Case AUTH/2714/5/14

CONSULTANT RHEUMATOLOGIST v PFIZER

Conduct of a representative

A consultant rheumatologist, complained about the conduct of a Pfizer medical representative and that of his/her manager.

The complainant explained that he/she had agreed to a 'ten minute catch up' with the representative and on the day the line manager accompanied the representative. The representative started by enquiring about the complainant's health as the previous year the complainant had been unwell. The complainant submitted that he/she found this extremely uncomfortable and inappropriate as he/she did not really know the representative and believed they had only met briefly once before. The complainant considered that his/her health problems were a private issue and did not appreciate the representative discussing them, particularly in front of his/her line manager who the complainant had not spoken to before. In the complainant's view this was clearly a misguided attempt to appear 'pally'.

The complainant submitted that the representative then discussed Enbrel (etanercept) in psoriatic arthritis and ankylosing spondylitis. The complainant explained that he/she did not currently prescribe biologics for these conditions because of work done with regional specialists. The representative then asked what the complainant would use first line in these conditions; the complainant would normally use a monoclonal antibody, not Enbrel. The representative asked why, and the complainant replied because there was better data available for it with regard to extra-articular manifestations. The representative then asked the complainant why and what information that was based upon. The complainant reminded the representative that he/she did not have to justify prescribing decisions to him/her; this might be discussed with peers but not the representative. At this point the representative 'backed off' the questioning but shortly afterwards pressed the complainant again about prescribing habits and why he/she would prescribe a monoclonal antibody first. The complainant told the representative to stop pressing him/her about this and reiterated this was not his/her role. The complainant considered that the representative was trying to put on a show for his/her manager who had not said anything to the representative although it was clear that the complainant had got quite angry on two occasions.

Despite this, the representative asked why the complainant would use a monoclonal antibody as they had a longer half-life and then asked if the complainant knew that he/she had had a patient in the intensive therapy unit (ITU) over Christmas who had taken golimumab (Simponi co-marketed by Merck Sharp & Dohme and Janssen). The complainant explained that firstly, this was none of the representative's business; as the representative was not a clinician he/she should not discuss individual patients with anyone. It was completely inappropriate for the representative to try and discuss this with the complainant as the representative would not know the full story and whether golimumab was involved. The complainant stated that he/she would not expect any of the representatives from Merck Sharp & Dohme or Janssen to discuss any potential complication on Enbrel. At this point the complainant ended the meeting.

The complainant was extremely angry about the meeting and so called the representative's line manager. The complainant expected the manager to state that the representative had overstepped the mark, behaved inappropriately and apologise. If he/she had done that then the complainant would probably have accepted the apology. However the manager's reply was that when the representative realised that maybe he/she had gone too far' he/she 'backed off'. The complainant explained to the manager that this was not so; although the representative backed off initially he/she returned to the same line of questioning. The complainant considered that the manager was defending the representative's actions and certainly did not apologise for them. The manager did apologise if the complainant considered that the representative had gone too far but not that the representative acted inappropriately. That was very different from apologising for the representative's actions.

The complainant previously had good relationships with Pfizer and was therefore quite shocked as he/she had never been spoken to by any representative like that. The complainant had written to Pfizer but considered its response inadequate. The complainant had not had an apology from the representative or his/her manager.

The detailed response from Pfizer is given below.

The Panel invited further comments from the complainant and subsequently further information from Pfizer. Details were given below.

The Panel noted that there were differences in the parties' accounts of what happened 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 that the complainant felt extremely uncomfortable when the representative enquired about his/her health problem as it was a private issue and the complainant could not recall ever

meeting the representative before or mentioning any illness to him/her. The Panel noted Pfizer's submission that the complainant had previously mentioned his/her illness to the representative and therefore he/she considered it appropriate and courteous to ask about it before talking about Enbrel and in the representative and his/her manager's view the complainant engaged in the discussion and did not appear to be uncomfortable. The Panel did not know what had been said by each party regarding the complainant's health issue. The Panel considered that whilst a general enquiry from a representative about a personal health issue might be appropriate and courteous, for a representative to initiate a detailed conversation about a personal medical matter might not be so and particularly when others were present.

Pfizer submitted that with regard to the patient on ITU, the representative stated that the case was previously disclosed by the complainant when they met in April 2013 and at no point did the representative have any personal information about the patient. The complainant disagreed that he/she had ever discussed any patient with an infection on monoclonal antibody with the representative and had no recollection of the April 2013 meeting. The Panel noted that the interaction between the repesentative and the complainant in April 2013 was, according to Pfizer's call records, at a group meeting that both had attended rather than a one to one call.

The Panel noted Pfizer's submission that whilst the representative recognized that on two occasions the complainant was irritated by his/her approach, he/she quickly broadened the discussion or changed the subject in an attempt to de-escalate the situation. The complainant, however, submitted that in his/her view there was no indication that the representative recognised that he/she was irritated during the consultation and queried why he/she felt the need to return to the discussion about extra-articular manifestations of psoriatic disease if he/she was aware of the complainant becoming irritated on the first occasion.

The Panel noted the complainant's allegation that the representative had questioned his clinical judgment. The Panel noted Pfizer's submission that in the course of a meeting between a company representative and a health professional it would not be unusual to discuss a clinician's prescribing strategy or appropriately challenge a clinician's prescribing strategy with fair and balanced information to suggest reasonable alternative prescribing decisions.

The Panel noted that the complainant stated that he/she had not discussed any patient with an infection on a monoclonal antibody. The only one patient he/she had ever had on golimumab remained well and the complainant stated that he/she had had no one admitted to ITU on any biological therapy since he/she had started working at the hospital. The Panel noted that according to Pfizer the complainant and representative had attended a meeting in April where the discussion about the patient in ITU took place. Pfizer had not commented further on the complainant's statements in this regard. The Panel considered that the health professional would know what had happened to his/her patients.

The Panel noted that it was unfortunate that the complainant was upset by the interaction, nonetheless, it considered that there was no evidence before it to indicate on the balance of probabilities that the two elements of the discussion referred to by the representative were such as to disparage the complainant. It was impossible to determine where the truth lay. The Panel thus ruled no breach of the Code. This ruling was appealed by the complainant.

The Panel noted the differences between the accounts which involved one person's word against another. It also noted the cumulative effect of the matters raised by the complainant. The Panel considered however that there was not sufficient evidence to show that on the balance of probabilities that either the representative or the company had failed to maintain high standards; no breaches of the Code were ruled including Clause 2. These rulings were appealed by the complainant.

The Appeal Board considered that, upon appeal, the complainant had provided evidence to show that the patient in ITU on golimumab did not in fact exist. The Appeal Board noted from the complainant that this was the focus of the appeal as the complainant disputed, on a point of principle, the representative's submission that he/she had ever discussed any of his/her patients with any medical representative. The complainant could find no records to correlate with Pfizer's CRM entries for meetings with the representative. The complainant could not recall previously meeting the representative or his/her manager before the meeting at issue in January 2014. The complainant acknowledged that he/she might have seen them at some point but could not recall a meeting. Any meeting would have been limited to a greeting. The complainant also stated that the nature of his/her previous illness was known and the representative might have easily found out about it from other staff.

The Appeal Board was extremely concerned that Pfizer had not re-interviewed the representative or the manager in light of the new evidence provided in the appeal. This was despite the fact that the company agreed that the new evidence suggested that the ITU patient did not exist and that the prior meeting might have been misremembered or not happened. The Appeal Board was concerned that Pfizer had not questioned its representative or line manager to establish whether he/she had mistaken the complainant for a different doctor in a different hospital or had, in fact, fabricated the previous interaction. Either way the Appeal Board considered that on the balance of probabilities, it was satisfied that the representative had not discussed a patient in ITU on golimumab with the complainant in April 2013.

The Appeal Board noted that the representative's CRM entry for the meeting in April 2013, at which he/she stated he/she had discussed the patient in ITU with the complainant, did not include any notes about the meeting. Only one of the five CRM

entries had a note. The complainant disputed the representative's submission. The Appeal Board considered that Pfizer should have explored the lack of CRM notes. The Appeal Board was concerned that the meeting at which the representative claimed to have first discussed a patient in ITU on golimumab with the complainant was nine months before the meeting at issue in January 2014 and yet, without any call notes to refer back to, the representative had managed to recall detailed information about that discussion.

The Appeal Board noted that Pfizer recognized that there were significant discrepancies between the complainant's account of the meeting in January and that of the representative and manager.

The Appeal Board noted the complainant's submission that he/she never discussed his patients with medical representatives. The Appeal Board considered that, given the evidence before it, on the balance of probabilities, in April 2013 the representative could not have discussed with the complainant one of his patients who was on golimumab and admitted to ITU as such a patient did not exist within the complainant's hospital either then or since; the reference to such a discussion at the meeting in January 2014 was thus unacceptable. The Appeal Board considered therefore that the representative had failed to maintain a high standard of ethical conduct; a breach of the Code was ruled. The appeal on this point was successful. Noting this ruling and its comments above the Appeal Board also considered that Pfizer failed to maintain high standards and it ruled a breach of the Code. The appeal on this point was successful.

The Appeal Board noted at the appeal that the complainant indicated that the appeal did not relate to the alleged disparagement. The Appeal Board thus upheld the Panel's ruling of no breach of the Code. The appeal on this point was unsuccessful.

The Appeal Board did not consider that the circumstances of this case warranted a ruling of a breach of Clause 2 and it upheld the Panel's ruling in that regard. The appeal on this point was unsuccessful.

A consultant rheumatologist, complained about the conduct of a Pfizer medical representative, and his/her manager.

COMPLAINT

The complainant explained that he/she had agreed to a 'ten minute catch up' with the representative in question. On the day, the representative had turned up with his/her line manager although he/she had not previously indicated that the manager would be there. The representative started by enquiring about a serious health problem that the complainant had had the previous year which required surgery and some time off work. The complainant submitted that this was extremely uncomfortable and inappropriate as he/she did not really know the representative and believed he/she had only met him/her briefly once before. The complainant considered that his/her health problems were a private issue and he/she did not appreciate the representative's discussing them, particularly in front of his/her line manager who the complainant had not spoken to before. The complainant considered that this was clearly a misguided attempt to appear 'pally' with him/her, but he/she did not appreciate it at all.

The complainant submitted that the representative then discussed Enbrel (etanercept) and its use in psoriatic arthritis and ankylosing spondylitis. The complainant explained that he/she did not currently prescribe biologics for these conditions because of work done with regional specialists. The representative then asked what the complainant would use first line in these conditions and the complainant stated that he/she would normally use a monoclonal antibody, not Enbrel. The representative asked why, and the complainant replied that there was better data available for it with regard to extra-articular manifestations. The representative then asked why the complainant considered that and what information that was based upon. The complainant submitted that at this point he/she reminded the representative that he/she did not have to justify his/her prescribing decisions to him/her; he/she might discuss this sort of thing with peers but not him/her. At this point the representative 'backed off' the questioning but shortly afterwards started pressing the complainant again about his/her prescribing habits and why he/she would prescribe a monoclonal antibody first. The complainant told the representative to stop pressing about this and reiterated that it was not his/her role to quiz him/her on this. The complainant strongly considered the representative was trying to put on a show for his/her manager who had not said anything to the representative although it was clear that the complainant had got quite angry on two occasions.

Despite this, the representative asked why the complainant would use a monoclonal antibody as they had a longer half-life. The representative then asked if the complainant knew that he/she had had a patient in the intensive therapy unit (ITU) over Christmas who had taken golimumab (Simponi co-marketed by Merck Sharp & Dohme and Janssen). The complainant explained that firstly, this was frankly none of the representative's business; as the representative was not a clinician he/she should not discuss individual patients with anyone. It was completely inappropriate for the representative to try and discuss this with the complainant as the representative would not know the full story and whether golimumab was involved. The complainant stated that he/she would not expect any of the representatives from Merck Sharp & Dohme or Janssen to discuss any potential complication on Enbrel. At this point the complainant told the representative to stop talking as it was not his/her business and shortly afterwards said goodbye.

The complainant submitted that he/she was left feeling quite upset and extremely angry about the meeting and so called the representative's line manager to ask how he/she considered the representative had behaved. The complainant expected the manager to state that the representative had overstepped the mark, behaved inappropriately and apologise. If he/she had done that then the

complainant stated that he/she probably would have accepted the apology. However the manager's reply was that when 'the represenative realised that maybe he/she had gone too far' he/she 'backed off'. The complainant explained to the manager that he/she did not consider that was so; although the representative backed off initially he/she returned to the same line of questioning. Without saying much the complainant considered that the manager was defending the representative's actions and certainly did not apologise for them. The manager did apologise if the complainant considered that the representative had gone too far but stated that he/she did not consider that the representative acted inappropriately. That was very different from apologising for his/her actions.

The complainant submitted that he/she had previously had very good relationships with the Pfizer team and was therefore quite shocked to have been treated like this; he/she had never in his/her medical career been spoken to by any representative like that. The complainant had written to Pfizer but considered its response (copy provided) inadequate. The complainant had not had an apology from the representative or his/her manager.
When writing to Pfizer, the Authority asked it to consider the requirements of Clauses 2, 8.2, 9.1 and 15.2 of the Code.

RESPONSE

Pfizer acknowledged that the representative in question and his/her manager visited the complainant for a planned call in January 2014. The meeting lasted approximately 20-30 minutes and started with the representative introducing his/her manager and asking the complainant if he/she had any objections to the manager being there. The complainant did not raise any objections to the manager's presence.

The representative first asked how the complainant was as he/she had previously mentioned his/her illness to the representative and therefore he/she considered it appropriate and courteous to start by asking how the complainant was before talking about Enbrel. Pfizer submitted that the complainant engaged in this discussion and spoke about his/her recovery and a subsequent return to work. The complainant commented that he/she had not seen either the representative or the other local representative for several months. In response, the representative stated that they had not wanted to disturb the complainant when he/she had just returned to work. During this opening conversation the complainant stated that he/she had recently taken on a role at a university and that this occupied a fair amount of time. Overall this opening lasted about 5-10 minutes. Pfizer submitted that the complainant appeared to engage in the conversation and did not appear to be uncomfortable.

The next 5-10 minutes of the meeting were spent discussing Enbrel in relation to psoriatic arthritis. The complainant stated that his/her opportunities to prescribe in psoriatic arthritis were limited as it was departmental policy to refer patients who required a biologic in psoriatic arthritis to another consultant. Pfizer stated that the representative asked the complainant, if he/she was able to prescribe biologics in psoriatic arthritis in the future, what he/she would use. The complainant said he/she would not use Enbrel because of the risk of uveitis and that he/she would use a monoclonal antibody, probably adalimumab. This was a common point of discussion within this disease area and would be an appropriate topic for a specialist representative to discuss with a consultant. The representative discussed the incidence of uveitis with the complainant and highlighted that other local experts in the field had suggested that the risk of developing uveitis would not affect their prescribing decisions. The complainant stated that that was up to them and whilst he/she agreed it was a relatively low incidence it was real enough for him/her to prefer to use a monoclonal antibody before Enbrel. The complainant stated that he/she had reviewed all the clinical data and had been involved in a clinical review about it and that was his/her conclusion. During this part of the call the complainant appeared to speak with a raised voice. The representative asked if the complainant would like a colleague from the medical department to speak to him/her about Enbrel and uveitis but he/she declined on the basis that he/she had reviewed the literature.

As the representative recognised that the complainant was irritated with the conversation, he/she broadened it to discuss the overall efficacy and safety profile of Enbrel. The representative did return to the topic of uveitis and asked whether the benefits of Enbrel that he/she had described might outweigh the relatively low incidence of uveitis? The complainant stated that he/she did not like the discussion and said in his/her view, the representative had questioned his/her clinical judgment. The representative tried to clarify that he/she was just trying to convey the clinical benefits of Enbrel and understand the complainant's position. The representative absolutely did not question the complainant's clinical judgment in any way.

The representative mentioned a patient case history that the complainant had spoken to him/her about in April 2013. The representative had no personal information about the patient and had not heard about the patient from any source other than the complainant. The complainant had mentioned during the previous call in April that the patient had been on ITU and had received a monoclonal antibody, ie golimumab. The patient had problems with infection and had been complicated to manage, although cause and effect could not be confirmed. In response to this example the complainant noted that this was of course just one patient and not a clinical trial and therefore conclusions should not be drawn from it. The complainant confirmed that he/she used Enbrel in patients with rheumatoid arthritis but would not use it in patients with psoriatic arthritis or ankylosing spondylitis. The representative stated that he/she was sorry if the complainant had been irritated by the discussion and he/she changed the topic completely to discuss medical education.

The final 5-10 minutes of the meeting were spent discussing an educational programme and also an upcoming company-sponsored educational meeting.

The complainant was very complimentary about the educational content of both meetings. Both the representative and his/her manager thought that the meeting concluded amicably.

Pfizer submitted that discussion of a personal medical matter was neither the purpose nor objective of the call. Similarly the company did not endorse nor support the recording of such information by company employees either in customer relationship management databases (CRMs) or informally. The representative's inquiry of how the complainant was following his/her return to work was intended only to be a genuine pleasant exchange before the start of the formal part of the call. The complainant had discussed his illness with the representative before and therefore it was courteous to ask how he/she was. The complainant engaged in this discussion about his/her return to work and actively shared and participated in this conversation (which lasted 5-10 minutes) and did not demonstrate any discomfort in discussing it at the time.

Pfizer provided a print out from the customer relationship management (CRM) database for review. A briefing document clearly described what should and what should not be entered by representatives in the CRM system.

Pfizer stated that no promotional materials were used in this meeting. The complainant requested a clinical paper and this request was forwarded to medical information.

With regard to the patient on ITU, the representative stated that the case was previously disclosed by the complainant when they met in April 2013. During this meeting the complainant had mentioned that the patient had experienced problems with infection and had been complicated to manage. At no point did the representative have any personal information about the patient. The representative did not hear about the patient from any source other than the complainant at their previous meeting.

The representative recognized that the complainant became irritated on two occasions. On the first occasion the representative was sensitive to this and broadened the discussion to talk about the overall efficacy and safety profile of Enbrel and then put the relatively low incidence of uveitis in the context of the overall benefits. On the second occasion the representative was again sensitive to this and changed the topic completely to discuss educational meetings.

Pfizer stated that in the course of a meeting between a company representative and a health professional it would not be unusual to discuss a clinician's prescribing strategy. Similarly it would not be unusual to appropriately challenge a clinician's prescribing strategy with fair and balanced information that would suggest alternative prescribing decisions were plausible. In this case, the representative highlighted that the development of uveitis was uncommon and went on to place this in the context of the overall efficacy and safety profile of Enbrel.

The representative's manager did not intervene in the call because the representative broadened the discussion the first time the complainant became irritated and then changed the topic completely on the second time. The representative apologized to the complainant and made it clear that he/she would move the discussion away from Enbrel and talked about Pfizer's educational meeting programmes. The complainant was complimentary about these educational meetings and the representative and his/her manager thought that the call ended amicably.

Pfizer provided a copy of the screen shots from its CRM that documented the call. As the complainant contacted the representative's manager after the call to make a complaint, the representative was asked to write up the call notes for an internal investigation rather than enter them in the CRM as per a routine call. This was why the notes were not in the CRM system. The complaint was escalated in mid January to the representative's manager's manager and then to a senior director. The complainant was contacted by a senior director three day's later.

Pfizer confirmed that both colleagues had passed their ABPI representative exam.

While Pfizer recognized that the meeting between the complainant the representative and his/her manager was a difficult interaction, it did not consider that this case represented a breach of Clauses 8.2, 15.2, 9.1 or Clause 2 of the Code.

Pfizer stated that with respect to Clause 8.2, the complainant's scientific or clinical opinion was never disparaged. The representative clearly recognized that on the two occasions the complainant was irritated by his/her approach, he/she quickly broadened the discussion or changed the subject in an attempt to de-escalate the situation. At no point did the representative claim or state that the complainant was incorrect or that his/her clinical or scientific opinions were unfounded. The representative merely provided an alternative interpretation of the relative importance of uveitis in the clinical decision making process based on the overall efficacy and safety profile of Enbrel and the interpretations of other experts in the field. As such Pfizer denied a breach of Clause 8.2.

With regard to Clause 15.2, although the representative referred to a previous conversation about a patient on ITU that had suffered an infection and was complicated to manage while receiving an alternative medication, Pfizer did not believe that this was evidence of a breach of this clause. At no point did the representative have any personal information about the patient. The representative did not hear about the patient from any source other than the complainant at their previous meeting.

With respect to a concern that the representative was over familiar with the complainant in the preliminary part of the call, Pfizer noted that the representative had only referred to the complainant's previous illness in the context of inquiring about his/her well being. The complainant had discussed this previously with the representative and it was

therefore considered appropriate and courteous to ask how he/she was. At no point during this preliminary part of the call did the complainant express a wish to change the subject and he/she actively engaged in the discussion. Pfizer recognized that there was a line between over familiarity and professional courtesy, however, it did not believe that the representative's actions represented a breach of the high standard of ethical conduct in the discharge of his/her duties, and as such it denied a breach of Clause 15.2. Furthermore the representative had met the complainant several times before so Pfizer considered that a certain level of familiarity was acceptable.

With regard to Clauses 9.1 and 2, Pfizer noted that it provided relevant briefings and guidance to its representatives on the appropriate conduct expected of them. Additionally, Pfizer had ensured that its representatives had been briefed on the appropriateness of content to be recorded in its CRM system. Similarly, Pfizer made it a priority to ensure that its representatives were trained appropriately on the materials that they used and it confirmed that both the representative and his/her manager were up-to-date with their training. Pfizer took the complaint very seriously and it launched an internal investigation into the conduct of the representative and his/her manager as soon as it received the complainant's letter. The investigation did not find any evidence of serious misconduct or breaches of the Code. As such Pfizer did not consider that it had failed in its responsibilities to maintain high standards and, as such, had not brought discredit to, or reduced confidence in the pharmaceutical industry.

Pfizer apologized for the anxiety and distress caused to the complainant and that had been expressed to him/her both verbally and in writing by senior Pfizer staff throughout the time from the initial complaint in January through to Pfizer's recent letter to the complainant.

FURTHER COMMENTS FROM THE COMPLAINANT

The complainant submitted that he/she did not ever recall meeting the Pfizer medical representative before and certainly did not recall mentioning any illness to him/her and considered that the statement was inaccurate.

The complainant did not feel that at any stage of the consultation, the representative recognised that he/she was becoming irritated despite the fact that the complainant clearly told the representative that it was not his/her role to question the complainant's clinical judgement. The complainant stated that he/she mentioned all the extra-articular manifestations of seronegative spondyloarthroapthies, not just uveitis and queried why the represenatives manager did not stop the representative at that point and why the representative felt the need to return to the discussion about extra-articular manifestations of psoriatic disease if he/she was aware of the complainant becoming irritated on the first occasion. The complainant felt that his/her clinical judgment was being questioned and that there was no indication from the representative that he/she recognised that the complainant was irritated with him/her during the consultation. The complainant alleged that the representative continued to push the same subject rather than change topics.

The complainant disagreed that he had ever discussed any patient with an infection on monoclonal antibody with the representative and therefore could only assume that she was lying to cover his/her back. The complainant believed that it was a complete fabrication which appeared to question his/her honesty, integrity and professionalism which was of grave concern. The complainant stated that he/she had only ever had one patient on golimumab (for a completely separate indication and they remained well) and had no one admitted to ITU on any biologic therapy since starting work at his/her hospital in September 2012. The complainant could not recall ever meeting the representative but agreed to the meeting as he/she previously knew and had a good working relationship with the representative's sales colleague. The complainant reiterated that he/she had no recollection of meeting the representative in April 2013 and got the impression that he/she was trying to show off to his/her line manager throughout the consultation.

The complainant stated that at no point during or subsequent to the consultation had he/she had an apology from the representative or his/her manager.

The complainant agreed that the representative inroduced his/her manager and he/she did not raise any objections when asked if he/she was happy for the manager to remain in the call. However, the complainant stated that he/she was not forewarned that the representatives manager would be present.

The complainant stated that overall the response from Pfizer had many inaccuracies and after reading it believed that the represenative had lied to try and cover his/her back. The complainant considered that this had taken it past a simple difference in opinion as suggested and his/her honesty, integrity and professionalism had now been brought into question as he/she had never discussed individual patients with any pharmaceutical representative. The complainant considered that the response received from Pfizer was nebulous and did not offer an apology from the representative or their manager. The response stated that Pfizer 'were sorry for the distress' that the complainant had experienced as a result of the consultation but in the complainant's view this was not an apology or an admission that its representatives were in the wrong.

FURTHER COMMENTS FROM PFIZER

In response to a request for further information, Pfizer submitted that there were five entries in its CRM system for interactions between the complainant and its sales representative; the first record dated 3 March 2013 confirmed an appointment was booked with the complainant for a future face to face meeting; the second record dated 18 March 2013 was the record of that meeting, the

objective of which was documented and provided. The third record dated 9 April 2013 detailed a group meeting which both the complainant and representative attended; the fourth record dated 27 September was of a similar nature. The final record was the meeting that took place on 16 January which was the subject of the complaint. In addition, the representative submitted that he/she met and spoke to the complainant in his/her office (shared with a colleague) on 20 November 2013, a screen shot for this meeting was provided.

PANEL RULING

The Panel noted that there were differences in the parties' accounts of what happened during the meeting and other information provided; 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 Pfizer's submission that the meeting in question took place on 16 January 2014. The complaint was received in May 2014. The Panel noted that the complainant agreed that he/she had not raised any objections when the representative introduced his/her line manager and queried if he/she could remain in the call. However, the complainant stated that he/she was not forewarned that the line manager would be present.

The Panel noted that the complainant stated he/she felt extremely uncomfortable when the representative enquired about his/her health problem as it was a private issue and the complainant could not recall ever meeting the representative before or mentioning any illness to him/her. The Panel noted Pfizer's submission that the complainant had previously mentioned his/her illness to the representative and therefore he/she considered it appropriate and courteous to ask about it before talking about Enbrel and in the representative and his/her manager's view the complainant engaged in the discussion and did not appear to be uncomfortable. The Panel did not know what had been said by each party regarding the complainant's health issue. The Panel considered that whilst a general enquiry from a representative about a personal health issue might be appropriate and courteous, for a representative to initiate a detailed conversation about a personal medical matter might not be so and particularly when others were present.

Pfizer submitted that with regard to the patient on ITU, the representative stated that the case was previously disclosed by the complainant when they met in April 2013 and at no point did the representative have any personal information about the patient. The complainant disagreed that he/she had ever discussed any patient with an infection on monoclonal antibody with the representative and had no recollection of the April 2013 meeting. The Panel noted that the interaction between the repesentative and the complainant in April 2013 was, according to Pfizer's call records, at a group meeting that both had attended rather than a one to one call.

The Panel noted Pfizer's submission that whilst the representative recognized that on two occasions the complainant was irritated by his/her approach, he/she quickly broadened the discussion or changed the subject in an attempt to de-escalate the situation. The complainant, however, submitted that in his/her view there was no indication that the representative recognised that he/she was irritated during the consultation and queried why the representative felt the need to return to the discussion about extra-articular manifestations of psoriatic disease if he/she was aware of the complainant becoming irritated on the first occasion.

The Panel noted the complainant's allegation that the representative had questioned his/her clinical judgment. The Panel noted that Clause 8.2 required that health professions and the clinical and scientific opinions of health professionals must not be disparaged. The Panel noted Pfizer's submission that in the course of a meeting between a company representative and a health professional it would not be unusual to discuss a clinician's prescribing strategy or appropriately challenge a clinician's prescribing strategy with fair and balanced information to suggest reasonable alternative prescribing decisions.

The Panel noted that the complainant stated that he/she had not discussed any patient with an infection on a monoclonal antibody. The only one patient the complainant had ever had on golimumab remained well and the complainant stated that he/she had had no one admitted to ITU on any biological therapy since he/she had started working at the hospital. The Panel noted that according to Pfizer the complainant and representative had attended a meeting in April where the discussion about the patient in ITU took place. Pfizer had not commented further on the complainant's statements in this regard. The Panel considered that the health professional would know what had happened to his/her patients.

Companies and representatives had to maintain high standards. The Panel noted that it was unfortunate that the complainant was upset by the interaction, nonetheless, it considered that there was no evidence before it to indicate on the balance of probabilities that the two elements of the discussion referred to by the representative were such as to disparage the complainant. It was impossible to determine where the truth lay. The Panel thus ruled no breach of Clause 8.2. This ruling was appealed by the complainant.

The Panel noted the differences between the accounts which involved one person's word against another. It also noted the cumulative effect of the matters raised by the complainant. The Panel considered however that there was not sufficient evidence to show that on the balance of probabilities that either the representative or the company had failed to maintain high standards; no breach of Clauses 9.1 and 15.2 were ruled. The Panel noted its rulings above and consequently ruled no breach of Clause 2. These rulings were appealed by the complainant.

APPEAL FROM THE COMPLAINANT

The complainant stated that whilst he/she still had multiple concerns about the consultation (previously detailed) and appreciated the Panel's ruling that there were '…differences between the accounts which involved one person's word against another', the main issue was the Pfizer sales representative's suggestion that the complainant had previously discussed a patient with the representative who was on a competitor's medicine. The complainant considered that this suggestion questioned his/her professionalism, honesty and integrity.

The complainant alleged that the representative initially stated that he/she had mentioned 'during a previous call in April' that he/she had had a patient who was talking golimumab who had ended up on ITU with 'problems with infection'. The representative also stated that 'he/she was sorry' if the complainant had been irritated by the discussion. The complainant noted that he/she had never received an apology from the representative or his/her manager. From the Panel's ruling, the complainant noted that the representative stated that the initial discussion actually took place at a group meeting rather than at a one-to-one call.

The complainant stated that he/she had only had one patient on golimumab whilst working at his/her hospital (the complainant provided an anonymised list of patients on golimumab registered to his/her hospital) and that patient was on golimumab for a different indication and was started on it in January 2014. The department had only had 12 patients on golimumab and, after reviewing their notes, none appeared to have been admitted to ITU. None of the complainant's colleagues could recall this 'admission'.

Furthermore, since starting at the hospital the complainant had had 2 patients admitted to ITU; one in February 2014 with a completely different illness and not on golimumab and one in March 2013, again with a completely different illness and not on golimumab (the complainant provided details of patients treated and admissions to ITU). The complainant had no idea why the representative came up with his/her suggestion that the complainant had discussed such a patient with him/her and could only conclude that he/she had fabricated the story.

The complainant agreed with the Panel's statement that 'The complainant bore the burden of proof on the balance of probabilities' and that 'extreme dissatisfaction was usually required before an individual was moved to complain' and that the complainant '… would know what had happened to his/her patients'. The complainant hoped that the extra evidence that he/she had provided would help resolve this case satisfactorily. The complainant submitted that the time and stress taken to follow up this complaint demonstrated how upset he/she was with the situation.

The complainant stated that he/she had had hundreds of interactions with representatives in his/her career and had never previously felt the need to complain. The complainant noted the Panel's observation that '… the meeting in question took place on 16 January 2014.' and that 'The complaint was received in May 2014'. This delay was purely because the complainant approached Pfizer first (the complainant contacted the representatives manager on the day of the meeting and then formally complained on 17 January) and he/she was awaiting its response. The complainant alleged that Pfizer's response (letter dated 2 May from a senior Pfizer director, copy provided) was inaccurate as there was no admission that the representatives were in the wrong and no apology (other than sorry for any distress caused). The complainant also provided correspondence that he/she had had with Pfizer previously (letter dated 21 February from the investigating manager at Pfizer).

The complainant alleged that he/she had never and would never discuss an individual patient or his/her case with any representative in any situation whatsoever, particularly at a group meeting, and the representative's suggestion that he/she had, reflected very poorly on the complainant and therefore he/she had taken the matter further. The complainant submitted that if he/she had received an adequate apology from the representative and/or his/her manager at any point, with an acknowledgement that they were in the wrong, then this case would not have been escalated.

COMMENTS FROM PFIZER

Pfizer noted the complainant's reasons for appeal and that there was little mention of some of the topics of the original complaint. As such Pfizer restated its response to the initial complaint. Pfizer also recognized that additional evidence had been submitted and it would also address a number of the comments raised by this correspondence.

Summary of Response To The Original Complaint

Pfizer stated that in its view, although the meeting between the complainant and its representative and his/her manager was a difficult interaction, this case did not represent a breach of Clauses 2, 8.2, 9.1 and 15.2.

Pfizer submitted that with respect to Clause 8.2, at no time during the call was the complainant's scientific or clinical opinion disparaged. Pfizer stated that its representative clearly recognized that on the two occasions that the complainant became irritated by his/her approach, he/she quickly broadened the discussion or changed the subject in an attempt to de-escalate the situation. The representative did not claim or state that the complainant was incorrect or that the complainant's clinical or scientific opinions were unfounded. Pfizer submitted that the representative merely provided an alternative interpretation of the relative importance of uveitis in the clinical decision making process based on the overall efficacy and safety profile of Enbrel and the interpretations of other experts in the field. As such Pfizer did not believe that the representative's actions or those of his/her manager were in breach of Clauses 8.2 or 15.2.

Pfizer submitted that although the representative referred to a previous conversation about a patient on ITU, it did not believe that this was evidence of a breach of Clause 15.2. The representative never had any personal information about the patient. The representative did not hear about the patient from any source other than the complainant at their previous meeting. Similarly the representative raised the competitor medicine not to disparage it or the complainant's clinical approach, but to highlight where etanercept might be an alternative medicine due to its different pharmaceutical properties eg half-life.

With respect to the concern that the representative was over familiar with the complainant in the preliminary part of the call, Pfizer noted that the representative only referred to his/her previous illness in the context of inquiring about his/her wellbeing. As the complainant had discussed this previously with the representative it was appropriate and courteous to ask how he/she was; the complainant did not express a wish to change the subject and actively engaged in the discussion. Pfizer recognized that there was a line between over familiarity and professional courtesy, however the representative's actions did not represent a breach of the high standard of ethical conduct in the discharge of his/her duties, and as such Pfizer denied a breach of Clause 15.2. Furthermore, as previously described, the representative had met the complainant several times before so a certain level of familiarity was acceptable. Pfizer stated that it took the complainant's complaint very seriously, and immediately following its receipt, it embarked on an internal investigation into the conduct of its representative and their manager. The investigation did not find any evidence of serious misconduct or breaches of the Code.

Pfizer submitted that with regard to Clause 9.1 and 2, it provided relevant briefings and guidance to its representatives on the appropriate conduct it expected of them. Additionally Pfizer had ensured that its representatives were briefed on the appropriateness of content to be recorded in its CRM system as previously described. Similarly Pfizer made it a priority to ensure that its representatives were trained appropriately on the materials that they used and both the representative and their manager were up-to-date with their relevant training. Pfizer did not consider that it had failed in its responsibilities to maintain high standards and as such it had not brought discredit to, or reduced confidence in, the pharmaceutical industry.

Response To The Appeal

Pfizer submitted that the complainant's main issue was that his/her professionalism had been brought into question by the representative's suggestion that together they had previously discussed a patient who was on a competitor's medicine. While Pfizer acknowledged that while the complainant might consider this to be so, it did not believe that this equated to a breach of Clause 8.2, namely that the complainant's clinical and scientific opinions had been disparaged. It was not uncommon for health practitioners to share anonymised, clinical vignettes with representatives to illustrate some of the nuances of clinical decision making. Pfizer did not consider that such educational discussions called a health practitioner's integrity or professionalism into question. For the avoidance of doubt, Pfizer had never had any cause to debate the complainant's professionalism, honesty or integrity.

Pfizer noted the complainant's submission that he/she had never received an apology from the employees at issue following the face-to-face meeting on 16 January 2014. Pfizer noted that its letter of 2 May to the complainant, stated 'We are sorry for the distress that you experienced. It was not our representative and his/her manager's intention to cause any anxiety or distress'. Pfizer's letter also highlighted that as both employees had acted on behalf of the company that this apology should come from the company. Pfizer also noted that it had taken the complainant's complaint seriously. Pfizer had commenced a thorough internal investigation within 28 days of receipt of the complaint. Evidence of this was provided as an attachment to the complainant's appeal (Pfizer letter dated 21 February from its investigating manager). The complainant stated 'I can honestly say that I can't recall any previous interactions with [the representative or his/her manager] in the past'. This statement was in contrast to Pfizer's CRM records previously provided which showed at least three previous meetings between the representative and the complainant before the call on 16 January 2014. Pfizer considered that the anonymised list of patients on golimumab dated 28 July 2014 and the anonymised undated chart of patient admissions provided by the complainant with his/her appeal supported the Panel's observation that 'The Panel considered that the health professional would know what happened to his/her patients'. Pfizer did not consider that this data should impact on the appeal as it merely provided consistency with the Panel's previous stance that the representative had not disparaged the complainant's clinical or scientific opinion and as such was not in breach of Clause 8.2.

Pfizer recognized that there were significant discrepancies between the complainant's account and that of its representatives. However, Pfizer challenged the complainant's assertion that its representative 'fabricated' the story regarding the ITU patient. The representative had repeatedly stated that this clinical case was shared when he/she met the complainant in April 2013 (a meeting documented in Pfizer's CRM). Pfizer took these internal investigations very seriously and noted that an employee who was knowingly not truthful would be in breach of its internal disciplinary procedure. Such a breach would represent gross misconduct and might result in summary dismissal, in line with Pfizer's disciplinary policy. As such Pfizer challenged the assertion that the representative had knowingly fabricated a story and re-told it in the course of an internal investigation while also being aware of the potential severity of the consequences.

Pfizer again formally apologized for the anxiety and distress caused to the complainant by this interaction. Similarly, Pfizer stood by its previous apology made to the complainant, both verbally and

in writing by senior staff throughout the time from the initial complaint in January through to its letter to the complainant in May 2014.

FINAL COMMENTS FROM THE COMPLAINANT

There were no further comments from the complainant.

APPEAL BOARD RULING

The Appeal Board considered that the complainant had provided evidence to show that the patient in ITU on golimumab that he/she was purported by the Pfizer representative to have discussed did not in fact exist. The Appeal Board noted from the complainant that this was the focus of the appeal as the disputed, on a point of principle, the representative's submission that he/she had ever discussed any of his/her patients with any medical representative. The complainant stated at the appeal that he/she could find no records in his/her or his/her secretary's diary to correlate with Pfizer's CRM entries for meetings he/she was stated to have previously had with the representative. The complainant could not recall previously meeting the representative or his/her manager before the meeting at issue in January 2014. The complainant acknowledged that he/she might have seen them at some point but could not recall a meeting. Any meeting would have been limited to a greeting; he/she had not sat down and talked to them. The complainant also stated that the nature of his previous illness was well known amongst his department and thus the representative might have easily found out about it from other staff. The Appeal Board noted that the complainant had stated that he/she had a good working relationship with another Pfizer representative.

Those representing Pfizer at the appeal submitted that the company was satisfied that the representative had had a discussion about the ITU patient in question as that was what he/she had stated consistently in its investigation. The Appeal Board was extremely concerned that those representing Pfizer at the appeal confirmed, in response to questioning, that the company had not re-interviewed the representative or his/her manager in light of the new evidence provided in the appeal (lists of patients on golimumab and admissions to ITU) because its internal investigation had closed in March. This was despite the fact that the company agreed that the new evidence suggested that the ITU patient did not exist and that the prior meeting might have been misremembered or not happened. The Appeal Board was concerned that Pfizer had not questioned its representative or his/her manager to establish whether he/she had mistaken the complainant for a different doctor in a different hospital or had, in fact, fabricated the previous interaction. Either way the Appeal Board considered that on the balance of probabilities, it was satisfied that the representative had not discussed a patient in ITU on golimumab with the complainant in April 2013.

The Appeal Board noted that the representative's CRM entry for the meeting in April 2013, at which he/she stated she had discussed the patient in ITU with the complainant, did not include any notes about the meeting. Indeed, of the five meetings recorded between the representative and the complainant only one CRM entry had a note. The complainant disputed the representative's submission that he/she attended a further meeting between him/her and a colleague with whom he/she shared an office. The Appeal Board considered that Pfizer should have explored the lack of CRM notes. The Appeal Board was concerned that the meeting at which the representative claimed to have first discussed a patient in ITU on golimumab with the complainant was nine months before the meeting at issue in January 2014 and yet, without any call notes to refer back to, the representative had managed to recall detailed information about that discussion.

The Appeal Board noted from the complainant and the notes of the manager that there were no raised voices during the meeting in January; this did not correlate with Pfizer's response in which it stated that the complainant had raised his/her voice. The manager's notes referred to the representative's mention of a patient with infection issues who the complainant had discussed with the representative at a previous call. The Appeal Board noted that Pfizer recognized that there were significant discrepancies between the complainant's account of the meeting in January and that of the representative and manager.

The Appeal Board noted from the complainant that had the representative or his/her manager apologised for the representative's actions he/she probably would not have complained. The Appeal Board noted that both parties agreed that the meeting had not gone well and yet Pfizer had only apologised for distress caused to the complainant and not about the conduct of its representatives which it submitted was acceptable even in light of the new evidence provided in the appeal.

The Appeal Board noted the complainant's submission that he/she never discussed his/her patients with medical representatives. The Appeal Board considered that, given the evidence before it, on the balance of probabilities, in April 2013 the representative could not have discussed with the complainant one of his/her patients who was on golimumab and admitted to ITU as such a patient did not exist within the complainant's hospital either then or since; the reference to such a discussion at the meeting in January 2014 was thus unacceptable. The Appeal Board considered therefore that the representative had failed to maintain a high standard of ethical conduct; a breach of Clause 15.2 was ruled. The appeal on this point was successful. Noting this ruling and its comments above the Appeal Board also considered that Pfizer failed to maintain high standards and it ruled a breach of Clause 9.1. The appeal on this point was successful.

The Appeal Board noted at the appeal that the complainant indicated that the appeal did not relate to the alleged disparagement. The Appeal Board thus upheld the Panel's ruling of no breach of Clause 8.2. The appeal on this point was unsuccessful.

The Appeal Board did not consider that the circumstances of this case warranted a ruling of a breach of Clause 2 and it upheld the Panel's ruling in that regard. The appeal on this point was unsuccessful.

Complaint received **8 May 2014**

Case completed **7 November 2014**
