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**