CASE AUTH/2962/7/17

ANONYMOUS SALES REPRESENTATIVE v PIERRE FABRE

Call rates and certification of meetings

An anonymous representative who promoted Toviaz (fesoterodine) for Pierre Fabre, complained on behalf of a group of representatives about call rates and the certification of meetings. Toviaz was indicated for the treatment of symptoms of overactive bladder syndrome.

The complainant was particularly critical about the conduct of senior staff within the company with regard to the Code and stated that representatives had been instructed to see clinicians more than the average 3 times per year. At a recent sales meeting it was suggested that representatives should not take holidays as they would thus not be selling. The complainant alleged that none of the training used at the meeting had been certified. Similarly, promotional speaker meetings had not been approved or certified but representatives were told to go ahead anyway because the meetings were business critical and the risk was low.

The complainant queried whether an overseas corporate consultant understood UK regulations and whether he/she had sat the ABPI Examination.

The detailed response from Pierre Fabre is given below.

The Panel noted that the sales meeting presentation at issue discussed sales activity and marketing strategy and in this regard it considered that the presentation was briefing material which needed to be certified. Pierre Fabre acknowledged that the presentation had not been certified and in that regard the Panel ruled breaches of the Code.

With regard to overcalling, the Panel noted that during their initial training course the Toviaz representatives had been instructed about the requirements of the Code regarding the number of calls they could make on health professionals. There had been some confusion on this matter at the sales meeting in June 2017 and the representatives had been orally rebriefed at that event and had received approved written instructions but not until August. A presentation at the sales meeting included individual data on sales and bonuses. The data was not set within the context of the number of calls allowed under the Code. In the Panel's view, such data might put pressure on representatives to increase their activity and potentially breach the Code. Despite these concerns and the sales force recording system logged calls such that face-to-face calls could not be differentiated from group calls, the Panel noted that the complainant bore the burden of proof. The Panel considered that it had not been shown on the balance of probabilities that representatives had been instructed to see clinicians more than three times a year on average. There was no evidence of overcalling. No breaches of the Code were ruled. The rulings were upheld on appeal.

The Panel noted that the corporate consultant did not fulfil the definition of a representative; he/she did not call upon health professionals in relation to the promotion of medicines. There was thus no requirement for him/her to take the ABPI Examination and in that regard the Panel ruled no breach of the Code. This ruling was upheld on appeal.

The Panel noted the complainant's concerns that representatives' meetings had not been approved or certified. The Panel noted that the Code required companies to check all meetings to ensure compliance with the Code and to certify those which involved travel outside the UK. The Panel did not consider that the representatives meetings needed to be certified; the arrangements had been documented and approved. No breach of the Code was ruled. This ruling was upheld on appeal

The Panel noted its comments and rulings above and also ruled no breach of Clause 2 of the Code. The complainant's appeal of this ruling was successful; the Appeal Board ruled a breach of Clause 2.

Apart from his/her appeal of the Panel's ruling of no breach of Clause 2, the complainant's appeal was largely unsuccessful as detailed above. However, in submitting his/her reasons for appeal, the complainant noted that in its response, Pierre Fabre had not submitted the whole of the presentation used at the sales meeting. The Appeal Board considered that the additional slides fell within the scope of the complaint and could be considered. The Appeal Board considered that the Panel's rulings with regard to the presentation not being certified applied to the newly submitted slides as acknowledged by Pierre Fabre.

The Appeal Board noted that Pierre Fabre had initially provided an incomplete set of slides from the sales meeting. This omission was a serious matter; it was essential that pharmaceutical companies provided complete and accurate information to the Panel and so the Appeal Board decided that, in accordance with Paragraph 11.3 of the Constitution and Procedure, Pierre Fabre should be publicly reprimanded. The Appeal Board noted that this case had raised serious concerns about Pierre Fabre's compliance structure. However, comprehensive and timely action had been taken including wholesale changes to address the issues highlighted. On balance, the Appeal Board thus decided not to require an audit of the company's procedures.

The complainant stated that part of the sales team working at Pierre Fabre in the Toviaz (fesoterodine) franchise were concerned about representatives' call rates and the certification of meetings. They would like to remain anonymous. Toviaz was indicated for the treatment of symptoms of overactive bladder syndrome. The marketing authorization holder was Pfizer.

COMPLAINT

The complainant explained that the representatives concerned had all joined Pierre Fabre full of enthusiasm six months previously and now regretted that decision. In that regard, the complainant named an employee from an overseas affiliate who had taken up a corporate consulting position in the UK and was now instructing the sales force.

The complainant stated that the representatives had been instructed to see clinicians more than the average 3 times per year. The previous sales manager tried to push back to be in line with the rules, but the Toviaz team was now being instructed verbally to see more than that. The complainant submitted that the activity rate and what was expected would show that the representatives were not in tune with the rules and alleged that senior staff seemed to have a 'nudge-nudge, wink-wink' attitude to the Code. At a recent sales meeting (15/16 June) representatives were told that if they wanted to remain in their roles, they should not take vacation as they would be off-patch (and not selling). This was unacceptable. The complainant stated that none of the training received at the meeting in June seemed to have been certified and that in the representatives' previous roles, all material was thoroughly checked and certified.

The complainant explained that as part of their role, the representatives had been asked to arrange speaker meetings. However, the instructions from senior staff seemed to be different from the rules set out by the Code. None of the promotional meetings had been approved or certified, but the representatives had been told to go ahead anyway as the meetings were business critical and the level of risk was low (presumably the company did not expect to receive a complaint). The complainant stated that the representatives did not feel comfortable as they considered that this was not in line with their procedures and might be in breach of the Code.

The complainant alleged that the overseas corporate consultant did not seem to understand the UK regulations. The representatives would like to know if he/she had sat the ABPI Examination.

The complainant stated that the representatives had approached the PMCPA as a last resort as they could not rely on any internal process to combat such behaviour, especially given the seniority of the staff criticised. The complainant stated that the representatives did not want to endure such unprofessional behaviour and be made to break the rules.

When writing to Pierre Fabre, the Authority asked it to respond in relation to the requirements of Clauses 2, 9.1, 14.1, 15.4, 15.9, if relevant, 16.3 and 22.1.

RESPONSE

Pierre acknowledged that the agenda and certain slides presented at the cycle meeting in June 2017 had not been certified in accordance with the Code, in breach of Clauses 14.1 and 15.9 and also in breach of internal procedures.

Pierre Fabre also submitted that branded materials in these slides included materials that had been pre-approved in accordance with Clause 14.1 and internal procedures. Pierre Fabre acknowledged that some of the oral statements led to initial confusion as to targets regarding calls and contacts of the Toviaz sales team, and to confusion as to entitlement to vacations. When a named senior member of staff was present at the meeting the entitlement to vacations was explained and that there were no changes to the call and contact rates issued by regional business managers (RBMs). The RBMs also orally re-briefed sales targets during the meeting.

Pierre Fabre stated that it had followed up with the individuals concerned regarding the need to strictly comply with the Code and policies and had re-communicated which managers were authorised to instruct Toviaz representatives. The company was also implementing other steps as described below in accordance with the Code and in-house policies.

Pierre Fabre did not consider that there had been a breach of Clause 15.4 at the cycle meeting because:

- the RBMs who were authorised to instruct representatives on call and contact rates provided instructions on call and contact rates which complied with the Code, and orally agreed these instructions with their representatives on 16 June
- oral confirmation of expected call and contact rates which complied with the Code was provided to representatives on 15 June to clarify the confusing information in the slides at issue
- the targets were realistic.

Pierre Fabre submitted that for two speaker meetings held in July 2017 using slide content which had been pre-approved in accordance with the Code, no final signatory approval was provided within the deadlines set by company procedures. Copies of the Zinc documents were provided. For one of the meetings on 7 July, the original intended speaker was replaced by another.

The records documented how signatories checked the proposed speaker meetings described in a detailed 'Meeting Approval Form' and commented on the suitability of the arrangements. Pierre Fabre considered that the educational content was acceptable.

For both these meetings, content such as the slides and the contract for speaker services had been pre-approved. The contract for speaker services was signed before the meeting. This clearly set out a

policy for disclosure. The honoraria agreed with the speakers were consistent with the Code, the venues suitable and costs per person for meals (sandwiches and a buffet meal) on a subsistence basis was reasonable and within the Code.

At the verbal request of each speaker, an invitation letter in standard format containing an agenda was only sent to the speaker. No other invitations or agendas were sent to delegates by the representative.

Based on the above, Pierre Fabre suggested that although its procedures were not fully observed, there was no breach of Clause 22.1 or of the guidance provided on certification of meetings in February 2016. Pierre Fabre denied breaches of Clauses 9.1, 14.1, 15.9 and 22.1 in relation to speaker meetings.

Pierre Fabre stated that by September (allowing for vacation absences and completion of internal disciplinary procedures) it would have completed discussions, and was taking steps to address the breaches of company procedures in accordance with the Code and in-house policies. Further investigations were ongoing.

In relation to the role of the overseas corporate consultant, Pierre Fabre denied a breach of Clause 16.3.

In relation to the matters raised, Pierre Fabre accepted it was in breach of Clause 9.1 as it had not maintained high standards but it did not consider that there had been a breach of Clause 2.

Role of overseas corporate consultant

Pierre Fabre stated that the role of the named employee from an overseas affiliate was to provide advice as a corporate consultant on the marketing of Toviaz in urology. He/she was not a representative, as defined in Clause 1.7; he/she did not call on health professionals or other relevant decision makers in relation to the promotion of medicines. For this reason, he/she was not expected to sit the ABPI examination as required for representatives (Clause 16.3).

Pierre Fabre submitted that the previous UK national sales manager resigned in April 2017 and left in mid-June 2017. Recruitment for a successor was continuing and this successor would be appointed in September 2017. In May and June 2017 representatives received sales data from the Toviaz product manager and from the named corporate consultant. From August the corporate consultant would provide sales data and feedback on Toviaz in Europe and expert advisory services only to the UK managing director.

Pierre Fabre acknowledged that in the weeks between the national sales manager's resignation and 15 June 2017, the corporate consultant had contacted the Toviaz sales force on sales and marketing data analysis, and used the job title 'interim national sales manager' which had caused confusion. After some of the Toviaz sales force voiced their confusion on targets and vacations at the June 2017 cycle meeting, this job title was no longer used.

The Toviaz sales team had been managed since November 2016 by RBMs who had direct authority to brief and instruct their teams. Pierre Fabre provided copies of emails from the corporate consultant regarding sales activity on Toviaz and responses of senior management.

Pierre Fabre also provided copies of slides that accompanied the statements made at the June meeting with information about the promotion of Toviaz in UK and Ireland. The company acknowledged that the slides were confusing and uncertified and so a senior employee orally briefed the representatives on 15 June during the presentation, and then the next day the RBMs re-clarified these briefings with oral instructions. Briefings made by the senior employee and the RBMs were consistent with the Code. When he/she was in attendance at this part of the cycle meeting (until a slide on 'Holiday Periods') the senior employee also explained what was meant by the comments regarding vacations and call rates.

Pierre Fabre stated that with regard to call and contact rates the RBMs, before and on 16 June orally, instructed Toviaz sales teams to set their customer targets as described below. Approved instructions were most recently provided to this sales team on 22 August 2017. This was based on relevant target customers, the average of 180 days a year of field activity and a minimum of 200 customers (targets) in a calendar year: the order of preference to see these targets was:

1 urology consultants/decision makers.
2 obstetrics and gynaecology consultants/decision makers.
3 care of the elderly consultants/decision makers.
4 GPs with an interest in urology overactive bladder.

For Cycles 1-3 the target was to plan to see each of the 200 targets once each cycle. For Cycle 4 RBMs assessed the activity from Cycles 1-3, any targets not yet seen three times would become a priority for Cycle 4, with remaining activity plans focussed on new priority customers identified during the year who had not been seen three times.

Information about vacations was then communicated at the cycle meeting by the RBMs.

Training materials for managers authorised to instruct Toviaz representatives at the cycle meeting were certified and approved before the June 2017 meeting.

Pierre Fabre explained that the planning, review and approval of promotional meetings were covered by and subject to in-house procedures and training. In company training, arrangements for speaker meetings were instructed to be made in accordance with the Code. Training and approved materials were provided on this.

Pierre Fabre stated that representatives could continue to raise any concerns with the RBM or other managers, or anonymously with helplines; the Toviaz representatives did not raise concerns when asked in June 2017 if they had any.

Pierre Fabre submitted that the senior employee regarded compliance with the Code as a key priority and had engaged at all levels across the UK company and a senior employee in European compliance supported him/her in this regard. The corporate consultant was employed by Pierre Fabre Global Region to focus on urology sales data and sales force effectiveness for Toviaz. These two individuals were therefore not employed by the same company and had substantially different roles. The senior employee focussed on activities relating to the UK and Ireland for medicinal products, had contacts with UK health professionals, with managers of UK hospitals and authorities. The other person provided consultancy services, including marketing and data reports on Toviaz business performance and activity, his/her analysis of the data and his/her views on how it might be more effective – only within the Pierre Fabre Group. He/she had no contacts with UK customers. These individuals had received different training and did not benefit from the same incentive schemes.

Furthermore, it was wrong to state that these individuals were conspiring to breach the Code when on 15 June the senior employee instructed all the Toviaz representatives and RBMs to follow the RBM's instructions not the views expressed by the corporate consultant. On other occasions the senior employee had also responded to the corporate consultant's views, though representatives might not have been aware of these responses.

Pierre Fabre stated that its leadership team and senior management were extremely alarmed that breaches of the Code and of its procedures had occurred. The company very much regretted these failings and confusions and the acute disappointment they caused to the complainant. The company acknowledged that Clause 9.1 was breached from the combined breaches of Clauses 14.1 and 15.9 at the cycle meeting and of the breaches of internal procedures at two speaker meetings in July. The company set itself high standards and it acknowledged that in these instances they were not achieved.

Pierre Fabre noted that it insisted on full disclosure of all transfers of value to health professionals; it had established a local compliance network in the UK and had openly encouraged staff to raise questions and report any concerns they might have about the Code or policies, even anonymously. The company stated that it would continue to learn from mistakes in the use of titles.

After careful assessment, Pierre Fabre denied a breach of Clause 2. As required by the Code, the company had clear policies and procedures, it trained and supported its employees and had applied its procedures to identify, report, address and remedy the breaches. The breaches and activities had not led to risks for patient safety and had not brought discredit upon or reduced confidence in the industry.

Pierre Fabre stated that it continued to monitor compliance with the Code and its procedures and further details were provided below on future steps. Senior management had highlighted and would continue to model how compliance with the Code and policies was fundamental to business in the UK.

Pierre Fabre expressed its full and unreserved apologies for the breaches and that its procedures and training did not prevent their occurrence. Senior directors and other managers would continue to set the high standards of the Code in all activities in the UK. More details of steps to model and promote these standards were provided.

Since discovery of the breaches, all immediate steps had been taken to address the breaches and remedy them including calls with management and the sales force about the complaint. Further steps were planned as detailed below. All of the senior management team shared a commitment to ensure the Code continued to be at the core of all its activities.

As of August 2017, Pierre Fabre had internally circulated information about this complaint and the Code. It had re-communicated to the Toviaz sales force a Briefing Document on 2017 Activity.

Future steps and initiatives would include:

- re-train individuals who were found not to comply with compliance with procedures
- continue to raise awareness about the Code, about the importance of certifying and approving all materials for use in promotional meetings as well as with speaker meetings
- appoint Code champions in every function and organizing a Code Awareness Day in 2017
- conducting an internal audit into compliance with the Code in the third of fourth quarter of 2018, and conduct 'spot' checks in the meantime
- take all other steps the UK Leadership Team considered appropriate after review of these breaches and of the outcomes of confidential internal investigations.

With its response Pierre Fabre provided an enclosure on background and facts. The document stated that the marketing authorization holder for Toviaz in the UK was Pfizer Limited. Pierre Fabre was responsible for the promotion of Toviaz in Europe and other markets under the terms of a promotion agreement with Pfizer. In accordance with this agreement, Pfizer and Pierre Fabre were jointly responsible for review and approval of all Toviaz promotional materials, with Pierre Fabre taking responsibility for informing the Pfizer signatory of all relevant items in development and use.

Pierre Fabre was solely responsible for the briefing and training of its staff, including its field force when the content of that briefing or training was not related to Toviaz product information.

Pierre Fabre submitted that if first promoted Toviaz in the UK and Ireland from early December 2016. Representatives who promoted only Toviaz were divided into two regions (North and South). They reported for all instructions and matters to two RBMs who in turn, until mid-June 2017, reported to the national sales manager. In May and June 2017 the regional sales manager reported their own expenses, targets and vacations to the managing director. Representatives and regional managers also received information on marketing messages from the Toviaz product manager and from the sales force effectiveness team.

Representatives were invited by the national sales manager to attend the cycle meeting in June to review market developments, sales progress and to take part in a role play where managers would pretend to be customers meeting their representatives to discuss Toviaz.

Pierre Fabre submitted that the corporate consultant who attended and presented at the meeting on 15 June worked on the promotion of Toviaz, and was the internal expert on marketing in urology and the European and global experience of marketing messages for Toviaz. The Toviaz product manager, attended to support with knowledge and experience of marketing activities by Pierre Fabre in the Republic of Ireland and other EU markets.

Pierre Fabre submitted that the corporate consultant was not authorised to instruct the Toviaz sales force and had no certification or approval authority under the Code. It was common knowledge within Pierre Fabre UK that the individual concerned had not been trained in the UK pharmaceutical industry. He/she was invited to present at the cycle meeting to share information about marketing Toviaz in EU markets and to help prepare representatives for a role play. RBMs were then planning to discuss with representatives their individual and team targets and plans the following day.

Pierre Fabre submitted that before the role play, the corporate consultant presented data on Toviaz activity for April 2017. The regional sales managers understood that this meant slides that had been approved for use at the cycle meeting when in fact they were slides prepared by the corporate consultant and the product manager to review sales progress in April 2017, and to discuss marketing in urology, but not intended to provide instructions to representatives for the purposes of the Code. None of the slides presented by the corporate consultant or the RBMs were circulated to the representatives.

FURTHER INFORMATION FROM PIERRE FABRE

In response to a request for further information Pierre Fabre stated that the investigations extended beyond the scope of the questions raised by the Panel and were being disclosed in the interests of transparency. Pierre Fabre clarified that the breaches were not identified sooner because the staff concerned were not available to authorise access to their email accounts.

Outcome of investigations

Pierre Fabre submitted that it first reviewed all promotional activities for Toviaz in the UK and specifically the compliance of job bags since August 2016 with the Code and company SOPs. This review included instructions given to the sales force, based on interviews with marketing staff who communicated with the sales force and review of emails they sent to the Toviaz sales force. This sales force only promoted Toviaz.

The findings of its global and local compliance team were provided with details and copies of the Zinc documents. Where Pfizer did not certify or examine materials, it was because Pierre Fabre did not send the materials to Pfizer.

Apologies and commitments

On behalf of its senior management in the UK and Europe Pierre Fabre apologised unreservedly that in these instances high standards it set had not been met. The breaches had been brought to the full attention of Pierre Fabre Global Management. It was acknowledged that they should not have occurred. The acting managing director of Pierre Fabre UK, apologised personally that these breaches occurred under previous Pierre Fabre UK leadership.

Pierre Fabre UK submitted that it had and was taking the following steps:

- discontinue the promotion of Toviaz in UK with effect from 21 September 2017 until further notice
- urgent appointment of a national sales manager, a senior marketing manager with significant experience of the Code and a compliance officer
- urgent appointment of a further senior medical advisor
- re-train all staff and sales force on the Code and SOPs, in October 2017
- run an ABPI Code Day
- urgent review of SOPs with new documents issued where appropriate.

Pierre Fabre UK also acknowledged that after the introduction of Zinc and specific SOPs, followed by training on their use, it was disappointing that despite clear attempts by staff to comply with the Code and with SOPs, there were breaches of the Code.

Pierre Fabre submitted that notwithstanding this training, there were errors in complying with its processes which were designed to comply with or be stricter than the Code.

The critical importance of Pierre Fabre's Code of Ethics, the ABPI Code and the EFPIA Code was restated at a presentation on 19 September to all head office staff and representatives.

In response to questions from the Panel, Pierre Fabre stated that the y axis on one of the graphs used at the cycle meeting (slide 20, 'Holidays Period') stated the number of days of vacation requested (after approval from the RBM), for the

period January to end of May 2017. It did not state the number of days' vacation taken. The data taken from the company's sales force reporting system was a snapshot of vacations booked in May 2017. The slide was shown so staff at the meeting could see the vacations booked. It was not intended to reduce absence and 'over-target'. It was shown to encourage representatives who had not yet booked their summer vacation to include this in the sales force reporting system. At the presentation, after this slide created confusion, the senior employee intervened. It should not have been shown without clear explanations.

In relation to questions about when and how the representatives were first briefed about targets, Pierre Fabre submitted that the representatives were briefed on targeting and calls as part of the induction training in November 2016; the briefings and training were approved in accordance with the SOPs. The initial briefing was clear and representatives did not raise questions.

Pierre Fabre submitted that after a clear briefing and detailed training during the induction training in November 2016, it was felt appropriate to provide a further written briefing after confusion arose at the June cycle meeting. This further briefing was certified by 18 August and communicated to the sales force on 22 August 2017. Pierre Fabre referred to the RBMs' explanation that they had, on the morning of 16 June, re-explained key messages to their representatives and how holidays could still be booked as before. They also had agreed action plans with their representatives and presented slides that had been approved in Zinc.

Pierre Fabre submitted that during the initial training period the representatives each received a hard copy of the 2016 Code. In November 2016 it also provided training on Transfers of Value, internal SOPs and the detailed online training. Representatives were also provided with training on the Code in accordance with Pierre Fabre SOPs, including specifically on Clause 15.4.

Pierre Fabre submitted that the meeting application form for the meeting on 7 July 2017 was examined, and included the stamp 'Amend and Resubmit' by a medical reviewer (not a Code signatory) because multiple typographical errors were identified. The marketing reviewer did not add the necessary stamp. However, the arrangements and logistics of the meeting had been accepted prior to the meeting and were considered appropriate under the Code.

Pierre Fabre submitted that with regard to payment of external speakers meetings in July 2017, each speaker at each meeting was paid as agreed in their respective contracts.

With regard to the instructions about the 'meetings in a box', Pierre Fabre submitted that after slides were circulated for information following a verbal briefing, certified slides were circulated on 16 May 2017 and the following instructions were provided by Pierre Fabre UK to representatives: UK/TOV/0417/0037a – First Briefing document after verbal briefings – circulated on 30 June as a version with typographical errors. Pierre Fabre acknowledged that the first briefing was not certified in accordance with its SOPs and with the Code.

Four meetings were held between June and August. Pierre Fabre submitted that the meeting content had been certified and the arrangements examined as required by the Code. However, Pierre Fabre UK SOPs were stricter than the Code as they required certification of the meeting arrangements, and this certification had not been completed.

Pierre Fabre submitted that the statement 'open more doors' contained in an email of 20 February 2017, from the corporate consultant, was aimed at three members of the sales force and was intended to provide support and time of the RBM and head office team. This also included 'one on one' training and support that the representative might need to respond more effectively to customer contacts. The representatives concerned worked in territories with extensive distances between customer centres and complexities for access. RBMs would provide advice. Head office staff would provide support based on their experience of dealing with customers in these regions. For example, one of the representatives did not know that specialist registrars could also be contacted in addition to other urology professionals. This information was provided by his/her RBM. Another form of support was to sponsor hospital meetings if requested in the territories of those representatives, as described in an attachment.

With regard to the targets of one member of staff, Pierre Fabre submitted that he/she did not act as a representative in the UK.

Pierre Fabre submitted that it was not aware that a representative had made more than three unsolicited calls to a particular health professional since Pierre Fabre started to promote Toviaz in December 2016. Pierre Fabre referred to the briefings and slides provided since it started promoting Toviaz.

Pierre Fabre submitted that it was not possible for Pierre Fabre to collate data that distinguished between solicited and unsolicited calls. Its sales force reporting system recorded all of the following as a 'call' in a group total – a 'face to face' meeting, or a 'group' meeting. A review of data on the system showed that between 1 January and 9 September 2017, the sales force reported contacts with 3,878 health professionals in the UK of which 597 were contacted more than three times. This data would include attendance at group meetings, solicited and unsolicited calls. Pierre Fabre submitted that it would continue to monitor reports of representatives and to provide training on the Code and on its instructions.

In conclusion, Pierre Fabre submitted that the decision to discontinue promotion of Toviaz in the UK and to change staff showed how seriously the Pierre Fabre Group had taken the breaches. Pierre Fabre was preparing a detailed remedial plan and was learning from the failings.

Pierre Fabre acknowledged a breach of Clause 9.1 based on the breaches of Clauses 14.1 and Clause 15.9 and of the breaches of its internal procedures.

Pierre Fabre submitted that the group set high standards for all of its teams with regard to the Code and all its procedures. Pierre Fabre acknowledged that they were not met and after conducting necessary investigations it had taken immediate action.

After detailed analysis of the breaches, Pierre Fabre submitted that there was no breach of Clause 2; the company had clear policies and procedures, it had provided training and also tested its employees on their knowledge. Clear standards were set for senior management in the UK. When these standards were not met, after necessary investigations Pierre Fabre had taken action.

Pierre Fabre submitted that it would continue to expect all staff to fulfil their obligations under the Code. It also submitted that there were no risks for patient safety and denied that it had brought discredit upon or reduced confidence in the industry.

Pierre Fabre UK submitted that it continued to monitor compliance with the Code and its procedures and further details were provided on future steps it would take. Senior management has highlighted and would continue to model how compliance with the Code and policies was fundamental to business in the UK.

PANEL RULING

The Panel noted that Clause 15.9 of the Code required companies to prepare detailed briefing material for representatives on the technical aspects of each medicine which they would promote. Briefing material must comply with the relevant requirements of the Code and, in particular, was subject to the certification requirements of Clause 14. Briefing material must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code. The supplementary information to Clause 15.9 stated that the briefing material referred to in the clause consisted of both the training material used to instruct representatives about a medicine and the instructions given to them as to how the product should be promoted.

The Panel noted that the presentation at issue included slides which discussed sales activity and included comments on the importance of staying in the field, the number of urologists to be seen and the frequency with which they should be seen. The presentation also included slides on the marketing strategy for the UK and Republic of Ireland which included technical aspects of each medicine and claims presented by the product manager. The Panel considered that the presentation was briefing material for representatives and therefore required certification but noted Pierre Fabre's submission that the presentation had not been certified. The Panel thus ruled a breach of Clause 14.1 as acknowledged by Pierre Fabre. This meant that the presentation failed to comply with the Code and thus a breach of Clause 15.9 was ruled. The Panel considered that failing to certify representatives' briefing material meant that high standards had not been maintained and a breach of Clause 9.1 was ruled as acknowledged by Pierre Fabre.

The Panel noted the allegation that representatives had been instructed to see clinicians more than the average 3 times per year. The Panel noted Pierre Fabre's submission that during the initial training course representatives were trained on the Code and company SOPs. The training, dated October 2016, contained information on Clause 15.4 with regard to call and contact rates including an extract from the supplementary information to Clause 15.4 about the number of visits. The Panel further noted Pierre Fabre's submission that the RBMs, before and on 16 June, verbally instructed Toviaz sales teams to set their customer targets based on relevant target customers and an average of 180 days a year of field activity. Given the confusion caused by the presentation at the cycle meeting on 15 June the Panel queried why approved written instructions were not provided to the sales team until 22 August 2017. The Panel noted that the presentation given at the cycle meeting included data on sales on an individual named basis and who had received what bonus which might be seen to put pressure on representatives to increase their activity and potentially breach the Code in doing so. The presented data was not set within the context of the relevant requirements of Clause 15.4 and its supplementary information. In the Panel's view the presentation indirectly advocated a course of action likely to lead to a breach of the Code. The Panel, however, noted Pierre Fabre's submission that verbal briefings in line with the Code were given by a senior member of staff at the meeting on the same day and the RBMs the day after. The company was not aware that a representative had called on a particular health professional more than three times as an unsolicited call since Pierre Fabre started promoting Toviaz in December 2016. The Panel was concerned to note that Pierre Fabre could not distinguish between solicited and unsolicited calls. The sales force reporting system recorded a 'face to face' meeting, or a 'group' meeting as a 'call' in a group total. The Panel queried how in the absence of such differentiation Pierre Fabre could be confident that its representatives complied with the relevant requirements of the Code. The Panel noted that whilst it had some concerns, the complainant bore the burden of proof and considered that he/she had failed to prove on the balance of probabilities that representatives had been instructed to see clinicians more than the average of three times per year. There was no evidence of overcalling. The Panel ruled no breach of Clauses 15.4 and 15.9. This ruling was appealed by the complainant.

Clause 1.7 of the Code defined 'representative' as a representative calling on members of the health professions and other relevant decision makers in relation to the promotion of medicines. Clause 16.3 required that representatives take an appropriate examination within their first year of employment as a representative and pass it within two years of starting such employment.

The Panel noted the corporate consultant's job description and Pierre Fabre's submission that the role was not covered by the definition of representative under Clause 1.7 as the person did not call on health professionals. The Panel considered as the individual did not call upon health professionals in relation to the promotion of medicines there was no requirement to take and pass an appropriate examination. The Panel therefore ruled no breach of Clause 16.3. This ruling was appealed by the complainant.

The Panel noted the complainant's concern that none of the representatives' promotional meetings had been approved or certified. The Panel noted that the supplementary information to Clause 22.1 required that companies ensured that all meetings which were planned were checked to see that they comply with the Code. In addition, meetings which involved travel outside the UK must be formally certified as set out in Clause 14.2. The Panel noted Pierre Fabre's submission that for two speaker meetings held in the UK in July 2017 no final signatory approval was provided within the deadlines set by company procedures. Copies of the Zinc documents were provided. The records documented how signatories checked the proposed speaker meetings described in a detailed 'Meeting Approval Form' and commented on the suitability of the arrangements. The Panel did not consider that these meeting arrangements required certification. The Panel further noted Pierre Fabre's submission that for both these meetings, content such as the slides and the contract for speaker services had been pre-approved, copies of the certificate was provided. The Panel therefore ruled no breach of Clause 14.1. The Panel did not consider that Pierre Fabre had failed to maintain high standards in this regard and no breach of Clause 9.1 was ruled. This ruling was appealed by the complainant.

The Panel noted that a ruling of a breach of Clause 2 of the Code was a sign of particular censure and was reserved for such circumstances. The Panel noted its comments and rulings above and did not consider that the matter warranted such a ruling. This ruling was appealed by the complainant.

APPEAL BY THE COMPLAINANT

The complainant appreciated the transparency and explanation provided by Pierre Fabre regarding promotional meetings, call rates, and the other associated documentation and now understood this was not in line with company procedure and not in breach of the Code. However, the complainant submitted that some of the information in Pierre Fabre's response was inaccurate as detailed below. The complainant stated that he/she was not a Code expert and left it to the PMCPA to decide if the evidence provided was in breach of Clauses 9.1, 15.4, 15.9, 16.3 or 2.

Role of sales effectiveness

The complainant alleged that Pierre Fabre's statement that the corporate consultant was 'not a sales director', 'did not have the authority to instruct the sales force', had no contact with UK customers' and 'provided consultancy services… for Toviaz' was not entirely true as he/she had instructed the sales team since December 2016, two weeks after it started promoting Toviaz. The complainant provided a copy of an email dated 14 December 2016 to demonstrate the type of communication the representatives were subjected to. This demonstrated that the corporate consultant acted as a sales director (albeit with a different title), especially as the national sales manager was copied into this email who also had to get permission from the corporate consultant before he/she could carry out any activities pertaining to the sales team. The complainant submitted that his/her oncology colleagues also received communication from the corporate consultant (email dated, 27 April 2017). If the individual was a global consultant for Toviaz, why did he/she instruct the Navelbine (oncology) team? Why would a global colleague who was supposed to be providing consultancy support communicate directly with the urology and oncology sales teams, if not in the capacity of a sales director/manager? The complainant alleged that the individual had seen both UK and Irish customers. This also took place during larger meetings, eg the European Association of Urology, March 2017 in London which the individual attended as part of the UK team.

Management of the Toviaz sales team

The complainant stated that when Toviaz was launched in December 2016, the representatives had a national sales manager and an RBM. A representative based outside the UK and was promoted to the RBM to include UK territories in the first quarter of 2017. Since the complaint, this person had been told not to instruct UK representatives until he/she completed the ABPI examination.

The complainant noted slide number 66 of the Business Review Slides were presented as part of the UK's business review on 13 February 2017. The Toviaz slide in question was presented by the corporate consultant; if he/she was not acting as a sales director, what was the intention presenting the slide which indicated which representatives should have their probationary period extended, those that were 'OK Now' and those that should be terminated.

The complainant wanted to understand if the above actions were those of a global consultant that only provided 'consultancy support'. The complainant alleged that he/she had indicated that the consultant was functioning as sales director and had direct involvement with the Toviaz sales team, although the official title might not have reflected that.

Slides and workings of the June cycle meeting – framework and cycle meetings slides

'… [ ] was invited to present at the cycle meeting to share information about marketing Toviaz in EU markets ….'

'… slides prepared by […] to review sales progress in April 2017, and to review sales progress in April 2017, and to discuss marketing in urology, but not

to provide instructions to representatives for the purpose of the Code ….'

The complainant noted Pierre Fabre's statement that the corporate consultant was invited to the meeting. However, to suggest that the individual was invited as a guest was disingenuous at best given that he/she ran the June cycle meeting; he/she oversaw the meeting and had full control. This was also similar to the April cycle meeting in 2017. A significant part of the presentation focused on the calibrage activity presented by the corporate consultant. However, the complainant noted that there were only 2 slides on Calibrage' ('calibration') provided in the enclosure; this was not accurate – there had been at least a dozen. This was a market research activity run by the corporate consultant and a colleague, and the results were shared at the cycle meeting. The complainant was tasked to seek feedback from health professionals about the efficacy of Toviaz and adverse event profiling vs competitors. The representatives were also instructed to use market research results to better focus promotional calls for Toviaz. This summary slide was riddled with typographical errors and poor grammar, eg instead of BBB (blood brain barrier), BBC, and there was reference to sex, etc. The complainant was concerned that the full slide deck was not presented to the PMCPA; probably to downplay the corporate consultant's involvement in the affiliate.

The complainant stated that the representatives had been placed on paid leave and wanted to resume their duties. Although the complainant appreciated the steps taken by Pierre Fabre (replacing the staff), he/she was concerned that there were still inaccuracies around the corporate consultant's role in the UK. The complainant was also surprised by the lack of oversight Pfizer had over the running of Toviaz by Pierre Fabre. Having reviewed the material and evidence provided by both Pfizer and Pierre Fabre, the complainant alleged that there seemed to be a concerted effort by both companies to hide and misrepresent certain facts.

RESPONSE FROM PIERRE FABRE

Pierre Fabre UK, and its European Management and Global Management, apologised unreservedly that Pierre Fabre UK had not yet been able to identify all past breaches of its Code of Ethics and of the Code previously noted. Pierre Fabre also apologised that it had not provided all of the slides that were presented at the June cycle meeting for Toviaz representatives, and thereby misled the Authority on facts that were not the focus of the complaint. The reasons for this partial omission were explained below. Such an omission was unacceptable. Pierre Fabre had also apologised to Pfizer for this omission.

From the outset Pierre Fabre UK had been transparent of its plans to conduct investigations after the complaint was received. Pierre Fabre UK would continue to report to the Authority the breaches of the Code that it identified. The company had also started a process of culture change in the UK and had focused on the recruitment of new senior management in order to achieve change; in parallel it would conduct investigations and self-report as promptly as possible thereafter.

Within two months, Pierre Fabre had made senior interim and permanent appointments and had started to select new leadership. The company had also implemented revised processes and ongoing training programmes to clearly reflect the high standards the Pierre Fabre Group set itself and its teams.

<u>Agreement with Pfizer regarding the promotion of Toviaz and steps taken in September 2017</u>

Pierre Fabre submitted that it had also continued to consult closely with Pfizer.

For both Pfizer and Pierre Fabre, promotion of Toviaz in the UK would not recommence until Pfizer, Pierre Fabre UK, Pierre Fabre Europe & Global, and the interim UK & Ireland compliance officer were satisfied that the compliance culture – which Pierre Fabre Group expected – was fully re-established in the UK. Pierre Fabre submitted that both it and Pfizer had acted responsibly and decisively and with the necessary level of oversight. Both companies would continue to independently monitor progress of the remediation plans implemented in Pierre Fabre.

<u>New management team of Pierre Fabre UK and steps taken since September 2017</u>

Pierre Fabre submitted that it was at the start of a series of steps to re-create and maintain a culture that complied with its code of ethics and with the Code. This would include a new structure, remediation plans, training and other steps. The new structure together with a review of processes, further training and associated culture changes, would help to prevent such breaches in the future.

Pierre Fabre highlighted that senior leadership (interim and permanent) roles had been replaced and that new compliance and senior marketing roles had been created and filled (organogram provided).

Pierre Fabre provided a summary of the ongoing remediation plan. Full cooperation and support for this remediation plan was available from all Pierre Fabre management.

Pierre Fabre submitted that after suspending all promotional activities for Toviaz in the UK, Pierre Fabre UK and Europe had implemented the following since September 2017:

- an interim medical director compliance officer and head of marketing for the UK and Ireland (November 2017)
- the roles of UK & Ireland General Manager and permanent UK head of marketing, medical director and compliance officer would be filled as soon as possible
- a Code refresher for all staff (head-office and field-based) (October 2017)
- more detailed Code training for all staff (head-office and field-based) (November 2017)
- an ABPI Code Day with UK teams (November

2017) (slides provided). Training with relevant European colleagues (December 2017)
- additional internal guidance on working with Pfizer in the UK provided
- remediation plan to include review of current SOPs and new SOPs prepared
- appointment of Code champions (November 2017)
- training for a first member of the Pierre Fabre Europe team to sit the ABPI Examination in 2018.

Admissions after new investigations into allegations of the complainant

After concluding investigations into the key allegations of the complainant, Pierre Fabre set out its findings and admissions below:

- Incomplete slides provided to the Authority – breach of Clause 9.1 and Clause 2.

Pierre Fabre submitted that because the June 2017 cycle meeting slides were not saved within Zinc, and because various versions of these slides were created, in August 2017 Pierre Fabre was unable to identify precisely which slides were presented in June and by whom. The person who had prepared the slides was not available in August for questioning and those who were had different recollections of the slides that were presented.

The senior member of staff decided in August to submit the slides that he/she recalled seeing during the June cycle meeting and to investigate the complainant's allegations. This investigation was planned to enable future self-reporting. The slides the senior member of staff remembered seeing at the June cycle meeting and that were submitted to the Authority included introductory slides about 'calibrage'. Investigations were commenced in September and October 2017 to respond to specific questions from the Authority and to conduct two internal audits. The arrival of the interim UK & Ireland compliance officer provided expert resource to start new investigations. One line of enquiry was into the June cycle meeting. The complainant's statement in his/her appeal identified quotations that were matched to a set of slides which had since been found. Pierre Fabre provided a copy of slides, that appeared to be the set that was presented to the complainant at the June cycle meeting. The slides that were not disclosed in August (slides 35 to 42) raised issues that were not the focus of the complaint. Pierre Fabre set out below the breaches of the Code that it had identified in these slides.

In Pierre Fabre's view the omission of some of the slides was in breach of the spirit of the Code and Clauses 9.1 and 2 and also Pierre Fabre's Code of Ethics. Pierre Fabre noted that it had already accepted breaches of Clauses 15.9, 14.1 and 9.1 of the Code regarding the June `cycle meeting slides.

- Promotion during calibration activities – 24 May to 8 June 2017 – breach of Clauses 15.9, 14.1 and 9.1.

After a review of slides 35 to 42, Pierre Fabre admitted a breach of Clauses 15.9, 14.1 and 9.1, for the promotion of Toviaz in the form of 'Calibrage' (calibration) promotion activities to UK health professionals. Pierre Fabre submitted that 'Calibrage' ('calibration') referred to a 'snapshot' taken by Pierre Fabre sales force effectiveness teams during an internal benchmarking of promotional activity by Toviaz representatives. The purpose was to ensure consistency of message and to identify training needs. Calibration was conducted as follows: representatives conducted usual detailing to customers in accordance with a certified briefing document for the ipad sales aid (including the claim about the four pharmacological properties of Toviaz - UK/TOV/0916/0012b) and a certified document for promotional content in the sales aid - UK/TOV/0916/0012. When a representative considered it appropriate and with the customer's agreement the representative asked: 'What is your opinion about the 4 pharmacological properties of Toviaz that are responsible for 97% of patients being satisfied after 2 years?'. Representatives continued to routinely report the facts of their call with customers as part of their usual daily call reports (date, time, other factual information).

During a calibration, representatives would also be asked to capture qualitative feedback from customers on the key messages for a product. Representatives were free to input as few or as many of the responses of customers as they chose into their calibration reports. Only the feedback selected by representatives, at their discretion, was then logged by them into a database that was distinct from their usual call reporting database. The feedback inserted in the database included only the specialty of customers, and an optional identifier of no more than two characters. Pierre Fabre noted that representatives had been briefed on pharmacovigilance reporting in November 2016. The calibration database was only open for input of feedback by representatives for a finite period. The content of these responses had been re-reviewed by pharmacovigilance personnel in the UK. This data had been archived and would not be reviewed further. It would be destroyed in due course.

Pierre Fabre submitted that documents that recorded the data were entered into the database. The purpose of this promotional activity was to benchmark the effectiveness of a claim with qualitative information obtained in a usual promotional context, not to conduct market research. It was clear to customers that the purpose of a call and a question was promotional. It complemented training and role play that were used to give confidence to representatives in their messaging skills (bearing in mind representatives had only started to promote in December 2016).

The breaches Pierre Fabre had identified with regard to this promotional activity were failures to:

- provide written briefing to representatives (Clause 15.9)
- certify the question to be raised by representatives (Clause 14.1)
- maintain high standards (Clause 9.1).

Pierre Fabre apologised that these breaches occurred. The breaches were analyzed as soon as possible in the circumstances.

Allegations of the complainant in his/her appeal

With regard to specific matters raised by the complainant, Pierre Fabre UK response was as follows:

(a) June cycle meeting slides - omission of slides
Pierre Fabre UK admitted breaches of Clauses 9.1 and 2, as set out above.

(b) and (c) role of sales force effectiveness and call targets

Previous acknowledgements and admissions

Pierre Fabre admitted in August 2017 that an individual from an overseas affiliate had provided sales force effectiveness advice, services and opinions as a corporate consultant to support the business. This led to some representatives being confused as to how this role interfaced with that of the sales director. This confusion increased when the sales director resigned. It had acknowledged that communication with representatives regarding the role of the consultant should have been clearer and that emails and other directions to the representatives should not have occurred.

Pierre Fabre considered that effectiveness of promotion should be followed and tested. At that time Pierre Fabre did not employ resource with such strategic expertise and so such sales force effectiveness services were provided by the corporate consultant. The role of a sales director was operational and did not usually include responsibility for monitoring effectiveness of promotion.

Comments on new documents provided by the complainant

Emails of 14 December 2016 and 27 April 2017

Pierre Fabre provided emails to show that the national sales manager contacted representatives directly to review the end of their probation periods; issued instructions as a sales director would usually write, included his/her own slides in presentations and issued operational instructions to representatives.

European Association of Urology Congress in London on 24-28 March 2017

Pierre Fabre prepared a briefing document (provided) for all participants from the UK, other countries and other divisions of the Pierre Fabre Group, to explain how the Code would apply to customer-facing personnel and other Pierre Fabre resource at international congress. As information about the Pierre Fabre Group was available at the congress the corporate consultant attended as a member of Pierre Fabre corporate, along with other corporate colleagues. However, the corporate consultant might have had contacts with customers who attended the congress. He/she was not considered a promotional resource from his/her attendance records.

Pierre Fabre UK comments on new documents

Pierre Fabre submitted that the slides of a business review of February 2017 (conducted as a telephone conference) might not be the final version and were never used to brief representatives. These slides were not certified as they were for an internal business review.

Calibration activities

Pierre Fabre submitted that these activities were not the subject of the original complaint, but it had admitted the breaches in the above.

Pierre Fabre's commitments and apologies

Promotion of Toviaz in the UK would not recommence until Pfizer and Pierre Fabre were satisfied that the culture of Pierre Fabre and its processes would both secure compliance with the spirit and detail of the Code and of the Pierre Fabre Code of Ethics.

In addition to managing complex remediation plans and audits, Pierre Fabre had continued to admit breaches of the Code that fell within and outside the scope of the complaint, and would continue to further investigate and report breaches that might be identified. The April 2017 cycle meeting documents already fell within the scope of ongoing investigations and would be the subject of self-reporting.

The senior management of Pierre Fabre UK and Pierre Fabre Europe, restated their unreserved apologies that the high standards Pierre Fabre set itself had not been met.

FINAL COMMENTS FROM THE COMPLAINANT

The complainant acknowledged the steps taken by the current Pierre Fabre management and was pleased that the April cycle meeting would be the subject of self-reporting. The complainant also acknowledged the further additional breaches of the Code admitted by Pierre Fabre. However, the complainant submitted that the actions highlighted in the company's latest correspondence would not have been carried out if he/she had not complained.

The complainant was not convinced by the rationale as to why the complete June 2017 cycle meeting slides were not provided to the PMCPA. If there was doubt on the slides presented, why was confirmation not sought by checking with the other managers present during the meeting? Surely not all present would have been unable to recall a significant section of the presentation. Or if the sales team had been approached it would have confirmed the correct version of the slide deck.

The complainant found it difficult to accept that no other personnel either affiliate or global level (Pierre

Fabre and Pfizer) were involved or were unaware of what was happening.

The complainant alleged that Pierre Fabre was disingenuous to state that the business review slides of February 2017 might not have been the final version. What was the final version? The complainant had shared the slides (and emails) to provide evidence that the corporate consultant was more than just a global consultant and had acted as a sales director. Who else could decide if members of the sales team passed or failed their probation?

APPEAL BOARD RULING

The Appeal Board noted that the complainant had made a very broad complaint and although he/she had appealed a number of no breach rulings the appeal did not focus on these or provide the specific reasons for appealing each clause. Instead, the appeal addressed what were alleged to be factual inaccuracies in Pierre Fabre's response to the complaint. In addition, the Appeal Board noted that Pierre Fabre had made a number of admissions as part of its response to the appeal. These were only considered insofar as they came within the scope of the original complaint.

The Appeal Board did not consider that it had any evidence before it to show that the corporate consultant's role was covered by the definition of a representative under Clause 1.7 as he/she did not call on health professionals in relation to the promotion of medicines, thus there was no requirement to take and pass an appropriate examination. The Appeal Board therefore upheld the Panel's ruling of no breach of Clause 16.3. The appeal on this point was unsuccessful.

The Appeal Board noted that the Panel had ruled no breach of Clause 14.1 as the speaker meeting arrangements did not require certification but had been checked. The meeting's material and the speaker contracts had been certified. The Appeal Board did not consider that Pierre Fabre had failed to maintain high standards in this regard and it upheld the Panel's ruling of no breach of Clause 9.1. The appeal on this point was unsuccessful.

The Appeal Board noted the allegation that representatives had been instructed to see clinicians more than the average three times per year and it further noted the Panel's ruling and concerns above on this point. The Appeal Board also noted that whilst there were 597 health professionals who had been contacted more than three times, the company's procedures did not determine whether these were unsolicited or solicited and the complainant had not provided any further evidence on the point. The Appeal Board considered that as there was no new evidence before it to show that there had been overcalling it upheld the Panel's ruling of no breach of Clause 15.4. The appeal on this point was unsuccessful. The Appeal Board also upheld the Panel's ruling of no breach of Clause 15.9. The appeal on these points was unsuccessful.

The Appeal Board noted that although slides 35 to 42 that featured the promotion of Toviaz in the form of 'Calibrage' (calibration) for the June cycle meeting were not seen by the Panel they were part of the evidence that the complainant had seen and complained about. The Appeal Board considered that due to the broad nature of the complaint these slides fell within the scope of the original complaint and could be considered. In that regard, the Appeal Board noted that the version of slides provided by Pierre Fabre in response to the complaint included two slides that referred to 'Calibrage' ('calibration'). The Appeal Board noted that according to Pierre Fabre 'Calibrage' ('calibration') referred to a 'snapshot' taken by its sales force effectiveness teams benchmarking a promotional claim used by Toviaz representatives. The Appeal Board noted that 'Calibrage' ('calibration') required representatives during a promotional call to ask health professionals 'What is your opinion about the 4 pharmacological properties of Toviaz that are responsible for 97% of patients being satisfied after 2 years?' when they considered it was appropriate, and if the customer agreed. Pierre Fabre submitted that in relation to 'Calibrage' ('calibration') it had failed to provide a written briefing to representatives or certify the question. The Panel had ruled that the presentation had not been certified and was thus in breach of Clauses 14.1, 15.9 and 9.1 of the Code. The Appeal Board considered that this ruling applied to the seven newly submitted slides as admitted by Pierre Fabre.

The Appeal Board noted its comments and the rulings of breaches of the Code by the Panel. Taking all the circumstances into account, the Appeal Board considered that Pierre Fabre had brought discredit upon, and reduced confidence in, the pharmaceutical industry and ruled a breach of Clause 2. The appeal on this point was successful.

The Appeal Board noted that the slides for the June cycle meeting provided by Pierre Fabre in response to the complaint were incomplete. Pierre Fabre was only able to provide the correct version of the slides which contained seven additional slides after being advised of the omission by the complainant in his/her appeal. In the Appeal Board's view, this omission was a serious matter. Noting the comments from the complainant, it queried the robustness of the company's original investigation and response on this point. The Appeal Board noted Pierre Fabre's submission that the responsible individual had since left the company. However, the Appeal Board noted and welcomed the fact that Pierre Fabre had taken significant and rapid action and had in place a comprehensive and timely action plan to make wholesale changes to address issues highlighted in this case. However, notwithstanding its comments the Appeal Board considered that it was essential that pharmaceutical companies provided complete and accurate information to the Panel and thus it decided that in accordance with Paragraph 11.3 of the Constitution and Procedure that Pierre Fabre should be publicly reprimanded. The Appeal Board noted that this case had raised serious concerns about Pierre Fabre's compliance infrastructure. Senior

management appeared to be taking this matter seriously and were proactive. It noted its comments above about the comprehensive and timely action plan. On balance, given the immediate steps taken, the Appeal Board decided not to require an audit on the information currently before it. It noted the company's comments about future voluntary admissions.

Complaint received **31 July 2017**

Case completed **5 January 2018**
