on his/her ability to ensure that his/her patient received the best medication possible, the complainant concluded that Bristol-Myers Squibb was actually promoting a prescription only medicine to members of the public.

This was in itself an insult to the medical profession who spent years studying and specializing to ensure the best possible treatments for patients. It was certainly not appropriate to be approached by an MP who had no specialist knowledge and be exposed to the out of context information that they had received from a pharmaceutical company.

2 Meeting in the Republic of Ireland

The complainant stated he/she was even more surprised to hear that in September 2016 Bristol-Myers Squibb had invited a colleague from the UK to a meeting on the use of nivolumab in Hodgkin lymphoma. The meeting was held in the Republic of Ireland. The complainant provided details of the meeting.

As a general rule the complainant did not see pharmaceutical representatives for these very reasons.

The complainant was concerned that should the press get hold of this – there would be a lot to answer for, from all perspectives and urged the PMCPA to look into the matter.

In writing to Bristol-Myers Squibb the Authority asked it to consider Clauses 2, 3.2, 9.1, 18.1, 22.1, 26.1 and 26.2 of the Code.

RESPONSE

1 Treatment of non-Hodgkin lymphoma (NHL)

Bristol-Myers Squibb submitted that there had been no promotion whatsoever of nivolumab for the investigational disease areas of non-Hodgkin lymphoma or Hodgkin lymphoma and therefore the company rejected the notion that it promoted nivolumab outside the terms of its marketing authorization or in a manner inconsistent with the particulars listed in its summary of product characteristics (SPC). The company denied a breach of Clause 3.2.

Accordingly, it also refuted the alleged breaches of Clauses 9.1, 18.1, 22.1, 26.1, 26.2 and Clause 2 and refuted that there was any pre-licence promotion of nivolumab to health professionals and the public.

Bristol-Myers Squibb submitted that to its knowledge, no Bristol-Myers Squibb employee had ever entered into discussions with any MP about nivolumab for use in NHL nor promoted its use. No Bristol-Myers Squibb employee had discussed the treatment of any MP's spouse or any individual patient.

NHL and Hodgkin lymphoma were distinctly different diseases, although Bristol-Myers Squibb noted there appeared to be some ambiguity between the two in the complaint.

The Bristol-Myers Squibb national policy and access manager for Haemato-Oncology (an entirely non-promotional role) had had discussions with some MPs about Hodgkin lymphoma, solely in relation to disease awareness and forthcoming Health Technology Appraisals (HTAs) of nivolumab in that indication, such as the complexity of forthcoming HTAs in a very small disease population. This would have been within the context of MPs meeting the Code criteria of 'other relevant decision makers'. None of the generic discussions covered detailed medical information, data or treatment pathways.

No materials and/or briefings in relation to NHL were given to the Bristol-Myers Squibb Access Team.

Bristol-Myers Squibb submitted that nivolumab was currently being investigated in NHL and there had been no EU marketing authorisation application.

Nivolumab was not currently available for Hodgkin lymphoma or NHL patients under the Early Access to Medicines Scheme (EAMS).

Bristol-Myers Squibb submitted that it categorically did not provide entertainment and any such provision of entertainment would be a serious breach of Bristol-Myers Squibb's internal policies.

Bristol-Myers Squibb did engage with selected parliamentarians on policy issues of shared interest, particularly in relation to specific diseases, NHS patients' access to medicines and broad healthcare policy. Authorised non-promotional employees might occasionally work with those MPs to hold events with the aim of bringing together other interested parties, supporting disease awareness, stimulating debate and informing policy development.

Occasionally, limited subsistence might be offered during the course of such events; which would be nominal and entirely secondary to the meeting itself.

In the past year, Bristol-Myers Squibb had been involved in organising three such events (two solely and one in partnership), where MPs attended and at which limited subsistence was provided. Such subsistence was only ever provided when the timing and duration of the event warranted it.

The three events were a parliamentary launch of a Bristol-Myers Squibb report on kidney cancer (held in May 2016), a parliamentary launch of a report on multiple myeloma in black communities (held in January 2016) and a round table on rethinking cancer following publication of the international longevity centre (ILC) report commissioned by Bristol-Myers Squibb (held in December 2015). The refreshments provided for these events were similar and mostly included tea, coffee, water and biscuits.

The above information did not include MP-attended events for which Bristol-Myers Squibb was simply an event sponsor. Examples include large conferences co-sponsored by Bristol-Myers Squibb at which a small number of MPs were speakers and patient advocacy group meetings in Parliament that received Bristol-Myers Squibb sponsorship, but in which the company had no further involvement.

The Panel asked Bristol-Myers Squibb's for more information.

Bristol-Myers Squibb stated that as in its original response, the only discussions with MPs in relation to Opdivo and Hodgkin lymphoma were undertaken by its national policy and access manager for haemato-oncology (an entirely non-promotional role). These were solely in relation to disease awareness and forthcoming health technology appraisals (HTAs) of Opdivo in this indication, such as the complexity of forthcoming HTAs in a very small disease population. This was within the context of MPs meeting the Code criteria of 'other relevant decision makers'. None of the generic discussions covered detailed medical information, data or treatment pathways. In no meeting was the treatment of any MP's spouse or any individual patient discussed.

Bristol-Myers Squibb stated that the focus of the anonymous complaint related to its alleged interaction with an MP regarding NHL and it previously confirmed that there were discussions with some MPs regarding Hodgkin lymphoma in the context of disease awareness and forthcoming HTAs. Bristol-Myers Squibb had therefore focused its attention and interpreted the PMCPA's request to provide further details of all meetings and discussions with MPs where Hodgkin lymphoma was discussed. The national policy and access manager for haemato-oncology met with five MPs at which Opdivo and Hodgkin lymphoma was discussed. Details of these meetings were provided including notes of the issues discussed and follow-up emails to the MP for each meeting.

These meetings all took place within the Parliamentary Estate (the MP's workplace), either in general meeting areas or the individual MP's private office. Bristol-Myers Squibb provided no subsistence.

Bristol-Myers Squibb stated that meetings with any individual MP were infrequent and the vast majority would not be repeated within a twelve month period.

MPs were selected by a national policy and access manager on the basis of them having a particular policy responsibility for, or verifiable professional interest in, a relevant issue: in this case the treatment of blood cancer or less-common cancers. Further details were provided.

Bristol-Myers Squibb attendees generally provided no subsistence at such meetings. Where this had occurred in the past, the subsistence would be a tea or coffee purchased from a café in Parliament.

Bristol-Myers Squibb stated that the three meetings took place on the Parliamentary Estate and room rental was not paid for any of these events.

Details of events that were sponsored by Bristol-Myers Squibb in the twelve months prior to 11 October 2016 (the date of the PMCPA's original communication on this case) and where Bristol-Myers Squibb was aware that catering was provided and at least one MP attended, were provided. All of these requests for sponsorship were unsolicited. As event sponsor, Bristol-Myers Squibb had no input into the format, agenda, attendance or catering arrangements for any of these events.

2 Meeting in the Republic of Ireland

Bristol-Myers Squibb submitted that its affiliate in the Republic of Ireland fulfilled a reactive request for a non-promotional haematology medical educational meeting. A leading consultant haematologist based

in the Republic of Ireland, originally requested this educational meeting for haematology health professionals in the local area. The UK speaker was one of the speakers originally identified by the meeting requestor.

All aspects of the meeting were approved internally within Bristol-Myers Squibb to ensure compliance with internal processes, standards and the Irish Pharmaceutical Healthcare Association (IPHA) Code. Additionally, there was also consideration of relevant clauses of the ABPI Code, such as the travel arrangements and hospitality for the UK speaker.

The meeting was held at a named hotel in the Republic of Ireland, with registration commencing at 6.30pm; the meeting started at 7pm and closed at 9pm. A light buffet dinner was provided as subsistence during registration.

The only UK health professional at the meeting was a speaker, a consultant at a hospital. The 30 minute presentation was a highly scientific, balanced overview of 'Relapsed Hodgkin lymphoma (HL) - new developments.' This presentation objectively discussed the Hodgkin lymphoma patient and the slides were examined by Bristol-Myers Squibb to ensure compliance with the IPHA Code.

A scientific advisor from Bristol-Myers Squibb Ireland and nine local health professionals attended (in addition to the two speakers and the original requesting consultant haematologist). The requestor selected the invitees and directed Bristol-Myers Squibb with respect to whom to invite. There were no other UK health professionals present at the meeting. Nor were any Bristol-Myers Squibb sales representatives or Bristol-Myers Squibb staff representing the commercial side of the organisation present at the meeting.

The costs for the light buffet dinner was €27.52 (excluding VAT) per person. Further details on the invitation and breakdown of the subsistence were provided.

Consultancy agreement, honorarium and travelling receipts for the UK speaker were provided.

In summary, Bristol-Myers Squibb submitted that subsistence was strictly limited to the main purpose of the event, was secondary to the purpose of the meeting and focused on appropriate subsistence only.

Whilst the meeting materials were approved in line with the IPHA Code, there was no requirement to examine/certify these materials in line with the ABPI Code as there were no UK delegates at the meeting. The arrangements for the UK speaker were examined as set out in Clause 14.2 of the ABPI Code.

Conclusion

Bristol-Myers Squibb was concerned to hear of the very serious allegations. It did all that it could to comply with the spirit and letter of both the ABPI and IPHA Codes.

As nivolumab was currently only an investigational agent in NHL and Hodgkin lymphoma the company always made comprehensive checks to ensure that any discussions with appropriate health professionals by Bristol-Myers Squibb were strictly in line with the ABPI and IPHA Codes requirements and internal policies.

There had been no promotion of nivolumab for NHL or Hodgkin lymphoma and therefore Bristol-Myers Squibb refuted the allegation of a breach of Clauses 3.2, 18.1, 26.1 and 26.2. The arrangements for meetings also complied with Clause 22.1 with regard to subsistence and venues.

Furthermore as already mentioned, Bristol-Myers Squibb submitted it was diligent in its checks, and conducted itself in a manner which it believed constituted the highest standards, which it expected of itself and in line with expected industry standards and the Code. It therefore failed to see how it could be found to be in breach of Clauses 9.1, or 2.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints would be accepted, but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. The Panel noted that, in general, extreme dissatisfaction was usually required on the part of an individual before he or she was moved to complain. All complaints were judged on the evidence provided by the parties. The complainant had not provided sufficient information so that the particular circumstances could be identified. The complainant could not be contacted for more information.

1 Treatment for non-Hodgkin lymphoma

The Panel considered that it was not necessarily unreasonable for pharmaceutical companies to discuss health care and treatments with a variety of audiences including MPs. Companies had to ensure that such activities were in line with the Code including the prohibition of advertising prescription only medicines to the public. The Panel considered that such discussions and activities were more likely to be about the general treatment of a particular disease than the use of a specific medicine for that disease. Companies should be confident that such discussions were only with people whose need for, or interest in, it could reasonably be assumed. The Panel also noted that MPs might be covered by the definition in Clause 1.5 for other relevant decision makers which included those, particularly with an NHS role, who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who were not health professionals. There would inevitably be instances where the provision of appropriate information to MPs might overlap with their own health or that of their friends and families. It was of concern that a health professional had considered that an MP had questioned his/her professional advice based on

information allegedly provided by a pharmaceutical company employee. Clause 26.4 of the Code was clear that requests from individual members of the public for advice on personal medical matters had to be refused and the enquirer recommended to consult his or her own doctor or other prescriber or health professional.

The Panel noted Bristol-Myers Squibb submission that the national policy and access manager for haemato-oncology role was non-promotional. The job description listed the function as market access with one of the key accountabilities to prepare, champion and execute national policy and access programmes to deliver access in key disease areas. This would surely include use of Bristol-Myers Squibb's products. It was difficult to see how this and other aspects of the role were not within the broad definition of promotion in Clause 1.2 of the Code as an activity undertaken by a pharmaceutical company or with its authority which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.

In this regard, the Panel noted that the file notes of meetings the Bristol-Myers Squibb national policy and access manager had had with various MPs and the follow-up emails to those MPs included references to specific Bristol-Myers Squibb medicines and to the MPs submitting parliamentary questions to raise issues Bristol-Myers Squibb considered were relevant. There was discussion with at least one MP about what was referred to as the access challenges for cancer medicines in general and Opdivo specifically in renal cell carcinoma. Mention was made of the likelihood of Bristol-Myers Squibb using political support to ensure patients were able to access dasatinib if a National Institute for Health and Care Excellence (NICE) decision was negative. Reference was made to a roundtable parliamentary discussion in November 2016 looking at access to treatments for lymphoma and treatment of Hodgkin lymphoma patients who had failed to respond to or relapsed on other therapies. Mention was made of Bristol-Myers Squibb negotiations with NHS England regarding the provision of dasatinib at a discounted price. Discussions also covered the size of the clinical trial for Bristol-Myers Squibb's medicine for Hodgkin lymphoma; that the clinical trial data was positive and the medicine was suitable for patients who had failed chemotherapy and a stem cell transplant so would not have further treatment options.

The parliamentary event regarding Hodgkin lymphoma was planned for 29 November. The Panel noted that this was after the date of the complaint (1 October 2016).

The Panel was concerned that it was only when Bristol-Myers Squibb was asked for additional information that the detailed information about the meetings with MPs was supplied.

The Panel considered that the national policy and access manager's work as shown by the email and file notes promoted specific medicines. Involving politicians and others in activities to increase access to Bristol-Myers Squibb medicines by a Bristol-Myers Squibb employee could not be anything other than promotion. In the Panel's view, certain aspects of the national policy and access manager's role would satisfy that of a representative as defined in Clause 1.7.

The Panel noted that there were a number of ways that companies could provide information about medicines or indications that were not licensed. Such activity was referred to in the Code, including Clause 3 as well as in the PMCPA Guidance on Clause 3. If companies were holding meetings for MPs and other non-health professionals then such meetings should follow the requirements of Clause 22 in relation to the arrangements. The Panel considered that specific decisions on formularies and treatment pathways were for health care providers rather than for individual MPs although of course MPs and local council members might be involved as part of a broader decision making group. Whether such individuals would qualify as other relevant decision makers would depend on their individual circumstances including the role of any decision making group.

In the Panel's view there was little evidence to link the company's activities with MPs to the situation the complainant had raised. The complainant had not provided sufficient information so that the particular circumstances could be identified and he/she could not be contacted for more information.

Although the Panel had some concerns about the meetings organised/sponsored by Bristol-Myers Squibb in relation to the points outlined above, it noted the information provided by the parties and that there appeared to be a difference of opinion. It noted that the complainant had not provided evidence to support his/her complaint and in the Panel's view had not proved on the balance of probabilities that Bristol-Myers Squibb had promoted its medicine for unlicensed indications to MPs as alleged. It was not clear whether the complainant was concerned about the provision of information to MPs prior to the licensing of Opdivo for any of its indications (according to its summary of product characteristics Opdivo was first authorized in June 2015) or for NHL. Bristol-Myers Squibb had been asked to respond in relation to Clause 3.2 not Clause 3.1. The Panel ruled no breach of Clause 3.2 of the Code. It also ruled no breach of Clauses 9.1 and 2.

The Panel did not consider that the complainant had established that Bristol-Myers Squibb's activities with MPs amounted to promotion of prescription-only medicines to the public. Insufficient detail had been provided. No breach of Clause 26.1 was ruled. Although concerned about the detail, the Panel did not consider that the complainant had shown, on the balance of probabilities, that the information was not factual nor presented in a balanced way. The Panel ruled no breach of Clause 26.2.

The Panel noted that the MPs had been provided with limited subsistence at meetings held by Bristol-Myers Squibb or sponsored by Bristol-Myers Squibb. It did not consider that the complainant had shown, on the balance of probabilities, that

gifts, pecuniary advantages or benefits-in-kind had been provided in connection with promotion or as an inducement to recommend any medicine. No breach of Clause 18.1 was ruled. Nor had the complainant established that MPs had been entertained as alleged. No breach of Clause 22.1 was ruled.

2 Meeting in the Republic of Ireland

The Panel noted that the meeting was held in the Republic of Ireland for health professionals in Eire. There were no UK health professional delegates. The meeting content therefore did not come under the scope of the ABPI Code and no breach was ruled in that regard.

The ABPI Code applied in relation to the arrangements for the UK health professional speaker. It did not appear that the arrangements for the UK speaker were unreasonable. The cost of subsistence, travel and accommodation were not unreasonable in relation to the requirements of Clause 22.1. The Panel therefore ruled no breach of Clause 22.1.

Complaint received **11 October 2016**

Case completed **19 January 2017**

ANONYMOUS NON-CONTACTABLE v GALEN

Trustsaver website

An anonymous, non-contactable complainant, who appeared to work in a clinical commissioning group (CCG), complained about Galen's Trustsaver website regarding potential savings with Galen's laxative Laxido (macrogol plus electrolytes).

The complainant noted that the site had a defined claim of potential savings of tens of millions of pounds across the UK health economy but queried whether this reflected England, Wales, Scotland and Northern Ireland all of which had devolved health economies.

The complainant noted that the site only had a saving comparison with the most expensive macrogol and not a like for like comparison and raised a number of questions.

The complainant stated that the CCG had been a large user of Laxido and was misled by the Trustsaver site and the claims which were clearly not going to be made in this budget cycle.

The complainant requested that the Trustsaver site with its retrospective claims on savings be taken down and that instead it illustrated prospective savings. These claims applied to all brands and not just Laxido; the complainant noted that the CCG also used other Galen products such as steripoules and diltiazem.

The complainant asked that Galen reflect the diverse nature of the health service in the devolved economies and split potential savings into each country. He/she asked the PMCPA to ask Galen to try to reflect savings of/or costs in year and not to seek to mislead the GP population. The complainant alleged that Galen could and would bring itself and the industry into disrepute.

The detailed response from Galen is given below.

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints would be accepted, but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant could not be contacted for more information.

The Panel noted the complainant's concerns with regard to the claim that 'Trustsaver has potentially saved the NHS over £36 million since it launched in 2010' which was qualified by the use of an asterisk with the explanation immediately beneath that 'The savings estimate refers to drug acquisition costs. It has been calculated using PCA data for the Trustsaver products and reflected the theoretical difference in costs, had 100% of prescriptions been for the market-leading competitor instead (excludes latest product additions and includes a past Trustsaver product)' and was referenced to data on file. The Panel did not consider it was necessarily misleading to give savings as one figure to the NHS rather than for each devolved nation. More detail could be obtained by using the personalised cost saving calculator and inputting relevant data. In addition, the Panel noted Galen's submission that all countries in the UK shared the same pricing policies for all Trustsaver products. It thus ruled no breach of the Code.

With regard to the cost comparison being against the market leader only, which the complainant referred to as the most expensive macrogol and not showing the prices of other available products, the Panel considered that it was clear that the website showed comparisons with the market leading brands. The Panel noted that Laxido Natural had been discontinued and therefore it was not misleading to omit it. In the circumstances it was not misleading to use potential retrospective savings for illustration based on average annual usage. There was no indication that using Laxido Orange was the cheapest option. Only that savings would be made compared to using the identified market leading brand. In addition, the Panel noted that if switches to Galen's product were made in year 1 the comparison with the cost of Laxido and the market-leading brand in year 2 were somewhat artificial. Further savings might be made by changing from a Galen product to an alternative, less expensive, medicine albeit not a market leader. It was not necessarily misleading to select products for comparison, it would depend on the basis of the selection and whether this had been made clear. The Panel did not consider it was necessarily misleading to use retrospective comparisons in relation to savings compared with the use of the market leading brand rather than potential prospective savings.

The Panel considered that the basis of the comparisons was clear and the complainant had not shown on the balance of probabilities that the material was misleading as alleged. The Panel ruled no breach of the Code.

The Panel was concerned that the page of the website which set out product information about Laxido Orange claimed '45% savings with Laxido Orange' as a heading to a graph which compared the other major macrogol 3350 plus electrolytes brand. This was followed by 'Did you know the NHS currently spends more than £67 million per year on prescribing osmotic laxatives' and the claim 'make significant drug acquisition cost savings by prescribing Laxido Orange by brand'. These might give the impression that the savings were more than just a comparison with the market leading brand. The introduction to the Trustsaver portfolio

at the top of the page referred to 'drug acquisition cost savings vs market-leading brands' whereas a prominent highlighted banner at the bottom of the page referred to significant drug acquisition cost savings by prescribing Laxido Orange by brand. There was no mention of this being in comparison to market-leading brands. On balance, the Panel considered that given the content of the website and the context of the page itself, although this page could and should be improved, it was not in itself misleading. No breach of the Code was ruled.

The Panel noted its rulings above. It did not consider that the complainant had shown on the balance of probabilities that Galen had brought discredit upon or reduced confidence in the pharmaceutical industry. No breach of Clause 2 was ruled.

An anonymous, non-contactable complainant, who appeared to work in a clinical commissioning group (CCG), complained about Galen Limited's Trustsaver website.

COMPLAINT

The complainant noted that for some time, he/she had been targeted by members of his/her CCG about potential savings with Galen's laxative Laxido (macrogol plus electrolytes). The complainant stated that this was not unusual as the CCG strove to have cost efficient and quality prescribing. The complainant was reminded of a visit by a Galen representative who asked him/her to look at the Trustsaver website which was not an issue until the complainant noted the contents.

The complainant noted that the site had a defined claim of potential savings of tens of millions of pounds across the UK health economy but queried whether this reflected England, Wales, Scotland and Northern Ireland all of which had devolved health economies. The complainant asked if the potential saving should be split into each country within the union.

The complainant noted that the site only had a saving comparison with the most expensive macrogol and not a like for like comparison and raised the following questions:

1 Should the comparison not be on a like for like basis eg Laxido Orange vs CosmoCol and other orange preparations? This would mean in reality that Laxido actually cost the NHS quite a large amount of cash going forward.

2 Should Laxido Natural not be listed on the site and compared with other preparations such as CosmoCol plain? This again would show that going forwards as well as in the past a huge cost consequence for the NHS would be seen.

3 Should the comparisons actually not be retrospective but be based on potential prospective savings year on year ... reflecting the NHS budgeting cycle?

The complainant stated that the feedback from a successful switch to Laxido from all preparations showed that 15% of patients asked to switch back to Movicol Lemon and Lime. Now that the potential savings had been reviewed, it had been decided to change Movicol Lemon and Lime to CosmoCol Lemon and Lime and all generically prescribed unflavoured macrogol to a cost effective plain preparation.

The complainant requested that like for like comparisons were made to reflect the very real cost consequence associated with Laxido in year; the CCG was not focussed on savings it might have realised rather savings it might make in year and prospectively.

The complainant stated that the CCG had been a large user of Laxido and was misled by the Trustsaver site and the claims which were clearly not going to be made in this budget cycle, disappointing its GPs.

The complainant requested that the Trustsaver site with its retrospective claims on savings be taken down and that instead it illustrated prospective savings. These claims applied to all brands and not just Laxido; the complainant noted that the CCG also used other Galen products such as steripoules and diltiazem.

The complainant asked that Galen reflect the diverse nature of the health service in the devolved economies. He/she asked the PMCPA to ask Galen to try to reflect savings of/or costs in year and not to seek to mislead the GP population. The complainant alleged that Galen could and would bring itself and the industry into disrepute.

In writing to Galen the Authority asked it to bear in mind the requirements of Clauses 2, 7.2 and 7.3 of the Code.

RESPONSE

Galen submitted that it took these issues extremely seriously and was happy to cooperate fully. The complaint was anonymous which made it difficult to gain clarity as to the exact nature of the concerns. It was not possible to verify the assumption that the complainant worked in a CCG although Galen accepted the website was likely to be accessed by primary care organisation (PCO) medicines management.

The Trustsaver website (http://www.trustsaver.co.uk/home) had been available since 2010 and the underlying principles had remained the same. Through Galen's branded generic products, savings could be made versus branded market leaders. Since this date, Galen had had only three complaints regarding Trustsaver claims, the first was settled by the PMCPA in Galen's favour (Case AUTH/2494/3/12 Norgine v Galen), the second was resolved by inter-company dialogue with Stirling Anglian Pharmaceuticals and in the third, Galen was currently engaged in inter-company dialogue with Internis Pharmaceuticals. No complaints, except possibly this one, had been made by a health professional.

The Trustsaver concept had been consistent in its message of offering 'significant drug acquisition cost savings vs. market-leading brands' and as a result was not misleading health professionals in claiming to include all comparator preparations available.

Galen responded to each point of the current complaint in turn:

1 'The site has a defined claim of potentially saving tens of millions £££ across the UK health economy. I am not sure if this reflects England, Wales, Scotland and Northern Ireland all of which have devolved health economies …. My first question is should this not be split into each country within our union?'

Galen submitted that the Trustsaver website was United Kingdom specific (.co.uk) and clearly stated at the top of every page that it was intended for 'UK HCPs only'. All countries within the Union shared the same pricing policies for all the Trustsaver products. In addition, by referring to the NHS and not specifically NHS England, NHS Wales, NHS Scotland or NHS Northern Ireland, Galen submitted that it was clear regarding the territories concerned, although this did not seem to be a concern or complaint but a question from the complainant.

In addition, Galen provided the facility for more personalised saving models by individual PCO or by using an on-line calculator.

As a result Galen submitted that the statement was unambiguous and clear and therefore not in breach of Clause 7.2.

2 'Should the comparison not be on a like for like basis e.g. Laxido Orange Vs CosmoCol and other Orange preparations?'

Galen submitted that Laxido Orange (orange flavour) was introduced in 2008 and was the first product approved as a generic of Movicol (lemon & lime flavour). Both products had the same qualitative and quantitative active ingredients, the same pharmaceutical form and were indicated for the same purpose. In Case AUTH/2494/3/12 (Norgine v Galen, Trustsaver campaign) it was accepted that the Trustsaver campaign was simply about changing prescribing from one medicine to its less expensive generic equivalent, and Laxido Orange was, and continued to be, accepted as a generic equivalent of Movicol. In Case AUTH/2494/3/12, Galen demonstrated that a 90%+ conversion had occurred from Movicol to Laxido Orange in some areas.

As had been successfully and clearly demonstrated over the years since its launch, Trustsaver was based on savings vs market-leading brands (ie the most widely prescribed). This was clearly set out at the top of the Trustsaver homepage and as other brands such as the named Cosmocol were insignificant in terms of market share, Galen did not compare against it.

Based upon previous cases, and indeed all products being approved by the MHRA as generics to the brand originator, all products within the Cosmocol range were like-for-like with the brand originator Movicol, as was Laxido Orange.

In addition, a Prescribing Policy Document (which was reviewed in Case AUTH/2644/10/13 Norgine v Galen, Prescribing Policy for Laxido Orange) (which was no longer used by Galen) stated the following:

- Using Eclipse Live as an audit tool, only 0.007% of patients registered on the Isle of Wight who have been prescribed Laxido Orange have been prescribed MOVICOL®* subsequently.
- Issues such as differing taste, effectiveness of previous medication or a health care professional having recommended the previous product have not represented a significant barrier to change for the authors;
- Many PCOs have already undertaken the switch successfully.'

Interestingly, it seemed the complainant might also have misunderstood the competitors and their differences. For example, both Laxido Orange and Movicol had consistent pricing across their preparations, ie Movicol unflavoured, lime and lemon and chocolate flavoured products all share the same pricing policy, whilst Cosmocol had a different pricing strategy depending upon the flavour. CosmoCol Orange had a 3% market share in England as shown by PCA data from August 2016 and so clearly was not a market-leading brand.

Galen submitted that the Trustsaver website was clear by stating 'significant drug acquisition cost savings vs. market-leading brands' and, as a result, Galen submitted that the comparison was unambiguous, clear and on a 'like-for-like' basis, and so was therefore not misleading and not in breach of either Clauses 7.2 or 7.3.

3 'Should Laxido Natural not be listed on the site and compared with other preparations such as CosmoCol plain?'

Galen explained that Laxido Natural was last shipped from Galen on 1 May 2009 and the Dictionary of Medicines and Devices changed the flag to 'discontinued' on 16 September 2009.

The Trustsaver website was clear by stating 'significant drug acquisition cost savings vs. market-leading brands' and as a result was not misleading health professionals in claiming to include all preparations available and not in breach of Clauses 7.2 or 7.3.

Galen submitted that the comparison was unambiguous, clear and on a 'like-for-like' basis, and was therefore not misleading and not in breach of either Clauses 7.2 or 7.3.

4 'Should the comparisons actually not be retrospective but be based on potential prospective savings year on year … reflecting the NHS budgeting cycle.'

Galen submitted that prospective, by its very nature, was a forecast and hence unlikely to be accurate. As many of the markets were growing and competitor pricing might change, this could merely inflate or deflate any savings calculation and potentially lead to more claims of providing misleading information.

The website provided a calculator allowing the user to input their own annual average usage, as well as providing a slider tool to show the % of scripts

the users believed they could convert to a given Trustsaver product.

Case AUTH/2494/3/12 accepted the savings figures were illustrative and in accordance with Clause 7.2 and, as good practice, Galen had tried to be as accurate as possible in an attempt to give the best indication of the potential savings available.

As a result, Galen submitted the comparison was unambiguous, clear and on a 'like-for-like' basis, and therefore not misleading and not in breach of either Clauses 7.2 or 7.3.

5 'In reality the feedback from our successful switch to Laxido from all preparations showed a proportion of patients 15% who asked to switch back to Movicol Lemon and Lime at that time. Now that we have looked again at potential savings we have decided to change Movicol Lemon and Lime to CosmoCol Lemon and Lime and all generically prescribed macrogol unflavoured macrogol to change to a cost effective plain preparation.'

Galen accepted that not everyone would accept the change to Laxido Orange and this could be for a variety of reasons. Conversions had been made in a number of areas with a high degree of acceptance as the complainant acknowledged. Galen had not tried to portray that a conversion of 100% would occur and this was clearly stated in an open and transparent manner. Again, this point was reviewed in Case AUTH/2494/3/12.

As previously stated, the website provided a calculator allowing the user to input their own annual average usage as well as providing a slider tool to show the % of scripts the users believed they could convert to a given Trustsaver product.

In addition, the Prescribing Policy Document (which was reviewed by the PMCPA Case AUTH/2644/10/13 Norgine v Galen, Prescribing Policy for Laxido Orange) (which was no longer used by Galen) stated the following:

- Using Eclipse Live as an audit tool, only 0.007% of patients registered on the Isle of Wight who have been prescribed Laxido Orange have been prescribed MOVICOL®* subsequently.
- Issues such as differing taste, effectiveness of previous medication or a health care professional having recommended the previous product have not represented a significant barrier to change for the authors;
- Many PCOs have already undertaken the switch successfully.'

6 'In short I ask that like for like comparisons are made reflecting the very real cost consequence associated with Laxido in year we are not focussed on savings we may have realised rather savings we may make in year and prospectively.'

Galen submitted that prospective, by its very nature, was a forecast and hence unlikely to be accurate. As many of the markets were growing this could merely inflate any savings calculation and thereby potentially lead to more claims of providing misleading information.

The website provided a calculator allowing the user to input their own annual average usage as well as providing a slider tool to show the % of scripts the users believed they could convert to a given Trustsaver product.

Savings were only realised with continued branded prescribing and indeed further savings could be realised if Laxido Orange was prescribed vs both Movicol and generic scripts.

As a result Galen submitted that the comparison was unambiguous, clear and on a 'like-for-like' basis, and therefore not misleading and not in breach of either Clauses 7.2 or 7.3.

7 'I feel that we have been large user of Laxido and feel misled by the trustsaver site and the claims which are clearly not going to be made in this budget cycle, disappointing our GPs.'

Galen stated it was not clear exactly what the concerns were here. However, the Trustsaver website was not misleading and not in breach of either Clauses 7.2 or 7.3.

8 'Can you ask Galen to take down their site "trustsaver" with retrospective claims on savings and illustrate prospective savings? These claims apply to all brands and not just Laxido again we are users of other galen products such as steripoules and diltiazem.'

Galen submitted that prospective, by its very nature, was a forecast and hence unlikely to be accurate. As many of the markets were growing this would merely inflate any savings calculation and potentially lead to more claims of providing misleading information.

Galen's generic Saline Steripoules was removed from the website on 18 October 2016 for commercial reasons. However, at the time of removal the product had a NHS list price (£13.50) – significantly less than both the drug tariff (£16.91 Nov 2016) and the other market-leading competitor product on sale in the UK (£21.70).

As a result Galen submitted that the comparison was unambiguous, clear and on a 'like-for-like' basis, and therefore not misleading and not in breach of either Clauses 7.2 or 7.3.

9 'Can you ask Galen to reflect the diverse nature of our Health services in devolved economies?'

As previously stated, Galen did not see what additional benefit this provided, as the website was UK specific and all countries within the Union shared the same pricing policies for all the Trustsaver products. In addition, as stated clearly on the website, Galen provided the facility for more personalised saving models by PCO or by using an on-line calculator.

10 'Can you ask Galen to try and reflect savings of/or or [sic] and costs in year and not seek to mislead our GP population?'

Galen was unsure what was meant by this request but strongly denied that it had misled any health professional.

As previously submitted, the comparisons were unambiguous, clear and on a 'like-for-like' basis, and therefore not misleading and not in breach of either Clauses 7.2 or 7.3.

Galen totally refuted the allegation that it had brought the industry into disrepute.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints would be accepted, but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant could not be contacted for more information.

The Panel noted that there had been a previous complaint about Trustsaver, Case AUTH/2494/3/12 where no breaches of the Code had been ruled. There were differences between the complaints.

Turning now to the current complaint the Panel noted the complainant's concerns with regard to the claim that 'Trustsaver has potentially saved the NHS over £36 million since it launched in 2010' which was qualified by the use of an asterisk with the explanation immediately beneath that 'The savings estimate refers to drug acquisition costs'. It has been calculated using PCA data for the Trustsaver products and reflects the theoretical difference in costs, had 100% of prescriptions been for the market-leading competitor instead (excludes latest product additions and includes a past Trustsaver product)' and was referenced to data on file. The complainant was concerned that the potential savings should be split into each country ie instead of covering the UK, provide figures for Northern Ireland, Scotland, Wales and England. The Panel did not consider it was necessarily misleading to give savings as one figure to the NHS rather than for each devolved nation. More detail could be obtained by using the personalised cost saving calculator and inputting relevant data. The cost calculator could also show savings if a particular percentage of scripts were changed from the market leader brand to a Galen Trustsaver product. In addition, the Panel noted Galen's submission that all countries in the UK shared the same pricing policies for all Trustsaver products. It thus ruled no breach of Clauses 7.2 and 7.3 in this regard.

With regard to the cost comparison being against the market leader only, which the complainant referred to as the most expensive macrogol and not showing the prices of other available products, the Panel considered that it was clear that the website showed comparisons with the market leading brands. The Panel noted that Laxido Natural had been discontinued and therefore it was not misleading to omit it. In the circumstances it was not misleading to use potential retrospective savings for illustration based on average annual usage. There was no indication that using Laxido Orange was the cheapest option. Only that savings would be made compared to using the identified market leading brand. In addition, the Panel noted that if switches to Galen's product were made in year 1 the comparison with the cost of Laxido and the market-leading brand in year 2 were somewhat artificial. Further savings might be made by changing from a Galen product to an alternative, less expensive, medicine albeit not a market leader. It was not necessarily misleading to select products for comparison, it would depend on the basis of the selection and whether this had been made clear. The Panel did not consider it was necessarily misleading to use retrospective comparisons in relation to savings compared with the use of the market leading brand rather than potential prospective savings.

The Panel considered that the basis of the comparisons was clear and the complainant had not shown on the balance of probabilities that the material was misleading as alleged. The Panel ruled no breach of Clauses 7.2 and 7.3.

The Panel was concerned that the page of the website which set out product information about Laxido Orange claimed '45% savings with Laxido Orange' as a heading to a graph which compared the other major macrogol 3350 plus electrolytes brand. This was followed by 'Did you know the NHS currently spends more than £67 million per year on prescribing osmotic laxatives' and the claim 'make significant drug acquisition cost savings by prescribing Laxido Orange by brand'. These might give the impression that the savings were more than just a comparison with the market leading brand. The introduction to the Trustsaver portfolio at the top of the page referred to 'drug acquisition cost savings vs market-leading brands' whereas a prominent highlighted banner at the bottom of the page referred to significant drug acquisition cost savings by prescribing Laxido Orange by brand. There was no mention of this being in comparison to market-leading brands. On balance, the Panel considered that given the content of the website and the context of the page itself, although this page could and should be improved it was not in itself misleading. No breach of Clauses 7.2 and 7.3 were ruled.

The Panel noted its rulings above. It did not consider that the complainant had shown on the balance of probabilities that Galen had brought discredit upon or reduced confidence in the pharmaceutical industry. No breach of Clause 2 was ruled.

Complaint received **30 November 2016**

Case completed **13 January 2017**

CASE AUTH/2911/11/16 *NO BREACH OF THE CODE*

ANONYMOUS NON-CONTACTABLE v GALEN

Promotion of Laxido

An anonymous, non-contactable complainant complained about the promotion of Laxido by Galen at the recent Scottish Prescribers Association meeting. Laxido (macrogol plus electrolytes) was a laxative.

The complainant stated that his/her team recently returned from the meeting and had come to the collective view that misleading activity should be brought to the PMCPA and MHRA's attention. The complainant stated that he/she complained because of Galen's persistent activity repeated year after year. As an example, the complainant provided a photograph of a Laxido exhibition panel from an earlier meeting which he/she alleged contained a misleading comparison which referred to what was then an erroneous category M change which was reversed within months of the comparison. The complainant stated that the Galen representative consistently referred to potential savings with Laxido.

The complainant was concerned that Galen had brought the industry into some reputational challenge with continued misleading claims about potential future savings because Laxido Orange was more expensive than CosmoCol Orange and, even more troubling, Laxido Natural was more expensive than CosmoCol Plain in like for like and direct comparison.

The complainant noted that NHS Scotland used over 80% adherence to Laxido as a brand so the promotional materials reflecting a saving potential of several million pounds was clearly a claim that was not sustainable given the changes in Laxido pricing always in the upward trend since 2015 (sic).

The complainant submitted that the Galen representative seemed to have no clear understanding about the structure of NHS Scotland and the way in which the devolved health economy operated.

The representative assured the complainant that there was no need to switch to a lower price product (CosmoCol), as Galen would offer a rebate to cover the differential which was not permitted under standing financial rules in NHS Scotland. The complainant referred to a consistent misrepresentation of the company's pricing and not just Laxido. Examples were provided.

The complainant provided details of four substantive points, three with regards to misleading potential savings and a fourth that alleged Galen had suggested that a competitor company would not be afloat in 2016/17.

The detailed response from Galen is given below.

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints would be accepted, but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant could not be contacted for more information. The Panel noted the parties' accounts differed. The Panel noted the difficulty in dealing with complaints based on one party's word against the other; it was often impossible in such circumstances to determine precisely what had happened.

With regard to the allegation regarding the alleged erroneous category M change which had been reversed, the Panel noted that the complainant had provided no details. The Panel considered that without further information it was impossible for the Panel to consider this matter. In any event, the Panel noted Galen's submission that the category M change was only apparent in the Drug Tariff for England and Wales. The Panel ruled no breach of the Code.

The Panel noted the allegations about the cost saving claims and statements made by representatives about the rebate to cover the differential cost of using Laxido rather than switching to a lower price product. Representatives at the meetings had denied making the claims alleged.

The Panel noted Galen's submission that Laxido Natural was discontinued in September 2009. Whilst Laxido Orange was more expensive than CosmoCol Orange-flavoured and CosmoCol orange, lemon and lime-flavoured, Laxido Orange was less expensive than Cosmocol Lemon and Lime flavoured.

There was no claim that Laxido Orange was the cheapest product only that savings could be made compared to using the market leading brand. According to Galen, the cost of Laxido Orange had not increased since July 2014.

The complainant had not provided any materials regarding the potential savings of several million pounds. If Scotland was using 80% Laxido Orange then savings would depend on what was used for the remaining 20%. From Galen's submission it was not CosmoCol Orange.

On the material provided by the complainant the Panel was uncertain what the basis was for the alleged lack of understanding the Galen representative had about the NHS Scotland health economy.

The complainant had not provided any evidence about either the alleged rebate Galen offered to continue use of Laxido instead of changing to CosmoCol nor the price promise for Calceos.

Noting the totality of material before it and the complainant's burden of proof, the Panel did not consider that the complainant had established that misleading comparisons about cost savings and the comments about the rebate had been made. No breach of the Code was ruled.

With regard to the allegation that Galen had disparaged one company by referring to it as not being afloat in 2016/17, the Panel noted the differences in the parties' accounts. The complainant had provided no evidence and Galen had denied that its staff had made such statements. The Panel decided that on the balance of probabilities the complainant had not proved his/her complaint in this regard and therefore ruled no breach of the Code.

The Panel did not consider that the complainant had provided evidence to show that Galen had brought discredit upon or reduced confidence in the pharmaceutical industry. No breach of Clause 2 was ruled.

An anonymous, non-contactable complainant complained about the promotion of Laxido by Galen Ltd at the recent Scottish Prescribers Association meeting. Laxido (macrogol plus electrolytes) was a laxative.

COMPLAINT

The complainant stated that his/her team recently returned from the meeting and had come to the collective view that misleading activity should be brought to the PMCPA and MHRA's attention referring to the Code and the Blue Book. The complainant stated that he/she complained because of Galen's persistent activity repeated year after year. As an example, the complainant provided a photograph of a Laxido exhibition panel from an earlier meeting which he/she alleged contained a misleading comparison which referred to what was then an erroneous category M change which was reversed within months of the comparison. The complainant stated that the Galen representative consistently referred to potential savings with Laxido.

The complainant was concerned that Galen had brought the industry into some reputational challenge (Clause 2, disrepute) with the continued misleading claims about potential future savings. The complainant alleged claims about potential future savings were misleading as Laxido Orange was more expensive than CosmoCol Orange and, even more troubling, Laxido Natural was more expensive than CosmoCol Plain in like for like and direct comparison.

The complainant noted that NHS Scotland used over 80% adherence to Laxido as a brand so the promotional materials reflecting a saving potential of several million pounds was clearly a claim that was not sustainable given the changes in Laxido pricing always in the upward trend since 2015 (sic).

The complainant submitted that the Galen representative seemed to have no clear understanding about the structure of NHS Scotland and the way in which a devolved NHS Scotland health economy operated.

The representative assured the complainant that there was no need to switch to a lower price product (CosmoCol), as Galen would offer a rebate to cover the differential which was not permitted under standing financial rules in NHS Scotland. On further analysis of prescribing data and records of previous engagements with Galen representatives the complainant referred to a consistent misrepresentation of the company's pricing and not just Laxido. For example with Calcium and Vitamin D product (Calceos), Galen gave a price promise which was quietly dropped when other lower price products came to the complainant's and Galen's attention for example Acrete D3 (Internis' product) and theiCal D3 (Stirling Anglian's product). A promise not kept.

The complainant submitted that his/her substantive points were:

1 Galen showed a misleading picture of potential savings year on year. When a saving was made it remained the benchmark for the following months and year. Laxido in 2016 would have to show decrease in price vs Laxido 2015. The fact was that Laxido Orange had increased in price in 2016 and not delivered savings in contrast to CosmoCol Orange and CosmoCol Plain (the two like-for-like comparison products in that range). The complainant noted that there was a small amount of use of Movicol Lemon and Lime which was again more expensive than CosmoCol Lemon and Lime.

2 In order to claim savings for NHS Scotland, Galen should [not] refer to the direct comparison ie like-for-like in flavour and indeed the true reflection of the spend in the NHS Scotland osmotic laxative use and make the comparison relevant to those with whom they were engaging ie NHS Scotland which was a devolved part of the wider UK infrastructure with devolved budgets for prescribing as well as no prescription charge. The complainant noted the current picture of prescribing for NHS in respect of osmotic laxatives. In summary, the complainant queried how savings could be claimed and whether relevant savings should be based on the Scottish health economy and the comparisons made on a like-for-like basis?

3 The complainant submitted that Laxido Natural was more expensive than CosmoCol Plain. Laxido represented a cost increase and not a saving to NHS Scotland (and no doubt NHS England, NHS Wales, and NHS Northern Ireland). The complainant alleged this misled the NHS and with consistent variance in Laxido pricing in 2016, he/she was confused as to which price was the settled price for the product at the same time as others remained stable?

4 The complainant also noted that one of his/her colleagues had suggested that Galen had been

slagging off of a competitor company, suggesting that it would not be afloat in 2016/17.

The complainant stated that the above added up to a lowering of trust and confidence not only in Galen but more widely in the industry over misleading pricing, rebates, and comparisons that were not like-for-like.

When writing to Galen the Authority asked it to bear in mind Clauses 2, 7.2, 7.3 and 8.1.

RESPONSE

Galen submitted that it took these issues extremely seriously and was happy to cooperate fully, however, it questioned the validity of the complaint due to both its content and somewhat coincidental timing with Case AUTH/2892/11/16 and a letter it had recently received from Internis Pharmaceuticals. The company's concerns would become clear when reviewing its response. Plus there were numerous references to Stirling Anglian's products and one to Internis Pharmaceuticals.

In addition, Galen stated that the complaint was extremely vague and lacked clear evidence upon which Galen was able to respond, however, it endeavoured to respond fully and within the spirit of each comment provided.

Galen was disappointed and thought it was unusual for a complainant to make allegations about a meeting without providing any details of the meeting, date or location.

The complainant alleged that Galen's activity was misleading and had been persistent year after year. Galen had not received any complaint of this nature before and in the absence of specific information investigated its presence at this annual event.

Galen attended the Scottish Prescribing Association meetings in 2014, 2015 and 2016. It provided details about the dates and venues for the meetings, which Galen staff attended and the banner stands used. In 2014 the Laxido Orange (PMR-OCT-2014-0288) stand was used and in 2015 and 2016 the Trustsaver (PMR-MAY-2015-0150) stand was used. Photographs were provided.

Galen stated that the representatives who attended these meetings were interviewed and were asked a number of questions including the use of rebates to cover differential costs of Laxido Orange and CosmoCol Orange, other price promises regarding Calceos and discussions about Laxido Natural. All the representatives stated that these topics were not discussed. No representative agreed that they had ever disparaged a competitor company or suggested that it would not be around in 2016/17.

With regard to the photograph provided by the complainant (Galen pointed out that there was no date) and the alleged use of old materials, Galen assumed the reference to an earlier meeting was either 2014 or 2015 but the complainant was not specific.

Galen stated that the photograph provided by the complainant suggested the meeting was 4 November 2014. The materials used were approved in October 2014 and so were not out of date. The claims were based on the cost of Laxido Orange and the Drug Tariff at that time and were correct both for the UK and more specifically Scotland.

Galen questioned whether it was usual for a health professional to keep such a photograph for so long, to be able to find it and not being able to validate the date, time and location. It was also strange that a more recent example was not presented.

With reference to the complainant's mention of an 'erroneous Cat M change' Galen wondered what the Department of Health's reaction would be to that claim as Galen did not believe it could be substantiated. Indeed this change was not Galen's interpretation. It should, however, be noted that this 'erroneous change' was only apparent in the Drug Tariff for England and Wales.

Galen submitted that the banner stands used at the 2015 and 2016 meetings were compliant.

With regard to the complainant's statement that Galen made continued misleading claims about future potential savings but again provided no evidence, Galen agreed that it had made claims regarding savings vs drug tariff costs and market-leading brands. The savings were only achievable if health professionals prescribed and continued to prescribe Laxido Orange by brand.

Galen noted that the Trustsaver banner stand used in 2015 and 2016 made no reference to specific products and clearly supported the concept of Trustsaver and opened the door for further dialogue, as well as providing information regarding the website where specific information was available. As a result, it was unclear how this was misleading or anything other than statements of fact. In addition, the details of the Trustsaver website were clearly prominent and invited health professionals to look for more information. Trustsaver was introduced by Galen in 2010 and since then, the same underlying claims had been consistently made and accepted by the target audience.

Based upon previous cases, and indeed all products being approved by the MHRA as generics to the brand originator, all products within the CosmoCol range were like-for-like with the brand originator Movicol, as was Laxido Orange.

Laxido Orange (orange flavour) was introduced in 2008 and was the first branded generic for Movicol (lemon & lime flavour). Both products had the same qualitative and quantitative active ingredients. The market, Norgine and Case AUTH/2494/3/12 (Norgine v Galen, Trustsaver campaign) accepted that the Trustsaver campaign was simply about changing prescribing from one medicine to its less expensive generic equivalent and Laxido Orange had been accepted as being a generic equivalent of Movicol. In Case AUTH/2494/3/12 Galen demonstrated that a 90%+ conversion had occurred from Movicol to Laxido Orange in practice in some areas.

In addition, a Prescribing Policy document (which was reviewed in Case AUTH/2644/10/13 Norgine v Galen and was no longer used by Galen) stated:

- Using Eclipse Live as an audit tool, only 0.007% of patients registered on the Isle of Wight who have been prescribed Laxido Orange have been prescribed MOVICOL®* subsequently.
- Issues such as differing taste, effectiveness of previous medication or a health care professional having recommended the previous product have not represented a significant barrier to change for the authors;
- Many [primary care organisations] PCOs have already undertaken the switch successfully.'

The statement regarding Laxido Natural was factually incorrect – Laxido Natural was last shipped from Galen on 1 May 2009 and the Dictionary of Medicines and Devices changed the flag to discontinued on 16 September 2009.

The complainant's claim of 80% adherence to Laxido as a brand was not supported by any details as to how the figure was obtained and from what date.

Galen stated that the complainant's statement 'Laxido pricing always in the upward trend since 2015' was irrefutably incorrect and raised concerns regarding the complainant's motives and indeed questioned the validity of the complaint.

The NHS Dictionary of Medicines and Devices (dm+d) system showed that the price of Laxido Orange 30s had not changed since 7 July 2014 and on that date the price was reduced from £5.34 to £4.27. There had been no pricing changes 'since the 2015'.

In order to understand the current impact of using Laxido Orange vs generic macrogol in Scotland, Galen looked at the latest prescription cost analysis (PCA) data for Scotland (an extract of adult Macrogol on a like-for-like basis was provided). If all Laxido Orange had been prescribed as generic Macrogol then the gross ingredient cost would have been £5,716,016.16 vs £2,712,251.43, representing a saving of approximately £3,000,000 by prescribing Laxido Orange.

The current drug tariff price for generic macrogol prescriptions in Scotland was £9 vs £4.27 for Laxido Orange.

Savings were only realised with continued branded prescribing and indeed further savings could be realised if Laxido Orange was prescribed vs both Movicol and generic prescriptions.

Galen stated that the Trustsaver banner stand used in 2015 and 2016 made no reference to specific products and clearly supported the concept and opened the door for further dialogue, and provided information regarding the website where specific information was available. It did not provide specific banners for particular regions within the UK, as within Scotland and England there were differences at each primary care organisation level (CCG within England and Health Boards in Scotland), however, Galen provided the opportunity for each individual PCO to discuss specific savings models. These were offered by both the sales team and via the Trustsaver website.

The complainant specifically referred to 'Cosmocol' being a lower price than Galen's product, whilst earlier in the complaint the complainant tried to distinguish between the products in the range. Galen submitted this was misleading as CosmoCol as a brand had 3 different flavours with a different pricing policy across them. In December 2016 the prices of CosmoCol were orange, lemon and lime-flavoured, 20 = £2.75 and 30 = £3.95; orange-flavoured, 20 = £2.75 and 30 = £3.95; lemon and lime-flavoured, 20 = £3.56 and 30 = £5.34 and unflavoured, 30 = £3.95.

The price of Laxido Orange was 20 = £2.85 and 30 = £4.27.

Galen submitted that clearly CosmoCol Lemon and Lime was more expensive than Laxido Orange, and, according to the Prescription Cost Analysis from Scotland for 2015/16 by value CosmoCol Lemon and Lime represented the highest 'gross ingredient cost' out of all CosmoCol preparations in 2015/16: £1,481 for Lemon and Lime vs £1,322 for Orange and £389 for Orange, Lemon and Lime.

Galen stated that the allegation regarding references to 'rebates' was factually incorrect. The representatives who had attended this meeting over the last 3 years categorically denied making such a statement. In any case, any rebate would need the approval of the managing director who confirmed that this option had NEVER been on the table and would NEVER be approved.

With regard to the price promise and competitor pricing with regard to Calceos, Galen submitted that its product Calceos was marketed as the least expensive calcium/vitamin D3 chewable tablet. Accrete D3 was not the same form, ie it was not a chewable tablet. This was clear on all materials. The market was complex in the sense that most products differed in their quantitative ingredients. On 4 June 2014, the Galen sales team was instructed to stop promoting Calceos. There was a price promise for Calceos which offered savings until 2014 vs leading calcium/Vitamin D3 chewable tablets. Calceos maintained this position and thus the allegation that Galen did not keep this promise was factually incorrect.

Galen was committed to remaining competitive in the branded calcium/vitamin D market. Should the price of Adcal D3 or Calcichew D3 Forte drop to below the price of Calceos, then the price of Calceos would be lowered to at least match this price. The price reduction would occur within six months and the price pledge was in place until at least 2014.

The Stirling Anglian website stated that the iCal-D3 was launched Q4 2014. Galen had never received any complaint on this subject from anyone else in the UK.

Galen stated that the alleged '... misleading picture of potential savings year on year .... When a saving

is made this remains the benchmark for the following months and year' was extremely broad and there was no specific point to comment on. Galen denied it had, or was showing, a misleading picture of potential savings year-on-year. Within this complaint there were no details regarding what the 'misleading picture' was.

Laxido Orange 30s had not changed price since 7 July 2014, and on that date the price was reduced from £5.34 to £4.27. Laxido Orange had not increased in price in 2016.

Savings were only realised with continued branded prescribing and indeed further savings could be realised if Laxido Orange was prescribed vs both Movicol and generic prescriptions.

The Trustsaver banner used in 2015 and 2016 made no reference to specific products and clearly supported the concept and opened the door for further dialogue and provided information regarding the website where specific information was available.

CosmoCol Orange was introduced in 2014.

The allegation that 'Laxido represents a cost increase and not a cost saving' was factually incorrect. According to the Prescription Cost Analysis from Scotland for 2015/16, £868,972.03 of Movicol and £573,580.20 of generic macrogol compound was dispensed and, as shown below, Movicol was more expensive than Laxido as was the Scottish Drug Tariff for generic prescriptions.

The statement regarding 'others remaining stable in pricing in 2016' was factually incorrect. The Movicol Lemon and Lime 30s showed the price increased on the 2 May 2016 from £7.35 to £7.72.

With regard to the allegation that a competitor company was 'slagged off', Galen submitted it had investigated this point as fully as possible on the little information to substantiate the meeting date, meeting location or representative's name. However, assuming it referred to the meeting in 2014, representatives who attended these meetings since 2014 categorically denied any 'slagging off' of any competitor. Indeed, all representatives had exemplary records within Galen and had been with the company for many years with no complaints from either a competitor pharmaceutical company or a health professional. Anyone with any concerns regarding Galen's employees or promotional campaigns should raise them immediately and not 2 years later. There was no evidence of a breach of Clause 8.1.

Galen submitted that the allegation regarding a lowering of trust and confidence over misleading pricing, rebates and comparisons that were not like-for-like carried no weight based on all the content above. Having conducted a thorough investigation Galen could see no evidence regarding breaches of Clauses 7.2, 7.3, 8.1 and therefore Galen had not brought the industry into disrepute. At the time of use, the materials were accurate, balanced and certainly not misleading and there was no evidence that the sales team were disparaging competitors in any way. This was in contrast to the complainant, be it a health professional or competitor, who presented incorrect information designed to mislead and therefore disparage Galen.

PANEL RULING

The Panel noted that the complaint had been copied to the MHRA and referred to the Blue Book. The PMCPA could only consider cases in relation to the requirements of the Code.

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints would be accepted, but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant could not be contacted for more information. The Panel noted the parties' accounts differed. The Panel noted the difficulty in dealing with complaints based on one party's word against the other; it was often impossible in such circumstances to determine precisely what had happened.

With regard to the allegation regarding the alleged erroneous category M change which had been reversed, the Panel noted Galen's submission that the banner stand showed the cost of Laxido Orange and the macrogol Drug Tariff prices as at October 2014 and was used in November 2014. The complainant had provided no details about the alleged erroneous category M change. The Panel noted its comments above that the complainant had the burden of proof and was uncontactable. The Panel considered that without further information it was impossible for the Panel to consider this matter. In any event, the Panel noted Galen's submission that the category M change was only apparent in the Drug Tariff for England and Wales. The Panel ruled no breach of Clause 7.2.

The Panel noted the allegations about the cost saving claims and statements made by representatives about the rebate to cover the differential cost of using Laxido rather than switching to a lower price product. Representatives at the meetings had denied making the claims alleged. The Panel noted that the Trustsaver banner stand used in 2015 and 2016 bore the prominent claim 'Trustsaver Quality brands with the saving of generics'. A subheading referred to 'Cost savings' in yellow font and a subsequent bullet point read 'Significant drug acquisition cost savings vs market-leading brands'. No medicines were named. The Panel considered that given the banner and therapeutic area, it was not unreasonable to assume that cost savings were discussed by the representatives at the meeting. The Panel did not know what other material was available at the stand.

The Panel noted Galen's submission that Laxido Natural was discontinued in September 2009. Whilst Laxido Orange was more expensive than CosmoCol Orange-flavoured and CosmoCol orange, lemon and lime-flavoured, Laxido Orange was less expensive than Cosmocol Lemon and Lime flavoured.

There was no claim that Laxido Orange was the cheapest product only that savings could be made compared to using the market leading brand. According to Galen, the cost of Laxido Orange had not increased since July 2014.

The complainant had not provided any materials regarding the potential savings of several million pounds. If Scotland was using 80% Laxido Orange then savings would depend on what was used for the remaining 20%. From Galen's submission it was not CosmoCol Orange.

On the material provided by the complainant the Panel was uncertain what the basis was for the alleged lack of understanding the Galen representative had about the NHS Scotland health economy.

The complainant had not provided any evidence about either the alleged rebate Galen offered to continue use of Laxido instead of changing to CosmoCol nor the price promise for Calceos.

Noting the totality of material before it and the complainant's burden of proof, the Panel did not consider that the complainant had established that misleading comparisons about cost savings and the comments about the rebate had been made. No breach of Clauses 7.2 and 7.3 was ruled.

With regard to the allegation that Galen had disparaged one company by referring to it as not being afloat in 2016/17, the Panel noted the differences in the parties' accounts and its comments above in this regard. The complainant had provided no evidence and Galen had denied that its staff had made such statements. The complainant had provided very few details and no evidence to support his/her allegations. The Panel decided that on the balance of probabilities the complainant had not proved his/her complaint in this regard and therefore ruled no breach of Clause 8.1.

The Panel did not consider that the complainant had provided evidence to show that Galen had brought discredit upon or reduced confidence in the pharmaceutical industry. No breach of Clause 2 was ruled.

Complaint received **30 November 2016**

Case completed **13 January 2017**

ANONYMOUS, NON CONTACTABLE v JANSSEN

Conduct of medical science liaison employee

An anonymous, non-contactable complainant complained about the way in which one of Janssen's medical science liaison (MSL) team had offered information about the CANagliflozin cardioVascular Assessment Study (CANVAS) to a health professional at a primary care conference held in the UK. Canagliflozin (marketed by Janssen as Invokana) was indicated to improve glycaemic control in type 2 diabetes in adults.

The complainant stated that he/she saw the Janssen employee introduce him/herself to the health professional and ask him how he wished to receive information on the CANVAS study. When the health professional replied that he was uncertain about how to get such information, the MSL gave him a form to sign so the information could be delivered to him when the results were announced. According to the complainant this left the health professional, who would not complain personally, uncomfortable.

The detailed response from Janssen is given below.

The Panel noted that the parties' accounts about the exchange which had taken place differed; it was extremely difficult to know exactly what had transpired. It appeared that the complainant, who was non-contactable and so could not be asked for further information, had been an onlooker. The complainant bore the burden of proof on the balance of probabilities. A judgement had to be made on the available evidence. The complainant had provided very few details and no evidence to support his/her allegations. Conversely, Janssen had provided an email from the health professional in which he stated that he had no issue with the approach made to him by the Janssen MSL. This was inconsistent with the complainant's submission.

The Panel noted Janssen's submission that the health professional was one of the presenters at the meeting and that his presentation had included some data about the CANVAS study which was incorrect. In that regard the Panel considered that it was not unreasonable for the MSL to subsequently talk to him and draw attention to his error. The Panel noted that, provided that certain conditions were met, the Code excluded from the definition of promotion replies made in response to individual enquiries from health professionals or in response to specific communications from them whether of enquiry or comment, including letters published in professional journals. In the Panel's view, the MSL's response to inaccurate data being presented about the CANVAS study could take the benefit of that exemption provided that it was not inaccurate, misleading or promotional. Janssen submitted that as a result of his exchange with the MSL, the health professional asked to be kept updated on the emerging clinical data from the CANVAS study. Given the circumstances in which the exchange had arisen, the Panel did not consider that the MSL's reference to the CANVAS study, which had prompted the health professional to ask to be kept updated on the emerging clinical data, was such as to promote Invokana. No breaches of the Code were ruled including of Clause 2.

An anonymous, non-contactable complainant complained about the way in which one of Janssen's medical science liaison (MSL) team had offered clinical trial information to a heath professional at the 12th National Conference of the Primary Care Diabetes Society (PCDS), held in Birmingham on 24/25 November 2016. The clinical trial at issue was the the CANagliflozin cardioVascular Assessment Study (CANVAS). Canagliflozin (marketed by Janssen as Invokana) was a sodium glucose co-transporter 2 (SGLT2) inhibitor indicated to improve glycaemic control in type 2 diabetes in adults.

COMPLAINT

The complainant who did not wish to be contacted further, stated that he/she witnessed a member of the Janssen MSL team introduce him/herself to a health professional, and ask him how he wished to receive information on the CANVAS study. The MSL clearly did not know the health professional as he/she introduced him/herself stating they had not met before.

When the answer back was uncertain about how he would source such information, the MSL asked the health professional to sign a medical information form so the information could be delivered to him when the results were announced. According to the complainant this left the health professional uncomfortable. The health professional would not complain personally, but the complainant stated that he/she felt duty bound to highlight his dissatisfaction about the conduct of a member of the pharmaceutical industry.

When writing to Janssen, the Authority asked it to bear in mind the requirements of Clauses 2, 3.1, 3.2 and 9.1 of the Code.

RESPONSE

Janssen submitted that CANVAS was an ongoing cardiovascular outcomes trial for canagliflozin studying people with type 2 diabetes who were at high risk of cardiovascular events, and were within the CANVAS programme. The integrated analysis of the CANVAS programme would enable Janssen to meet the US Food and Drug Administration (FDA) post-marketing requirement to study the cardiovascular safety of canagliflozin, as well as evaluate the impact for cardiovascular outcome with canagliflozin in type 2 diabetics. The CANVAS programme was near completion and expected

to report in 2017. No outcome data were currently available. There was significant interest in the clinical community on cardiovascular outcome studies on SGLT2 inhibitors.

Janssen submitted that the PCDS represented all health professionals involved with primary care diabetes, including GPs, practice nurses, GPs with a special interest and clinical assistants. The Janssen MSL attended the 2016 conference to represent Janssen, to fulfil his/her educational needs, build networks with health professionals and key opinion leaders and respond to scientific questions or concerns about canagliflozin raised by health professionals.

The incident raised by the complainant occurred following a presentation given by the heath professional, organised by the PCDS; Janssen was not involved in the organisation of the presentation. The health professional presented a timeline slide where the information on CANVAS was incorrect. The MSL approached the health professional at the end of the session, after conference delegates completed their discussions with him to ensure their conversation was private, to introduce him/herself as the MSL responsible for his region and to politely draw his attention to the error in the presentation. The discussion took place in the meeting room, not at the company stand.

The health professional stated that he would like to be kept updated on emerging clinical data from the CANVAS programme during the discussion. Hence, the MSL asked him to complete the Emerging Clinical Data Request Form, allowing the Janssen medical affairs team to provide updates in the context of scientific exchange according to the clinical interest as specified, provided it was in line with the Code. For the avoidance of doubt, this was in response to the health professional's request and was unsolicited.

The Janssen medical lead visited the health professional on 14 December 2016 to understand his recollection of the incident in question and also to determine whether there were any areas where the Janssen medical team could improve and if the health professional was uncomfortable with any part of the recent interaction, as alleged by the complainant. The health professional confirmed that his request for further information on CANVAS was unsolicited and furthermore, in writing, refuted the complainant's accusation that the Janssen MSL left him uncomfortable and dissatisfied about the conduct of a member of pharmaceutical industry. The health professional confirmed 'I personally have no issue at all with the approach made to me by the Janssen representative at the PCDS conference on 24 November 2016'. A copy of his statement was provided.

Janssen submitted that no material was sent to the health professional as he did not request materials on CANVAS. There were no specific UK instructions to MSLs about the use of the CANVAS study because currently there was no data available. There was no MSL briefing document specific to the PCDS national conference 2016. There were no CANVAS related materials at the promotional stand. Over 2 days of the PCDS meeting with approximately 700 delegates in attendance, Janssen received 4 reactive Emerging Clinical Data Requests on the CANVAS programme as follows:

One from the health professional in question as discussed above.

A speaker who asked the Janssen MSL about the CANVAS programme results and requested an update when results were available.

A delegate enquired about recent adverse events related to the CANVAS study which was communicated recently with a Dear Healthcare Professional Letter, as well as cardiovascular data currently available with canagliflozin. After being informed there was no cardiovascular data on CANVAS available, the delegate asked to be informed when the data was available.

A delegate who met the MSL the previous week (16 November) and requested an update on CANVAS, had been unable to complete the form at that time due to time restraints, and so agreed to meet at the PCDS to complete the request form.

Janssen stated that it took the Code extremely seriously, it was paramount for Janssen to build a trusted and collaborative relationship with health professionals. The Janssen MSL responded to an unsolicited request from a health professional to be kept updated on clinical development, in the context of scientific exchange according to the clinical interest specified by the health professional. There was no evidence to suggest the Janssen MSL promoted the use of canagliflozin outside of its marketing authorization, nor proactively promoted results of a clinical study which was yet to be reported and hence Janssen refuted breaches of Clauses 3.1 and 3.2. The company submitted that it had demonstrated that the Janssen MSL maintained a high standard and therefore there was no breach of Clause 9.1. The basis of this complaint was unfounded and Janssen submitted that it had not brought the pharmaceutical industry into disrepute, there was no breach of Clause 2.

PANEL RULING

The Panel noted that there were differences between the parties' accounts about the exchange which had taken place between the MSL and the health professional; it was extremely difficult in such cases to know exactly what had transpired. It appeared that the complainant, who was non-contactable and so could not be asked for further information, had been an onlooker. The complainant bore the burden of proof on the balance of probabilities. A judgement had to be made on the available evidence. The complainant had provided very few details and no evidence to support his/her allegations. Conversely, Janssen had provided an email from the health professional concerned in which he stated that he had no issue with the approach made to him by the Janssen MSL. This was inconsistent with the complainant's statement that the health professional was uncomfortable.

The Panel noted Janssen's submission that the health professional was one of the presenters at the meeting and had included some timeline data about the CANVAS study which was incorrect. In that regard the Panel considered that it was not unreasonable for the MSL to subsequently talk to the health professional and draw attention to his error. The Panel noted that Clause 1.2 of the Code excluded from the definition of promotion replies made in response to individual enquiries from health professionals or in response to specific communications from them whether of enquiry or comment, including letters published in professional journals, but only if they related solely to the subject matter of the letter or enquiry, were accurate and did not mislead and were not promotional in nature. In the Panel's view, the MSL's response to inaccurate data being presented about the CANVAS study could take the benefit of that exemption provided that it was not inaccurate, misleading or promotional. The Panel noted Janssen's submission that the health professional confirmed verbally at a meeting with its medical lead that his request for further information on CANVAS was unsolicited; this was not confirmed in his subsequent email. Janssen submitted that as a result of his exchange with the MSL, the health professional asked to be kept updated on the emerging clinical data from the CANVAS study. Given the circumstances in which the exchange had arisen, the Panel did not consider that the MSL's reference to the CANVAS study, which had prompted the health professional to ask to be kept updated on the emerging clinical data, was such as to promote Invokana. No breach of Clauses 3.1 and 3.2 were ruled.

The Panel noted its comments and rulings above and considered that there was no evidence that the MSL had not maintained high standards. No breach of Clause 9.1 was ruled.

Given its rulings above, the Panel ruled no breach of Clause 2.

During its consideration of this case, the Panel was concerned to note that Janssen appeared to use Emerging Clinical Data Request Forms to allow it to send updates to health professionals *ad infinitum* off the back of one request. The Panel queried whether, following the first provision of data, each subsequent sending of information could benefit from the exemption to promotion for replies made in response to individual enquiries given in Clause 1.2 of the Code. In addition, the Panel queried Janssen's submission that its medical affairs team provided such updates in the context of scientific exchange. In the Panel's view, the data flow was all one way, from Janssen to health professionals. The Panel considered that Janssen would be well advised to review its arrangements for the provision of clinical updates to ensure that they complied with the Code.

Complaint received **5 December 2016**

Case completed **10 January 2017**

CASE AUTH/2914/12/16

HOSPITAL PHARMACIST v PIERRE FABRE

Navelbine bags distributed by representatives

A hospital pharmacist, complained on behalf of a group of pharmacists at a teaching hospital about the distribution of clear plastic bags for Navelbine (vinorelbine) Oral delivered by representatives from Pierre Fabre.

The bags were for pharmacists to give to patients when dispensing Navelbine Oral capsules. The bag was labelled as containing cytotoxic chemotherapy. Advice to keep the medicine in the refrigerator and how to take the capsules was included. The bag could be sealed.

The complainant stated that the bags seemed to be in poor condition. The sealant to close the bags at times did not work, which meant the very bag that was meant to transport the medicine might lead to patients losing their medication on their way home. More concerning was that some of the bags seemed to be dirty. It was reprehensible that Pierre Fabre would put patients at risk by providing such poor-quality material. The complainant queried whether the company had a quality department to check for such defects.

The complainant provided one of the bags after cleaning it and stated that if they had been provided to other hospitals they should be checked immediately.

The detailed response from Pierre Fabre is given below.

The Panel noted that bags which had been stored in a basement for around 3 years were provided to representatives to give to pharmacies. The bags were designed for Navelbine Oral which would be placed in the bag, sealed and given to the patient to take home. The Panel was concerned that the complainant described the bags as in a poor condition with soot and dust on the inside and that the sealant to close the bag at times did not work. The bags supplied to the Panel, one from the complainant and five from the company, did not look dirty but the complainant stated that one he/she sent had been cleaned. The sealants were different in that those supplied by the company had red tape over a flat clear sticky strip and the bag supplied by the complainant had clear tape over a yellow wrinkled sticky strip.

The Panel noted the email correspondence in that the bags had been found in the basement of Pierre Fabre's offices and the managing director instructed them to be distributed to the representatives. The correspondence indicated a difference of opinion in that one person said that the bags could not be used. This was confirmed by the medical director who stated that it would be inappropriate to send out the bags as the company was unaware of how long they had been left in unsuitable storage conditions and patient safety was in question.

The Panel considered that although it had no details on how the bags were stored in the basement, the complainant stated that he/she had received dirty bags with faulty seals. In the Panel's view this did not seem unreasonable given the bags had been in the basement for around 3 years. The email from the medical director referred to the bags having been left in unsuitable storage conditions. Other than a visual inspection by the managing director, it appeared that Pierre Fabre had not checked the quality of the bags before giving them to the representatives to distribute. The Panel considered that Pierre Fabre had not maintained high standards and ruled a breach of the Code.

The Panel was extremely concerned about the company's submission that the managing director having balanced the needs of the business had over-ruled the medical director's advice that the bags should not be distributed citing, *inter alia*, patient safety as a reason. In the Panel's view patient safety was paramount. It was not known how the bags had been stored in the basement nor how many of these had been distributed to the representatives. Similarly there was no information about how many bags had been given out by the representatives. The Panel did not know if every single bag had been visually inspected by the managing director before being given to representatives. The company had not commented specifically on the results of the visual inspection. The Panel considered that the circumstances brought discredit upon and reduced confidence in the pharmaceutical industry and therefore ruled a breach of Clause 2.

The Panel noted Pierre Fabre's submission that it had stopped supplying the bags to the representatives. It did not know whether the representatives had stopped supplying the bags they already had to pharmacies nor how many bags they had already given out. The Panel decided that as there was a potential safety issue with use of the bags it would require Pierre Fabre to suspend use of the bags if Pierre Fabre appealed the Panel's ruling pending the final outcome of the case. This was in accordance with Paragraph 7.1 of the Constitution and Procedure.

A hospital pharmacist, complained on behalf of a group of pharmacists at a teaching hospital about the distribution of bags for Navelbine Oral (vinorelbine) by representatives from Pierre Fabre Limited. Navelbine was available as an infusion and capsules and was indicated for the treatment of certain cancers.

The bags in question were for pharmacists to give to patients when dispensing Navelbine Oral capsules. The bag was clear plastic and was labelled as containing cytotoxic chemotherapy. Advice to keep the medicine in the refrigerator and how to take the capsules was included. The bag could be sealed.

COMPLAINT

The complainant stated that this was a matter of great importance with regard to patient safety.

The complainant stated that the hospital recently received a supply of the patient bags and the chief pharmacist had explained that they should only be used for Navelbine Oral when it was dispensed to patients. The bags, which were made of plastic, seemed to be in poor condition. The sealant to close the bags at times did not work, which meant the very bag that was meant to transport the medicine might lead to patients losing their medication on their way home. More concerning was that some of the bags seemed to be dirty – the complainant used tissue and got dust and soot-like material from the inside of the bags. Given that one of the major side-effects of Navelbine was neutropenia, the complainant found it reprehensible that Pierre Fabre would put patients at risk by providing such poor-quality material. The complainant queried whether the company had a quality department to check for such defects.

The complainant provided one of the bags after cleaning it and stated that if they had been provided to other hospitals they should be checked immediately.

The complainant confirmed that the bags were delivered by the local representative who claimed that they were 'found' by the managing director.

In writing to Pierre Fabre the Authority asked it to bear in mind the requirements of Clauses 2 and 9.1 of the Code.

RESPONSE

Pierre Fabre stated that it had been asked on numerous occasions to supply the Navelbine bags to hospitals. The demand for the bags was fed back to the company by its representatives and by pharmacists to head office. The bags were provided to patients to transport their Navelbine capsules from the dispensing hospital/pharmacy to their home. The bags served as a reminder to patients to keep the Navelbine capsules refrigerated, and provided warnings on what not to do with the medicine. The bags were provided to patients to aid the safe storage and consumption of Navelbine Oral.

The bags in question were originally certified in 2005 and reapproved in 2007. In 2011 the previous product manager decided that the bag was a service item for pharmacists and therefore they were not certified. Pierre Fabre appreciated that this indicated that the Navelbine bags had not been reapproved since 2009 (given the two year approval timeline from 2007). Staff responsible for reviewing or certifying the items were no longer in the employ of Pierre Fabre. To ascertain the approximate age of the bags, the company had a proforma invoice dated 22 April 2013.

Pierre Fabre submitted that the bags were stored in the basement of its offices in Winchester from 2013. During its recent relocation to Reading, the bags in question were discovered and visually inspected by the managing director who did not involve the quality assurance department to check their integrity.

The medical director advised that the bags should not be distributed citing patient safety and Code requirements. However, having balanced the needs of the business, the managing director decided to overrule this advice.

The bags were distributed to the sales team during a meeting, and no briefing document accompanied the bags.

The managing director had ensured that no further Navelbine bags were supplied to Pierre Fabre's sales representatives and stressed that the actions above were of his own volition and were in no way representative of the working processes of Pierre Fabre. [Post submission note: At the completion of this case Pierre Fabre confirmed that its representatives could continue to give out the bags until early January 2017.]

PANEL RULING

The Panel noted that bags which had been stored in a basement for around 3 years were provided to representatives to give to pharmacies. The bags were designed for Navelbine Oral capsules which would be placed in the bag, sealed and given to the patient to take home. The Panel was concerned that the complainant described the bags as in a poor condition with soot and dust on the inside and that the sealant to close the bag at times did not work. The bags supplied to the Panel, one from the complainant and five from the company, did not look dirty but the complainant stated that they had cleaned the one he/she had sent. The sealants were different in that those supplied by the company had red tape over a flat clear sticky strip and the bag supplied by the complainant had clear tape over a yellow wrinkled sticky strip. Neither bag bore an item code linking it to the item codes on the certificates provided. Material accompanying the original certification of the bag referred to Navelbine Oral being supplied in blister packs inside small boxes and the intention was that the boxes would be put in the plastic bag, sealed and given to the patient to take home. The average prescription comprised four small boxes. The bag would keep the boxes together and protect the boxes from any moisture in the patient's refrigerator during storage. The bag included space for a pharmacy label.

The Panel noted the recent email correspondence in that the bags had been found in the basement of Pierre Fabre's offices in Winchester and the managing director instructed them to be distributed to the representatives. The correspondence indicated a difference of opinion in that one person said that the bags could not be used. This was confirmed by the medical director in an email which stated that it would be inappropriate to send out the bags as the company was unaware of how long they had been left in unsuitable storage conditions and patient safety was in question. The medical director also referred to certification and that as the brand and generic names were present prescribing information was required.

The Panel considered that although it had no details on how the bags were stored in the basement,

the complainant stated that he/she had received dirty bags with faulty seals. The Panel noted that extreme dissatisfaction was usually required before an individual was moved to complain. In the Panel's view this did not seem unreasonable given the bags had been in the basement for around 3 years. The email from the medical director referred to the bags having been left in unsuitable storage conditions. Other than a visual inspection by the managing director, it appeared that Pierre Fabre had not checked the quality of the bags before giving them to the representatives to distribute. The Panel considered that Pierre Fabre had not maintained high standards and ruled a breach of Clause 9.1.

The Panel was extremely concerned about the company's submission that the managing director having balanced the needs of the business had over-ruled the medical director's advice that the bags should not be distributed citing, *inter alia*, patient safety as a reason. In the Panel's view patient safety was paramount. It was not known how the bags had been stored in the basement nor how many of these had been distributed to the representatives. Similarly there was no information about how many bags had been given out by the representatives. An email referred to 'numerous pharmacy bags' in the basement, and a subsequent email from the managing director stated 'Please distribute all these to the sales team'. The Panel did not know if every single bag had been visually inspected by the managing director before being given to representatives. The company had not commented specifically on the results of the visual inspection. The Panel considered that the circumstances brought discredit upon and reduced confidence in the pharmaceutical industry and therefore ruled a breach of Clause 2.

The Panel noted Pierre Fabre's submission that it had stopped supplying the bags to the representatives. It did not know whether the representatives had stopped supplying the bags they already had to pharmacies nor how many bags they had already given out. The Panel decided that as there was a potential safety issue with use of the bags it would require Pierre Fabre to suspend use of the bags if Pierre Fabre appealed the Panel's ruling pending the final outcome of the case. This was in accordance with Paragraph 7.1 of the Constitution and Procedure.

The Panel had no information about whether the problems with the bags occurred during storage in the basement, with the representatives or elsewhere. Pierre Fabre had not commented specifically on the faulty sealants. The Panel also noted that the use of the bags was optional. The medicine's packaging would be sufficient. The Panel considered that pharmacists would visually inspect the bags before using them. However the potential safety issue would have been avoided if the decision of Pierre Fabre's medical director had not been overridden by one individual and/or proper quality assurance had been carried out. This was prohibited by the same individual above. The Panel noted its ruling of a breach of Clause 2 which would mean that brief details of the case would be the subject of an advertisement. The Panel decided taking all the circumstances into account not to report Pierre Fabre to the Appeal Board for it to consider in accordance with Paragraph 8.2 of the Constitution and Procedure.

During its consideration of this case, the Panel was concerned about a number of matters. It was disingenuous of the managing director to state that the decision to circulate the bags in no way represented the working practices of Pierre Fabre given he set company standards and the impression given by his decision in this regard. In addition there seemed to be a lack of understanding about the Code: as the bags were to be given to patients they should not include prescribing information but when supplied to pharmacists they were promotional and prescribing information should have been provided. The Panel requested that its concerns be brought to Pierre Fabre's attention.

Complaint received **6 December 2016**

Case completed **31 January 2017**

ANONYMOUS, NON CONTACTABLE v JANSSEN and NAPP

Venue for promotional meeting

An anonymous, non-contactable complainant, who described him/herself as a health professional, complained about the venue for a forthcoming meeting organised to promote Invokana (canagliflozin) for use in type 2 diabetes. The invitation referred to Janssen-Cilag and Napp Pharmaceuticals and so the matter was taken up with both companies. The meeting was entitled 'A Practical Guide to Manage Type 2 Diabetes and its Complications'. It was held in December 2016 at a named restaurant.

The meeting started at 18.30 with registration and buffet dinner and the educational part of the meeting started an hour later. There were two speakers and the meeting concluded with 15 minutes for questions and closed at 21.30.

The complainant stated that he/she had received the invitation and was concerned that the venue was not appropriate; the venue and cuisine would be the main attraction for attending the meeting and not the educational content. The group of restaurants was world renown [sic]. The complainant provided screenshots from the restaurant website which featured celebrity endorsements.

The detailed response from Janssen is given below.

Case AUTH/2915/12/16

The Panel noted from the screenshots provided by the complainant that the celebrity endorsements were in relation to the restaurant used rather than others in the restaurant chain as submitted by Janssen. Similar celebrity endorsements appeared on the hotel website where the restaurant in question was located.

The Panel considered that the cost of the subsistence (food and drinks) at £48.88 per health professional attendee was on the limits of acceptability for a buffet at an evening meeting lasting two hours.

The Panel noted the meeting arrangements and the numbers invited. There was no description in the meeting invitation about the venue but it was likely it would be known by the invitees. It was not unexpected that the website for a restaurant would be very positive about the food and facilities offered. The Panel noted Janssen's submission that the venue was centrally located for attendees. Taking all the circumstances into account, the Panel considered that although the venue was on the limits of acceptability its use for the meeting in question did not amount to a breach of the Code and it ruled accordingly. Given this ruling the Panel did not consider that the company had failed to maintain high standards or had brought discredit upon or reduced confidence in the pharmaceutical industry. Thus the Panel ruled no breaches of the Code including Clause 2.

Case AUTH/2916/12/16

The Panel noted that Napp had not provided a separate response. Janssen stated that although the companies co-promoted Invokana, the meeting in question was a Janssen only meeting. The Panel was concerned that Napp's logo appeared on the invitation and considered that if the meeting was nothing to do with Napp then its name should not appear on the invitation. However, according to Janssen, Napp had had nothing to do with the meeting. The Panel therefore ruled no breaches of the Code including Clause 2.

An anonymous, non-contactable complainant, who described him/herself as a health professional, complained about the venue for a forthcoming meeting organised to promote Invokana (canagliflozin) for use in type 2 diabetes. The invitation referred to Janssen-Cilag Ltd and Napp Pharmaceuticals Limited and so the matter was taken up with both companies. The meeting was entitled 'A Practical Guide to Manage Type 2 Diabetes and its Complications'. It was held in December 2016 at a named restaurant.

According to the invitation the meeting started at 18.30 with registration and buffet dinner with the Chair speaking at 19.30 followed by two presentations each of 45 minutes; 'Hot topics in Management of Type 2 Diabetes' and 'Practical case study presentations addressing common management issues of Type 2 Diabetes'. The meeting concluded with 15 minutes for questions and closed at 21.30.

COMPLAINT

The complainant stated that he/she had received the invitation and was concerned that the venue choice for the meeting was not appropriate; the venue and cuisine would be the main attraction for attending the meeting and not the educational content. The group restaurants were world renown [sic]. The complainant provided screenshots from the restaurant website which featured a number of celebrity endorsements.

In writing to Janssen and to Napp, the Authority asked them to bear in mind the requirements of Clauses 22.1, 9.1 and 2 of the Code.

RESPONSE

Janssen submitted that the meeting was arranged to provide local primary care health professionals across the location with an opportunity to learn more around the topic 'A Practical Guide to Managing Type 2 Diabetes and its Complications' delivered by reputable local opinion leaders from primary and secondary care, as well as learn more about Invokana.

1 Educational content

Janssen stated that the purpose of the meeting was to give health professionals an opportunity to learn about advances in the management of type 2 diabetes in adults, to discuss treatment options with leading experts in the area by using pre-approved case studies and share their experiences. They could also learn more about how Invokana could be used in the treatment pathway.

The speakers were chosen from the same geographic area as the attendees. The Chair ran annual diabetes educational events, the speakers were local consultants and would provide local insights and knowledge sharing to attendees. The educational offering was clearly and prominently described in the invitation/agenda.

The meeting provided two hours of educational content from three locally respected experts, and one hour of buffet meal was provided as subsistence for an evening meeting.

Janssen submitted that this meeting presented a tremendous opportunity for invitees to advance their knowledge in the management of adults with type 2 diabetes with (1) the topics presented in the meeting, (2) the opportunity to meet and ask questions of local experts, (3) to share experiences amongst attendees and (4) the opportunity to discuss management decisions using case studies. Furthermore, the educational offering was clearly and prominently described in the invitation/agenda whereas the venue was only mentioned once without any description. Hence, the educational offering was the absolute core and only reason for invitees to join this meeting, not the subsistence offered as alleged by the complainant.

2 Meeting venue

Janssen submitted that the venue was secondary to the meeting content. The venue choice took into account the distance travelled by those invited and the speakers/Chair of the meeting. The venue was suitably located.

Details of three other venues which were reviewed as part of the venue selection process but rejected on the grounds of traffic and room rental charges were provided.

The venue selected offered a private meeting room for the presentations, a separate area in the restaurant for food prior to the start of the lectures, free parking and cost-effective catering. It was also suitably located for the attendees the majority of who travelled an average of 7 to 8 miles to attend.

The venue was part of a restaurant group, and did not have any prestigious award such as a Michelin star or AA Rosette. The hotel, within which the restaurant was situated, did not have any significant awards and was a 3 star hotel.

The venue did not charge for room hire and the estimated pre-event cost per head was £33.33 (excluding beverages). This was included as part of the internal review process with an estimated 60 health professional attendees and 3 health professional speakers which gave a pre-event health professional cost estimate of £2,100.

The final event cost for catering and beverages provided on the evening was £2,508. Included in this final cost were 3 Janssen account managers, 3 health professionals speakers and 46 health professionals attendees. In addition, 8 health professionals were unable to attend on the night which meant that the final catering cost per health professional was slightly more than originally estimated.

The total cost of the meeting including catering and beverages, but excluding the Janssen attendee catering costs (3 x £37.50), was £2,395.50 (catering, £2,100 plus beverages, £295.50). This gave a cost per health professional (that attended) of £48.88, well within the limits of the Code.

Attendees were invited based on their locality (CCG) and were invited by Janssen account managers only following engagement with them in person. In addition to the invitation, which contained a detailed agenda, attendees were also provided with a promotional leavepiece and an event feedback form.

The event was approved in line with the company internal review standards. All speaker contracts were signed and returned ahead of the scheduled event. Speakers were selected due to their expertise, relevance and were paid in line with fair market value.

Janssen submitted that at no point did it provide a link to, or make reference to, the venue website which had been updated subsequent to the date of the meeting approval, execution and complaint itself.

Janssen addressed the concern raised in relation to the previous version of the website however, it maintained the same applied to the current website.

Janssen submitted that the pictures and comments on the website regarding endorsement of the venue did not refer to the restaurant in question. These referred to the restaurants in other locations. This had been confirmed by a director for the restaurant chain, who clarified that 'None of the people mentioned in the testimonials have visited the [location] restaurant or have made any specific reference to [it]'.

Conclusion

Janssen submitted that it took the Code extremely seriously and upheld the principle that promotional meetings must be held in appropriate venues conducive to the main purpose of the event and that hospitality must be secondary to the purpose of the meeting.

Janssen submitted that it had demonstrated that:

1 The educational offering provided at the promotional meeting in question was clear in the invitations and was the core and only attraction to the meeting and provided local health

professionals with an opportunity to advance their knowledge in the management of type 2 diabetes via the topics discussed, by meeting local experts and discussing different treatment options.

2 The venue selected was appropriate based on the local geography and dietary requirements of the attendees (approximately 40 health professionals attendees were Muslim, requiring halal food), was well within the Code limits and was held in a private meeting/dining space away from the public. Janssen stressed that the website endorsements referenced by the complainant did not relate to the venue used.

3 The venue and subsistence provided was modest, secondary to the high quality educational content and well within the Janssen compliance framework and the Code. Therefore, Janssen refuted a breach of Clause 22.1.

The Janssen promotional meeting maintained a high standard and therefore the company refuted a breach of Clause 9.1.

The company stated that it had demonstrated that the basis of this complaint was unfounded and Janssen had not brought the pharmaceutical industry into disrepute, therefore it had not breached Clause 2.

Janssen stated that whilst it and Napp promoted Invokana in partnership in the UK, this event was sponsored, organised and delivered by Janssen only. Napp therefore did not submit a separate response.

Case AUTH/2915/12/16

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints would be accepted, but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant could not be contacted for more information.

The Panel noted the downloaded screenshots about the restaurant provided by the complainant. It was clear from the material provided that the quotations and comments about the food were in relation to the restaurant rather than the other restaurants in the chain as submitted by Janssen. Similar comments appeared on the hotel website for the restaurant. The comments from named individuals including the Queen and prominent politicians were extremely positive.

The Panel noted that Clause 22.1 stated that the costs involved in providing subsistence must not exceed the level which recipients would normally adopt when paying for themselves. The supplementary information to Clause 22.2, Maximum Cost of a Meal, stated that the maximum cost of a meal of £75 plus VAT and gratuities (or local equivalent) would only be appropriate in very exceptional circumstances such as a dinner at a residential meeting for senior consultants or a learned society conference with substantial educational content. The supplementary information to Clause 22 was clear that venues for meetings needed to be appropriate and conducive to the main purpose of the meeting. It should be the educational content that attracted delegates and not the associated hospitality or venue.

The Panel considered that the cost of the subsistence (food and drinks) at £48.88 per health professional attendee was on the limits of acceptability for a buffet at an evening meeting lasting two hours. It did not agree with Janssen that it was well within the limits in the Code given the type of event that was considered appropriate to justify the maximum cost of £75 plus VAT. The requirements of the Code were more than just the cost of subsistence.

The Panel noted the meeting arrangements and the numbers invited. There was no description in the meeting invitation about the venue but it was likely it would be known by the invitees. It was not unexpected that the website for a restaurant would be very positive about the food and facilities offered. The Panel noted Janssen's submission that the venue was centrally located for attendees. Taking all the circumstances into account, the Panel considered that although the venue was on the limits of acceptability its use for the meeting in question did not amount to a breach of Clause 22.1 of the Code and it ruled accordingly. Given this ruling the Panel did not consider that the company had failed to maintain high standards or had brought discredit upon or reduced confidence in the pharmaceutical industry. Thus the Panel ruled no breach of Clauses 9.1 and 2 of the Code.

Case AUTH/2916/12/16

PANEL RULING

The Panel noted that Napp had not provided a separate response. Janssen had stated that although the companies promoted the product in partnership the meeting in question was a Janssen only meeting. The Panel was concerned that Napp's logo appeared on the invitation and considered that if the meeting was nothing to do with Napp then its name should not appear on the invitation. However according to Janssen, Napp had had nothing to do with the meeting. The Panel therefore ruled no breach of Clauses 22.1, 9.1 and 2 of the Code.

Complaint received **12 December 2016**

Case completed **20 January 2017**

CASE AUTH/2917/12/16

ANONYMOUS, NON-CONTACTABLE v JANSSEN

Conduct of representative

An anonymous, non-contactable complainant, who stated he/she was a general practitioner submitted a complaint about a named Janssen representative.

The complainant alleged that the representative was appointed based on the roles of his/her family members in primary care. The representative's parent was the local clinical commissioning group (CCG) clinical lead and diabetic lead and the representative was married to a local general practitioner (GP) and the in-law of another.

The complainant stated that the representative and Janssen manager recently saw a colleague and the representative had since bragged about how this manager informed the complainant's colleague that the representative's previous companies were foolish to let the representative go when the representative's parent was the clinical diabetic lead and could influence prescribing of the product promoted by his/her child.

The detailed response from Janssen is given below.

The Panel noted that there would be occasions when representatives had links with health professionals and other relevant decision makers which would be of potential concern. In such cases it might be prudent for companies to consider changing a representative's territory so they did not call upon such people. The external perception of the arrangements was important.

It appeared in this case that the representative had a number of close relatives in the territory who were either health professionals or relevant decision makers. That the representative's parent was a locum GP was disclosed to the hiring manager during initial conversations about the employment opportunity with Janssen. It appeared that the hiring manager had not probed for more detail in that regard. The parent's position as chair of the local diabetes network only came to light in an email from the representative late in 2016. Given that the representative's parent had an interest in diabetes (as noted on the CCG website), the Panel queried why Janssen did not previously know about this before engaging the representative. The Panel noted that Janssen appeared to have only recently discovered that other GPs called upon by their representative with the same surname, were related.

The Panel noted that Janssen had a policy to ensure that staff disclosed interest or relationships which conflicted with the interests of the company. The policy included examples of conflicts or the appearance of a conflict and specifically referred to family members. It was stated that any activity which even *appeared* (emphasis added) to present a conflict must be avoided or terminated unless an appropriate level of management deemed otherwise. The representative had not informed the company of the close links he/she had with health professionals in one surgery and the role the representative's parent had as diabetes lead with the local CCG. In the Panel's view these close interests were a concern. There was no evidence that the representative had influenced the relatives but the company should have been informed so that it could take appropriate action to ensure there were no conflicts of interest be these actual or perceived. The Panel considered that the representative had not maintained a high standard of ethical conduct and therefore ruled a breach of the Code.

The Panel considered that although the company had a policy in place which the representative had not followed, it had also been presented with opportunities to follow-up on information provided by the representative. In that regard, the Panel disputed Janssen's submission that it had a rigorous process of reviewing potential conflicts of interest once identified. Further, having the representative call upon doctors with the same surname as the representative should have at least begged a question about possible relationships. Nonetheless, it appeared to the Panel that as Janssen did not know of the roles of the representative's family members then the representative could not have been appointed on that basis as alleged. The Panel therefore considered that the complainant had not proved his/her complaint on the balance of probabilities. In relation to the allegation, Janssen had not failed to maintain high standards and thus the Panel ruled no breach of the Code. The company had not brought discredit upon or reduced confidence in the industry and therefore the Panel ruled no breach of Clause 2.

An anonymous, non-contactable complainant, who stated he/she was a general practitioner complained about a local named representative who worked for Janssen-Cilag Ltd.

COMPLAINT

The complainant alleged that the representative was appointed purely on the basis of the roles of family members in primary care. The representative's parent was the local clinical commissioning group (CCG) clinical lead and diabetic lead and the representative was married to a local GP and the in-law of another.

The complainant named two other companies that the representative worked for and referred to two verbal complaints which the complainant alleged resulted in the representative leaving each company.

The complainant stated that the representative and Janssen manager recently went to see a colleague and the representative had since bragged about how

this manager informed the complainant's colleague that the representative's previous companies were foolish to let the representative go when the representative's parent was the clinical diabetic lead and could influence prescribing of the product promoted by his/her child.

The complainant stated that one of his/her colleagues had already asked Janssen to remove his/her name from the representative's list of GPs.

The complainant asked the PMCPA to investigate Janssen and to request transfer of the representative to an area where there was no clinical connection. The local GP had written to the NHS about the parent's alleged inappropriate use of his/her role.

The complainant did not want to disclose his/her identity as he/she had to work with the family.

In writing to Janssen the Authority asked the company to bear in mind Clauses 2, 9.1 and 15.2 of the Code.

RESPONSE

Janssen stated that it prided itself on upholding the highest standards of ethical business conduct and believed its recruitment process was both objective and rigorous. Furthermore, Janssen was confident that the representative's appointment was solely based on performance throughout the interview process and assessment centre, skills and ability to fulfil the appointment was further demonstrated by the subsequent validation scores (from the initial training course), thus the appointment was irrespective of any family connections as alleged.

Background

Following the internal promotion of the existing Janssen account manager for the territory in mid 2016. Janssen, following standard procedure, began the recruitment process. This position was for a temporary contract position promoting Invokana (canagliflozin).

The standard steps in the Janssen recruitment process were provided and included psychometric testing, CV screening, a screening interview and an assessment centre. The assessment centre day included a competency based interview and review of psychometric test, business simulation and presentation and roleplay.

Janssen stated that this process was followed in the representative's recruitment and provided details of critical aspects which it submitted clearly demonstrated that the representative was recruited solely based on skills and abilities irrespective of family members' roles in primary care. These included successful pharmaceutical sales experience in and around the locality. At no point in the recruitment process did Janssen look to recruit candidates with family connections. The representative was assessed in a competitive assessment centre against another candidate. The assessment centre was rigorous and was objectively scored by three other Janssen managers in addition to an independent actor/assessor and the hiring manager. None of the assessors on the day, other than the recruiting manager who conducted the screening interview, knew of the representative before the assessment centre. At assessment the representative achieved a high pass score. In contrast the other candidate failed. Upon employment the representative completed the full initial training programme and final validation assessments. The representative achieved a pass in the written knowledge test and a 'Pass' in two observed role plays which were completed by two other regional business managers (not the representative's line manager).

Janssen addressed specific questions regarding the recruitment.

1 Were family connections discussed at interview?

Janssen stated that the representative's family connection was never discussed during the interview process.

The representative stated that a parent was a retiring locum GP, without disclosing his/her position in local diabetes care, at initial discussion about the opportunity. No further discussions were had as clearly documented in the pre-screening interview and assessment centre notes.

During both pre-screen and assessment centre interviews, the interviewers (hiring manager and one other manager at pre-screen and three other managers at assessment centre) confirmed this was not discussed as did the representative.

2 What was the role of the representative's parent and what was the prescribing influence?

Janssen stated that before the interview process began, it was informed by the representative that a parent was a locum GP about to reduce his/her workload significantly for personal reasons and in the process of semi-retiring.

Janssen became aware that the parent also had additional responsibility as the diabetes network chair following an email communication from the representative late last year and triggered an additional review of the representative's conflicts of interest.

Further to the outputs of the additional review into the representative's conflicts of interest which, was completed prior to the receipt of the complaint, an investigatory interview was conducted with the representative with regards to the complaint. Based on this information it was Janssen's current understanding that:

- As disclosed to the hiring manager, the representative's parent was currently reducing clinical practice time, for personal reasons, acting as a locum GP
- Details about the CCG clinical and educational lead role were provided including that the representative's parent expressed a desire to step down from this role before the representative was appointed.

Janssen understood that the representative's parent had no responsibility nor influence in development of local CCG formulary and prescribing guidelines. The individual had clearly identified the representative's role as a pharmaceutical industry representative in the CCG conflicts of interest declaration.

As a locum GP, the representative's parent was able to prescribe medicines deemed appropriate.

3 When did Janssen (and manager) become aware of the role of the representative's parent?

Janssen stated that the representative informed the hiring manager that his/her parent was a locum GP during an initial discussion regarding the role, however at the same time Janssen was made aware that the parent was fully expected to either retire/ semi-retire as a locum GP in the very near future. At this time, the CCG role was not made clear.

The line manager became aware that the representative's parent was the chair of the diabetes network following receipt of an email from the representative in late 2016. This was immediately reported to senior management and initiated a process to further review the representative's conflicts of interest.

Janssen stressed that the additional conflicts of interest review process was initiated at the end of November and completed before it received this complaint. At the conclusion of this review the decision that the representative was not to call on family members in the future was communicated. Janssen was confident that the process and the actions taken were robust and that the fact that this process was completed before the receipt of this complaint further demonstrated its commitment to maintaining the highest standards.

4 Had the representative had any discussions with the manager or others about his/her parent's role/ influence?

Janssen stated that after the initial discussion between the representative and the hiring manager during the informal, pre-interview conversation as outlined above, no other conversations regarding the representative's parent took place until Janssen initiated the additional review into the representative's conflicts of interest subsequent to becoming aware of the parent's additional responsibilities.

5 What was the position of the other relatives?

Janssen stated that the complainant referred to two additional relatives of the representative. For completeness a third relative had been identified within Janssen's internal conflicts of interest declaration. All three relatives worked together and details were provided.

6 What safeguards, policies and processes were in place to address such conflicts of interest?

Janssen stated that it had a clear Business Conduct Policy and every employee received mandatory training and was required to sign confirmation of training both on hire and annually thereafter. This reinforced the importance of reporting and where possible avoiding conflicts of interest:

> 'Every employee has a duty to avoid business, financial or other direct or indirect interests or relationships which conflict with the interests of the Company or which divide his or her loyalty to the Company. Any activity which even appears to present such a conflict must be avoided or terminated unless, after disclosure to the appropriate level of management, it is determined that the activity is not harmful to the Company or otherwise improper.'

The representative's compliance record demonstrated that the representative completed and signed this policy in September 2016. Unfortunately, at this point the representative did not raise any additional conflicts of interest.

In addition, Janssen's supplier for contingency workers, through which the representative was employed also had a conflicts of interest declaration within the employment contract. Unfortunately, the representative did not raise any conflicts of interest when signing an employment contract. On detailed discussions after receipt of the complaint, the representative stated that the conflicts of interests were not registered immediately as the representative considered that they were minimal due the parent reducing his/her workload and stepping down from the CCG and the same was assumed about the three other relatives as they had low involvement in type 2 diabetes.

Conclusion

Janssen submitted that it demonstrated an objective, rigorous and unbiased process of recruitment and hence refuted the allegation by the anonymous complainant that an employee was appointed purely on the basis of his/her family members' roles in primary care.

The company acknowledged that despite the safeguards in place, including the Business Conduct Policy and the third party employer contract, the full extent of the conflict of interest was not disclosed by the representative. However, as soon as Janssen became aware of the full extent of conflict of interest it immediately took steps to investigate and subsequently mitigate by ensuring the representative no longer conducted sales calls on family members and instigating re-education of the representative with regards to the Business Conduct policy, with specific reference to the sections covering conflicts of interest.

Janssen regretted the representative's failure to fully disclose his/her conflicts of interest despite multiple formal opportunities to do so. As a consequence, and in addition to the immediate safeguards put in place, Janssen terminated the representative's third party contract. Due to the failure to disclose, Janssen accepted that the representative might not have maintained high standards stated by the Code.

Therefore, Janssen might potentially be in breach of Clause 15.2 as a result of this isolated case.

Janssen submitted that it had demonstrated that the competitive recruitment process was robust with multiple independent objective assessments made pertaining to candidate performance alone. In addition, Janssen's Business Conduct Policy clearly stated the importance of declaring conflicts where they existed. Furthermore, Janssen demonstrated a rigorous process of reviewing the potential conflicts of interest once identified, and acted promptly to mitigate any potential conflicts. Janssen had maintained a high standard and therefore it refuted a breach of Clause 9.1.

This was an isolated incident and Janssen submitted it had a robust process of recruitment for the declaration and management of conflicts of interest. As such Janssen did not believe it had brought the pharmaceutical industry into disrepute, and refuted a breach of Clause 2.

In addition to addressing the concerns raised regarding the appointment of the representative, Janssen noted its concern regarding the nature/intent of the complaint. Upon discussion with the representative the company was made aware that there were a number of statements that were wholly incorrect. The representative never received a verbal complaint when working at either of the companies named by the complainant. Nor was the representative asked to leave. Janssen submitted that these points should be taken in context when reviewing the complaint.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints would be accepted, but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant could not be contacted for more information.

The Panel noted Janssen's submission regarding the representative's previous companies.

The Panel noted that there would be occasions when representatives had links with health professionals and other relevant decision makers which would be of potential concern. In such cases it might be prudent for companies to consider changing a representative's territory so they did not call upon such people. The external perception of the arrangements was important.

It appeared in this case that the representative had a number of close relatives in the territory who were either health professionals or relevant decision makers. That the representative's parent was a locum GP was disclosed to the hiring manager during initial conversations about the employment opportunity with Janssen. It appeared that the hiring manager had not probed further for more detail in that regard. The parent's position as chair of the local diabetes network only came to light in an email from the representative in November 2016. Given that the representative's parent had an interest in diabetes (as noted on the CCG website), the Panel queried why Janssen did not previously know about him/her before engaging the representative. The Panel noted that Janssen appeared to have only recently discovered that other GPs called upon by the representative with the same surname were related.

The Panel noted that Janssen had a policy to ensure that staff disclosed interest or relationships which conflicted with the interests of the company. The policy included examples of conflicts or the appearance of a conflict and specifically referred to family members. It was stated that any activity which even *appeared* (emphasis added) to present a conflict must be avoided or terminated unless an appropriate level of management deemed otherwise. The representative had not informed the company of the close links with health professionals in one surgery and the role the representative's parent had as diabetes lead with the local CCG. In the Panel's view these close interests were a concern. There was no evidence that the representative had influenced the relatives but the company should have been informed so that it could take appropriate action to ensure there were no conflicts of interest be these actual or perceived. The Panel considered that the representative had not maintained a high standard of ethical conduct and therefore ruled a breach of Clause 15.2. The Panel noted that the company instructed the representative not to call on family members and had since terminated the representative's contract.

The Panel considered that although the company had a policy in place which the representative had not followed, it had also been presented with opportunities to follow-up on information provided by the representative. In that regard, the Panel disputed Janssen's submission that it had a rigorous process of reviewing potential conflicts of interest once identified. Further, having the representative call upon doctors with the same surname as the representative should have at least begged a question about possible relationships. Nonetheless, it appeared to the Panel that as Janssen did not know of the roles of the representative's family members then the representative could not have been appointed on that basis as alleged. The Panel therefore considered that the complainant had not proved his/her complaint on the balance of probabilities. In relation to the allegation, Janssen had not failed to maintain high standards and thus the Panel ruled no breach of Clause 9.1. The company had not brought discredit upon or reduced confidence in the industry and therefore the Panel ruled no breach of Clause 2.

Complaint received **21 December 2016**

Case completed **31 January 2017**

ANONYMOUS NON-CONTACTABLE v MERCK SHARP & DOHME

Conduct of representative

An anonymous, non-contactable complainant, who stated he/she was a general practitioner, submitted a complaint about a named representative who previously worked for Merck Sharp & Dohme, alleging that the representative would bring her daughter to meetings. A verbal complaint was made to her manager and she left that company.

The detailed response from Merck Sharp & Dohme is given below.

The Panel noted Merck Sharp & Dohme's submission that no verbal or written complaint had been received by the manager concerning the alleged attendance of the representative's daughter at any meetings or functions.

The Panel considered that the complainant had not shown, on the balance of probabilities, that the representative had not maintained a high standard of ethical conduct and therefore ruled no breach of the Code. The Panel did not consider that in the circumstances Merck Sharp & Dohme had failed to maintain a high standard nor had it brought discredit upon or reduced confidence in the industry. The Panel therefore ruled no breach of the Code including Clause 2.

An anonymous, non-contactable complainant, who stated he/she was a general practitioner, submitted a complaint about a local named representative who had worked for Merck Sharp & Dohme Limited.

COMPLAINT

The complainant stated that he/she had known the representative and her family for many years. The complainant alleged that when the representative worked for Merck Sharp & Dohme, she would bring her daughter to meetings. A verbal complaint was made to her manager and she left that company.

In writing to Merck Sharp & Dohme, the Authority asked the company to bear in mind Clauses 2, 9.1 and 15.2 of the Code.

RESPONSE

Merck Sharp & Dohme stated that it took compliance with the Code very seriously and acknowledged the high standard of ethical conduct required in all activities undertaken by its sales force.

Merck Sharp & Dohme confirmed the dates that the representative was employed. Following an interview with her line manager and a review of her human resource file, Merck Sharp & Dohme stated that no verbal or written complaint was received by the manager concerning the alleged attendance of the representative's daughter at any meetings or functions and that no disciplinary proceedings were brought against her. Merck Sharp & Dohme confirmed that the representative terminated her employment when she voluntarily resigned to take a position at another company.

Merck Sharp & Dohme did not believe that the conduct of the representative breached Clauses 15.2, 9.1 and 2 of the Code.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints would be accepted, but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant could not be contacted for more information.

The Panel noted Merck Sharp & Dohme's submission that no verbal or written complaint had been received by the manager concerning the alleged attendance of the representative's daughter at any meetings or functions.

The Panel considered that the complainant had not shown, on the balance of probabilities, that the representative had not maintained a high standard of ethical conduct and therefore ruled no breach of Clause 15.2 of the Code. The Panel did not consider that in the circumstances Merck Sharp & Dohme had failed to maintain a high standard nor had it brought discredit upon or reduced confidence in the industry. The Panel therefore ruled no breach of Clauses 9.1 and 2 of the Code.

Complaint received **14 December 2016**

Case completed **20 January 2017**

CASE AUTH/2921/12/16

VOLUNTARY ADMISSION BY GRÜNENTHAL

Promotion to the public

Grünenthal voluntarily admitted breaches of the Code in that a video, certified for internal use only, relating to Palexia SR (tapentadol prolonged release), had been uploaded to YouTube without its knowledge. The company considered that the video constituted promotion of Palexia to the public or would encourage a member of the public to ask their health professional to prescribe Palexia. On being notified of the posting on YouTube, the company ensured that the video was taken down immediately.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Grünenthal.

Grünenthal stated that the video in question was originally used in January 2015 to reinforce key aspects relating to the Palexia SR 2015 brand plan to promotional field-based employees. The video was developed by Grünenthal's advertising agency using a third party production company.

With Grünenthal's consent, the advertising agency submitted a shortened version of the video (minus references to sales targets and promotional material) for a pharmaceutical marketing award in January 2016. On successfully winning an award, and without the knowledge of Grünenthal or the advertising agency, the director of the video provided a copy of the shortened version to the actor who subsequently uploaded this to YouTube.

Grünenthal fully accepted that it was wholly inappropriate for the video to appear on a publicly accessible Internet site but that it was ultimately responsible for the activities undertaken by third party service providers working on its behalf even when these occurred without its knowledge or instruction and constituted activities that the company would never sanction. Grünenthal therefore also accepted that on this occasion high standards had not been met. In view of the fact that information relating to a prescription only medicine, which was intended for internal company use only, had appeared on a publicly accessible Internet site, Grünenthal understood the seriousness of the situation and why the Panel might also wish to consider the requirements of Clause 2.

The detailed response from Grünenthal is given below.

The Panel understood that creative agencies and individuals would want to be able to show examples of their work. Whilst the video had not been uploaded by Grünenthal or its agency, it had been sent and uploaded by contractors of the agency. It was an established principle under the Code that pharmaceutical companies were responsible for work undertaken by third parties on their behalf. Pharmaceutical companies had to ensure that prescription only medicines were not advertised to the public. The Panel considered that Grünenthal had been let down by the third party working on its behalf.

The Panel noted that the shortened video was presented as a broadcast from 'Arthur Tapentadol' from the 'Ministry of Chronic Pain Control' who described Palexia as 'a jolly good medicine' and 'a darned good product'. It was also stated that Tapentadol was 'just the ticket' and that persuading a doctor to prescribe it would be a 'piece of cake'.

The Panel noted that YouTube was an open access website and was not limited to professional use. The Panel considered that there was a difference between putting examples of pharmaceutical promotional material on an advertising agency's website, in a section clearly labelled in that regard and putting the same on YouTube. The Panel considered that placing a video on YouTube which referred to Palexia as, *inter alia*, 'a jolly good medicine', promoted a prescription only medicine to the public. The Panel considered that statements had thus been made in a public forum which would encourage members of the public to ask their health professional to prescribe Palexia. Breaches of the Code were ruled including that high standards had not been maintained. The Panel did not consider, however, that there had been a breach of Clause 2. Such a ruling was the sign of particular censure and reserved for such.

Grünenthal Ltd voluntarily admitted breaches of the Code in that a video for internal use only, relating to Palexia SR (tapentadol prolonged release), had been uploaded to YouTube without its knowledge. The company considered that the video constituted promotion of a prescription only medicine to the public.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Grünenthal.

VOLUNTARY ADMISSION

Grünenthal stated that the video in question was originally used in January 2015 to reinforce key aspects relating to the Palexia SR 2015 brand plan to promotional field-based employees. Palexia SR was a strong analgesic (Schedule II) indicated for the management of severe chronic pain in adults, which could be managed only with opioid analgesics.

The video was developed by Grünenthal's advertising agency using a third party production company. A master services agreement with the agency, covering the time period in question, documented that the agency was responsible for any sub-contractors engaged in the delivery of services under the agreement. The video content

was reviewed and certified for use as an internal company communication according to Grünenthal's standard operating procedure (SOP) for the approval of such material.

With Grünenthal's consent, the advertising agency submitted a shortened version of the video for a pharmaceutical marketing award in January 2016 where it received a Gold Award in the category for Corporate Communications. This shortened version omitted specific references to actual sales targets for 2015 and promotional material. The approved script for the original job (ref UK/P15 0001) was therefore different to the content of the actual video which appeared on YouTube.

Following receipt of the award, and without the knowledge of Grünenthal or the advertising agency, the director of the video from the production company contacted one of the actors to inform him of the award. The actor asked to see a copy of the video and the shortened version was sent to him by the director, again without the knowledge of Grünenthal or the advertising agency. The actor subsequently uploaded a copy of the shortened video to YouTube, presumably as an illustration of his work.

On 23 November 2016 (approximately 11am) Grünenthal received an email from a global headquarters colleague, based in Germany, informing the company that the video had been found on YouTube.

Grünenthal's procedures on the use of the Internet and social media did not allow staff to conduct routine Internet searches to find out information about Grünenthal's products. Grünenthal would therefore not routinely become aware of content relating to its products being available on social media sites. The presence of the video on YouTube was only picked up by global colleagues as Grünenthal GmbH was exploring options for the further use of digital media at a corporate level.

Upon notification of the presence of the video on YouTube, immediate action was taken to have it taken down by the actor through the third party video production company and this was achieved by 1pm the same day. During this process it was noted from the YouTube site that the video was posted in February 2016 and had been viewed 330 times.

Before addressing the issue of the presence of the video in the public domain, Grünenthal noted that it was important to be aware of the development and use of the video for its approved purpose.

Grünenthal explained that the video was intended to be a humorous parody of early television information broadcasts from the 1930s and was presented in black and white using a stereotypical character from that period. The video was one of the final pieces of communication to the sales force regarding the 2015 Palexia SR brand plan. Grünenthal realised that as a stand alone item, the video would not be appropriate as a representative briefing document. However, it followed a structured series of formal interactions with the representatives in December 2014 and January 2015 to inform them of the brand plan and strategy for Palexia SR for the coming year. As such it was designed to remind staff of some of the key points from the brand plan (eg overall sales target and the importance of effective sales calls) in a more light-hearted and alternative manner. The business objective of this video was to drive internal engagement with the 2015 brand strategy and to motivate the sales force for the coming year; this was achieved through a high level of interaction from the intended internal audience. It was approved for internal use only in this context. The sequence of events in December 2014 and January 2015 relating to the brand plan introduction were as follows (all associated materials had at least one common final signatory to oversee consistency):

- 1 December 2014: Field Marketing Group (comprising Palexia SR brand manager and one representative from each business unit across the country) briefed on 2015 brand plan by Palexia SR brand manager using approved slide presentation at an online meeting
- Various dates in December 2014: Field Marketing Group present brand plan to their teams at local business unit meetings using approved material
- 6 January 2015: online business unit 'kick off' meeting for 2015 with Grünenthal's managing director. Head of marketing presented brief summary of Palexia SR brand plan for 2015
- 13 January 2015: Approved one page summary of the Palexia SR 2015 brand plan sent to field-based personnel
- 21 January 2015: Approved video in question sent to representatives as a password- protected link embedded in an email. The video itself was hosted on a secure site not accessible via Internet searches
- 26 January 2015: Follow-up quiz on 2015 brand plan content sent to field-based personnel with the objective of encouraging engagement.

Grünenthal noted that when viewing the video it was important to keep in mind the context in which it was used ie as a concluding part of a multi-faceted, internal campaign to communicate the product brand plan and the intentional use of humour to drive memorability. Whilst on one level the video referred to interactions with members of the medical profession, the content and delivery was so far removed from the professional reality of the current pharmaceutical industry that the intended audience could never be expected to interpret the content literally and/or adopt the behaviours of the central character.

Having presented the way in which the video was used internally at Grünenthal, the company fully accepted that it was wholly inappropriate for it to appear on a publicly accessible Internet site. In mitigation, this was done by a third party contractor without Grünenthal's or its advertising agency's knowledge and, when informed, the company acted immediately to have the content taken down. It was, however, clear that the video was viewed 330 times in the nine months it was available on YouTube, presumably by members of the public. The content of the video was such that Grünenthal considered it constituted promoting a prescription only medicine

to the public and it acknowledged a breach of Clause 26.1 in this regard. Grünenthal noted that it might also constitute statements that could be seen as encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine, contrary to the requirements of Clause 26.2, although this was never the intention.

Grünenthal also accepted that it was ultimately responsible for the activities undertaken by third party service providers working on its behalf even when these occurred without its knowledge or instruction and constituted activities that the company would never sanction. In this case this would also include the actions of the freelance actor engaged by the video production company on behalf of Grünenthal's advertising agency. Grünenthal therefore also accepted that on this occasion high standards had not been met and it was in breach of Clause 9.1. In view of the fact that information relating to a prescription only medicine, which was intended for internal company use only, had appeared on a publicly accessible Internet site, Grünenthal understood the seriousness of the situation and why the Panel might also wish to consider the requirements of Clause 2.

As a result of this material appearing in the public domain, Grünenthal was reviewing its procedures for monitoring the availability of information on its products in the public domain, including social media platforms. The circumstances associated with this occurrence had also been shared across appropriate teams at Grünenthal and it was in the process of reminding third party service providers of their obligations under the company's master services agreements and, in particular, their responsibility to ensure that any sub-contractors they engaged must adhere to the rigorous requirements of working with the pharmaceutical industry.

Grünenthal was asked to provide the Authority with any further comments in relation to the requirements of Clause 2, 9.1, 26.1 and 26.2.

RESPONSE

Grünenthal stated that it accepted responsibility for Clauses 26.1 and 26.2 and due to the seriousness of the nature of this situation, could understand why the Panel would wish to consider a breach of Clause 2. The company submitted that it had provided a full overview of the situation leading up to the voluntary admission and had nothing further to add.

PANEL RULING

The Panel noted that the original video (ref UK/P15 0001) was certified for internal use in January 2015 to reinforce to the sales force, key aspects about the Palexia SR 2015 brand plan. The video had been developed with an advertising agency with which Grünenthal had a master services agreement in place to cover the project. The agency in turn sub-contracted a production company.

The Panel noted that Grünenthal agreed that the advertising agency could submit a shortened version of the video (with specific references to actual sales targets and promotional material omitted) for a pharmaceutical marketing award in January 2016 where it received a Gold Award in the category for Corporate Communications.

It appeared that in response to a request from the actor, after informing him of the award, the director of the production company forwarded him a copy of the shortened video. This was done without Grünenthal's or the agency's knowledge. The actor uploaded the video to YouTube, presumably as an illustration of his work.

The Panel understood that creative agencies and individuals would want to be able to show examples of their work. The Panel noted that the master service agreement between Grünenthal and its agency referred to the use of third parties and that all parties were bound by confidentiality obligations no less onerous than those set forth in the agreement. The Panel did not know what agreement was in place between the agency and the production company. Whilst the video had not been uploaded by Grünenthal or its agency, it had been sent and uploaded by contractors of the agency. It was an established principle under the Code that pharmaceutical companies were responsible for work undertaken by third parties on their behalf. Pharmaceutical companies had to ensure that prescription only medicines were not advertised to the public. The Panel considered that Grünenthal had been let down by the third party working on its behalf.

The Panel noted that the shortened video was presented as a broadcast from 'Arthur Tapentadol' from the 'Ministry of Chronic Pain Control' who described Palexia as 'a jolly good medicine' and 'a darned good product'. It was also stated that Tapentadol was 'just the ticket' and that persuading a doctor to prescribe it would be a 'piece of cake'.

The Panel noted that YouTube was an open access website and was not limited to professional use. The Panel considered that there was a difference between putting examples of pharmaceutical promotional material on an advertising agency's website, in a section clearly labelled in that regard and putting the same on YouTube. The Panel considered that placing a video on YouTube which referred to Palexia as, *inter alia*, 'a jolly good medicine', promoted a prescription only medicine to the public. A breach of Clause 26.1 was ruled. The Panel considered that statements had thus been made in a public forum which would encourage members of the public to ask their health professional to prescribe Palexia. A breach of Clause 26.2 was ruled. The Panel noted its rulings above and considered that high standards had not been maintained. A breach of Clause 9.1 was ruled. The Panel did not consider, however, that there had been a breach of Clause 2. Such a ruling was the sign of particular censure and reserved for such. No breach of Clause 2 was ruled.

During the consideration of this case the Panel was concerned to note Grünenthal's submission that as a stand alone item, the video would not be appropriate as a representative briefing document. The company

had submitted that the content and delivery were so far removed from reality that the audience would not be expected to interpret the content literally and/or adopt the behaviour of the central character. Nonetheless, the Panel noted that although the video was one of a number of pieces of communication to the representatives about the 2015 Palexia SR brand plan, all material subject to the Code must be capable of standing alone in relation to compliance with the Code. Certification for promotional material must certify that the signatory believed that the material, *inter alia*, complied with the Code. The Panel requested that Grünenthal be advised of its concerns in this regard.

Complaint received **20 December 2016**

Case completed **30 January 2017**

CASE AUTH/2924/12/16

ANONYMOUS, NON CONTACTABLE PHARMACIST v LINCOLN MEDICAL

Statements on website

An anonymous, non-contactable complainant submitted a complaint about the Lincoln Medical website. The complainant stated he/she was a pharmacist and was concerned about the advertising of prescription medicines to the public.

The complainant provided a copy of the 'About us' page which stated, at the bottom of the page, that Lincoln Medical was the marketing authorization holder for the adrenaline (epinephrine) auto-injector Anapen used by patients at risk of anaphylaxis, the severe end of an allergic reaction, and that the company was also the distributor of Hidrasec (racecadotril), a pure intestinal anti-secretory agent used in targeting the underlying cause of diarrhoea in children, and Wakix (pitolisant), an H3 receptor antagonist for the treatment of narcolepsy with or without cataplexy.

The complainant stated that patients frequently asked him/her for items which they had read about and it was unhelpful that Lincoln Medical had placed the product name/generic name and indication without any additional information to contextualise it, even if it had been for professionals. It was inappropriate for the public to have access to this information and it did little for the pharmaceutical industry in the eyes of the complainant and his/her colleagues.

The detailed response from Lincoln Medical is given below.

The Panel noted that the 'About us' page included product names and indications for prescription only medicines; Hidrasec Granules and Wakix were available in the UK although the Anapen auto-injector was not. The Panel considered that given the descriptions, this page advertised prescription only medicines to the public and the company had thus not complied with the relevant requirements of the Code. Breaches of the Code were ruled. The Panel noted that the company had immediately taken down the website. However advertising prescription only medicines to the public was a serious matter and thus the Panel ruled a further breach as high standards had not been maintained.

The Panel noted its rulings and comments above but did not consider that the circumstances were such as to warrant a breach of Clause 2 which was a sign of particular censure. No breach of Clause 2 was ruled.

An anonymous, non-contactable complainant submitted a complaint about the Lincoln Medical Ltd website. The complainant stated he/she was a pharmacist.

The complainant provided a copy of the 'About us' page which stated, at the bottom of the page, that Lincoln Medical was the marketing authorization holder for the adrenaline (epinephrine) auto-injector Anapen used by patients at risk of anaphylaxis, the severe end of an allergic reaction, and that the company was also the distributor of Hidrasec (racecadotril), a pure intestinal anti-secretory agent used in targeting the underlying cause of diarrhoea in children, and Wakix (pitolisant), an H3 receptor antagonist for the treatment of narcolepsy with or without cataplexy.

COMPLAINT

The complainant stated that he/she was concerned about advertising on the website as prescription medicines should not be advertised to the public. The complainant was trying to find Lincoln Health Centre's address when he/she came across the Lincoln Medical website. The page opened on the search at the 'About us' tab and this gave the information stated above. There was no warning screen for professionals before the product information was provided.

The complainant stated that patients frequently asked him/her for items which they had read about and it was unhelpful that Lincoln Medical had placed the product name/generic name and indication without any additional information to contextualise it, even if it had been for professionals. It was inappropriate for the public to have access to this information and it did little for the pharmaceutical industry in the eyes of the complainant and his/her colleagues.

When writing to Lincoln Medical, the Authority asked it to respond to Clauses 2, 9.1, 26.1 and 28.1.

RESPONSE

Lincoln Medical stated that it did not intend to promote prescription medicines to the public. However, it took this notification very seriously and the company accepted that the website required update and review. As a corrective measure, the website was immediately taken down upon receipt of the complaint and would not be republished until updated content had been fully certified via its copy approval system.

The company also launched an investigation. Lincoln Medical was unable to replicate the circumstances described by the complainant. Any search engine hits were directed to the 'Home' page, which did not contain any promotional information.

Results of searches performed using the UK versions of three search engines (accessed 3 January 2017) were as follows:

1 'Lincoln health centre' (and center)
No hits for Lincoln Medical Limited within the first 10 search pages for any search engine.

2 'Lincoln health centre (and center) address'
No hits for Lincoln Medical Limited within the first 10 search pages for any search engine.

3 'Lincoln medical centre' (and center)
One hit on the second search page for all search engines.

4 'Lincoln medical centre (and center) address'
One hit on the lower half of the first search page for all search engines.

None of the identified hits contained a direct link to the 'About us' page identified by the complainant.

Lincoln Medical stated that the 'Home' page linked to other website pages, including the 'About us' page. As noted in the complaint, the 'About us' page carried promotional text:

> 'Lincoln Medical is a UK based pharmaceutical company founded in June 2000, dedicated to the development, manufacturing, and supply of prescription-only medication throughout the world.
>
> A subsidiary of Bioprojet Pharma Sarl, Lincoln Medical are the Marketing Authorisation Holders for the adrenaline (epinephrine) auto-injector Anapen used by patients at risk of anaphylaxis, the severe end of an allergic reaction. Lincoln Medical are also distributors of the Hidrasec (racecadotril) product range in the UK, a pure intestinal anti-secretary agent used in targeting the underlying cause of diarrhoea in children, and Wakix (pitolisant), an H3 receptor antagonist for the treatment of narcolepsy with or without cataplexy.'

Similar wording also appeared on the 'Products' page.

Whilst Lincoln Medical agreed that the information about its products did not comply with the Code with respect to patients, it was clearly stated that the company supplied prescription only medicines. Product information was also restricted to the brand name, the international non-proprietary name and a brief statement of intended use. Lincoln Medical submitted that the impact was somewhat mitigated by the following:

- Anapen and Hidrasec capsules were not currently sold or marketed in the UK
- Web traffic was directed to the 'Home' page, which was non-promotional
- Information supplied on specific products was restricted
- Web traffic volumes for the site were relatively low, with around 4,400 hits per annum.

Lincoln Medical submitted that it took this issue very seriously and would review the Code and make any necessary amendments to the website in order for it to be compliant.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints would be accepted, but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant could not be contacted for more information.

The Panel was concerned about the complaint, particularly given Lincoln Medical's submission that its research showed that searches for 'Lincoln Health Centre' did not immediately identify the company's website and that if they did it would open on the 'Home' page and not the 'About us' page as alleged.

The Panel noted that Clause 26.1 prohibited the advertising of prescription only medicines to the public (other than approved vaccination campaigns). Clause 28.1 stated that promotional material about prescription only medicines directed to a UK audience which was provided on the Internet must comply with all relevant requirements of the Code. The supplementary information to Clause 28.1 stated that:

> 'Unless access to promotional material about prescription only medicines was limited to health professionals and other relevant decision makers, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified. This was to avoid the public needing to access material for health professionals unless they choose to. The MHRA Blue Guide stated that the public should not be encouraged to access material which was not intended for them.'

The Panel noted that the 'About us' page included product names and indications for prescription only medicines; Hidrasec Granules and Wakix were available in the UK although the Anapen auto-injector was not. The Panel considered that given the descriptions, this page advertised prescription only medicines to the public and ruled a breach of Clause 26.1. The company had thus not complied with the relevant requirements of the Code and a breach of Clause 28.1 was ruled. The Panel noted that the company had immediately taken down the website. However advertising prescription only medicines to the public was a serious matter and thus the Panel decided that high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted its rulings and comments above but did not consider that the circumstances were such as to warrant a breach of Clause 2 which was a sign of particular censure. No breach of Clause 2 was ruled.

Complaint received **21 December 2016**

Case completed **30 January 2017**

CODE OF PRACTICE REVIEW – February 2017

Cases in which a breach of the Code was ruled are indexed in **bold type.**

AUTH/2828/3/16	**Clinical nurse specialist v Vifor Pharma**	**Conduct of representatives**	**Breaches Clauses 2, 7.2, 7.4, 7.9, 9.1, 9.9, 15.2 and 15.9**	**Appeal by respondent**	**Page 3**
AUTH/2830/4/16	**Pharmacosmos v Vifor Pharma**	**Promotion of Ferinject**	**Breaches Clauses 7.2 and 8.1**	**Appeal by respondent**	**Page 24**
AUTH/2862/8/16	**Anonymous, non-contactable v Takeda**	**Engagement of a consultant and his/her training and consultancy company**	**Breach Clause 2** **Two breaches Clauses 9.1** **Breaches Clauses 18.1 and 18.6**	**No appeal**	**Page 50**
AUTH/2863/8/16	Anonymous, non-contactable v Lilly	Engagement of a consultant and his/her training and consultancy company	No breach	No appeal	Page 63
AUTH/2864/8/16	Anonymous, non-contactable v Boehringer Ingelheim	Engagement of a consultant and his/her training and consultancy company	No breach	No appeal	Page 69
AUTH/2865/8/16	Anonymous, non-contactable v Sanofi	Engagement of a consultant and his/her training and consultancy company	No breach	No appeal	Page 77
AUTH/2866/8/16	**Anonymous, non-contactable v AstraZeneca**	**Engagement of a consultant and his/her training and consultancy company**	**Breach Clause 9.1**	**No appeal**	**Page 84**
AUTH/2868/8/16	**Janssen v Sanofi Genzyme**	**Promotion of an unlicensed medicine**	**Breach Clause 3.1 and 9.1**	**Appeal by respondent**	**Page 92**
AUTH/2872/9/16	Consultant oncologist and a pharmacist v Lilly	Oncology handbook	No breach	No appeal	Page 102
AUTH/2874/9/16	Health professional v Shield	Promotion of Feraccru	No breach	No appeal	Page 105
AUTH/2875/9/16	**Health professional v Recordati**	**Promotion of Cleen and CitraFleet**	**Breach Clause 4.1** **Three breaches Clause 7.2** **Two breaches Clauses 7.3 and 7.10**	**No appeal**	**Page 107**
AUTH/2876/9/16	Health professional v AbbVie	Promotion of Humira	No breach	No appeal	Page 113
AUTH/2878/10/16	Member of the public v Meda	Alleged promotion to the public	No breach	No appeal	Page 116

AUTH/2879/10/16	Anonymous, non-contactable v Bristol-Myers Squibb	Orencia patient support service	No breach	No appeal	Page 117
AUTH/2880/10/16	Anonymous, Non Contactable v Bristol-Myers Squibb	Alleged pre-licence Promotion of Opdivo	No breach	No appeal	Page 124
AUTH/2892/11/16	Anonymous, non-contactable v Galen	Trustsaver website	No breach	No appeal	Page 131
AUTH/2911/11/16	Anonymous, non-contactable v Galen	Promotion of Laxido	No breach	No appeal	Page 136
AUTH/2913/12/16	Anonymous, non-contactable v Janssen	Conduct of a medical science liaison employee	No breach	No appeal	Page 142
AUTH/2914/12/16	**Hospital pharmacist v Pierre Fabre**	**Navelbine bags distributed by representatives**	**Breaches Clauses 2 and 9.1**	**No appeal**	**Page 145**
AUTH/2915/12/16 and AUTH/2916/12/16	Anonymous, non-contactable v Janssen & Napp	Venue for promotional meeting	No breach	No appeal	Page 148
AUTH/2917/12/16	**Anonymous, non-contactable v Janssen**	**Conduct of representative**	**Breach Clause 15.2**	**No appeal**	**Page 151**
AUTH/2919/12/16	Anonymous, non-contactable v Merck Sharp & Dohme	Conduct of representative	No breach	No appeal	Page 155
AUTH/2921/12/16	**Voluntary admission by Grünenthal**	**Promotion to the public**	**Breach Clauses 9.1, 26.1 and 26.2**	**No appeal**	**Page 156**
AUTH/2924/12/16	**Anonymous, non-contactable Pharmacist v Lincoln Medical**	**Statements on website**	**Breach Clauses 9.1, 26.1 and 28.1**	**No appeal**	**Page 160**

PMCPA | Prescription Medicines Code of Practice Authority

The Prescription Medicines Code of Practice Authority was established by the Association of the British Pharmaceutical Industry (ABPI) in 1993 to operate the Code of Practice for the Pharmaceutical Industry at arm's length from the ABPI itself. Compliance with the Code is obligatory for ABPI member companies and, in addition, over sixty non member companies have voluntarily agreed to comply with the Code and to accept the jurisdiction of the Authority.

The Code covers the advertising of medicines to health professionals and other relevant decision makers and also covers information about prescription only medicines made available to the public.

It covers:

- journal and direct mail advertising
- the activities of representatives, including any printed or electronic material used by them
- the supply of samples
- the provision of inducements in connection with the promotion of medicines and inducements to prescribe, supply, administer, recommend, buy or sell medicines by the gift, offer or promise of any benefit or bonus, whether in money or in kind
- the provision of hospitality
- the organisation of promotional meetings
- the sponsorship of scientific and other meetings, including payment of travelling and accommodation expenses
- the sponsorship of attendance at meetings organised by third parties
- all other sales promotion in whatever form, such as participation in exhibitions, the use of audio or video-recordings in any format, broadcast media, non-print media, the Internet, interactive data systems, social media and the like.

It also covers:

- the provision of information on prescription only medicines to the public either directly or indirectly, including by means of the Internet
- relationships with patient organisations
- disclosure of tranfers of value to health professionals and organisations
- joint working between the NHS and pharmaceutical companies
- the use of consultants
- non-interventional studies of marketed medicines
- the provision of items for patients
- the provision of medical and educational goods and services
- grants, donations and benefits in kind to institutions.

Complaints submitted under the Code are considered by the Code of Practice Panel which consists of three of the four members of the Code of Practice Authority acting with the assistance of independent expert advisers where appropriate. One member of the Panel acts as case preparation manager for a particular case and that member does not participate and is not present when the Panel considers it.

Both complainants and respondents may appeal to the Code of Practice Appeal Board against rulings made by the Panel. The Code of Practice Appeal Board is chaired by an independent legally qualified Chairman, Mr William Harbage QC, and includes independent members from outside the industry. Independent members, including the Chairman, must be in a majority when matters are considered by the Appeal Board.

In each case where a breach of the Code is ruled, the company concerned must give an undertaking that the practice in question has ceased forthwith and that all possible steps have been taken to avoid a similar breach in the future. An undertaking must be accompanied by details of the action taken to implement the ruling. Additional sanctions are imposed in serious cases.

Further information about the Authority and the Code can be found at www.pmcpa.org.uk

Complaints under the Code should be sent to the Director of the Prescription Medicines Code of Practice Authority, 7th Floor, Southside, 105 Victoria St, London SW1E 6QT

telephone 020 7747 8880
facsimile 020 7747 8881
by email to: complaints@pmcpa.org.uk.