

**CASE AUTH/3530/7/21**

## **EMPLOYEE v ABBVIE**

### **Concerns about instructions to representatives**

The complainant, a current employee of AbbVie UK, was very concerned about the conduct of the senior management, in encouraging the salesforce to act in conduct which would clearly bring the industry into disrepute. Especially during the Covid-19 pandemic.

The complainant provided screenshots of email correspondence between a representative and a senior manager (the response from the manager which was sent to the entire salesforce) and alleged that these described how the representative circumvented a hospital security system.

In addition, the complainant alleged that representatives had been told to meet in coffee shops, car parks, picnics and to text health professionals to offer ice creams/sandwiches.

The complainant alleged that sales teams across AbbVie were alleged to be currently targeted and incentivised to achieve 5 face to face calls with health professionals per week during a time when hospitals were not seeing many patients face to face.

The complainant subsequently provided further information that since the original complaint the sales team had received sales targets which were dependent on seeing 35 health professionals face to face during Q3. If the sales target was met but 35 health professionals were not seen, no bonus would be paid. Virtual calls no longer counted towards this target. This placed pressure on the sales team to circumvent trust policies still in place to restrict non-essential visitors within the acute setting.

The detailed response from AbbVie is given below.

The Panel noted the representative's email and was concerned at some of the language used in the email. Whilst the representative's reasoning to enter the hospital, when challenged, was to 'follow up a recent educational event with the nurses', it appeared to the Panel that this reasoning might have been inaccurate and only prepared by the representative to gain entry if challenged. The representative's reason for visiting the hospital, according to AbbVie, was the hope of securing an appointment with a health professional. The Panel was further concerned about the representative's reference to 'strategic loitering'. The Panel considered that the representative had failed to maintain a high standard of ethical conduct in this regard and a breach of the Code was ruled.

The Panel noted that the response from the representative's manager referred to the representative 'gaining promotional opportunities...which will help address the performance gap we are working to fix, deliver our ... messaging and win back dynamic opportunities from our competitor'. The manager also stated that 'Naturally we'd never

deliberately go against any local policies but staying within the Code of Practice and AbbVie's Code of Business Conduct we will be able to find ways to reconnect, just as you have done here.' The response ended with 'Thanks again for sharing and keep up the great work'.

With regard to AbbVie's submission that the manager's response email did not refer to the representative's description of the engagement as an example of best practice, nor did it encourage other members of the team to follow suit, the Panel considered that the circulation of the manager's response to his/her team would likely be seen as an endorsement that the representative's actions were acceptable to the company and were to be encouraged. In the Panel's view, it could thus be considered to be briefing material. The Panel did not consider that the manager's reference to AbbVie's Code of Business Conduct was sufficient to discourage representatives to act in a similar manner; it would not be unreasonable for readers of the emails to assume that the actions were within the bounds of the Code and AbbVie's internal Code of Business Conduct. There was no reminder in the correspondence of the requirement in Clause 15.4 of the Code.

The Panel considered that the manager's email to his/her entire team, in response to the representative's email, endorsed a course of action which would likely lead to a breach of the Code. High standards had not been maintained in this regard and the Panel ruled a breach of the Code.

With regard to the allegation that management had told representatives to meet in coffee shops, car parks, picnics and to text health professionals to offer ice creams and sandwiches, there was an implication that representatives were using the provision of hospitality as the reason for the meeting rather than the hospitality being secondary to the main purpose of the meeting and were holding meetings in venues where members of the public might be able to overhear them. The Panel noted that the complainant had provided no evidence in this regard or that ice cream had been offered or provided as hospitality.

The Panel noted that in a Compliance Matters newsletter dated 21 May 2021, sent to staff, guidance was given around meeting venues and appropriate hospitality with the return of face to face engagements. This advice was consistent with information sent to staff in July 2021 and the company's training.

The Panel was concerned that it appeared that AbbVie was encouraging the provision of coffee, meals etc as a business courtesy. There was an impression that hospitality could be provided at every meeting with a health professional and that this was a way of encouraging health professionals to see representatives. In addition to the requirement in the Code that hospitality should be strictly limited to the main purpose of the meeting, the level of subsistence must be appropriate and not out of proportion to the occasion.

Whilst the Panel was concerned about AbbVie's instructions, on balance, it did not consider that the instructions would encourage representatives to breach the requirements in the Code relating to the provision of hospitality. The Panel considered that the complainant had not established that high standards had not been maintained in relation to his/her allegation regarding the offering of hospitality or meeting venues and ruled no breach of the Code.

The Panel noted that it was unknown if local trust policies would have permitted access for all representatives in Q2 and Q3 when the face to face targets and incentive schemes had been set by AbbVie. The Panel, however, noted AbbVie's submission that it remained respectful to individual challenges and local constraints in this regard.

The Panel did not consider that the complainant had established that the targets set by AbbVie encouraged a course of action which would likely lead to a breach of the Code as alleged. The Panel did not consider that high standards had not been maintained in this regard and therefore ruled no breach of the Code.

The Panel did not know the specific arrangements and policies in place at the hospital visited by the representative, as referred to within the email in question. It appeared that access to the rheumatology department required a security pass, and the representative had been let in by a member of staff as they were exiting the building after showing his/her business card as proof of ID; the reasoning given was following up a recent educational event with nurses. Whilst the Panel queried the validity of that reason, it noted that a consultant had queried how the representative had got into the "locked" department and appeared satisfied with the representative's explanation.

Whilst the Panel was concerned with the representative's methods of entering the hospital department, it did not consider that the complainant had shown, on the balance of probabilities, that the representatives had called on the hospital in a way that caused inconvenience or did not observe the wishes of individuals and the arrangements in force at the hospital. The Panel, therefore, based on the complainant's allegation, ruled no breach of the Code.

The Panel did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and was reserved for such use. No breach of Clause 2 was ruled.

AbbVie provided the requisite undertaking and assurance and as the case completed at Panel level the Appeal Board received the case report as set out in Paragraph 13.4 of the Constitution and Procedure.

The Appeal Board was very concerned about circulation of the manager's response email to his/her team which in effect endorsed 'strategic loitering' by sales representatives to contact health professionals.

The Appeal Board was of the view that consideration should be given to the imposition of additional sanctions under Paragraph 11.1 of the Constitution and Procedure.

The detailed response from AbbVie to the possibility of further sanctions being imposed is given below.

The Appeal Board was particularly concerned that none of the recipients of the email raised any concerns about its content within the company nor had the complaint been addressed through any company whistleblowing procedure. It was only after AbbVie was notified of the complaint to the PMCPA that the company took action.

**The Appeal Board noted the submission of the company representatives that the email was sent when the field force was transitioning from virtual to face-to-face meetings and AbbVie's acknowledgement that in retrospect the company should have highlighted the importance of Code compliance to the field force during this time.**

**The Appeal Board welcomed the actions taken by AbbVie. The Appeal Board did not consider that there was evidence to suggest that the emails at issue were symptomatic of wider problems within the company. The Appeal Board noted the apparent contrition and the extent of the remedial action undertaken. The Appeal Board remained concerned that the recipients of the email in question had not spoken up internally. The Appeal Board gave consideration to the use of additional sanctions but decided that none were required.**

## **COMPLAINT**

The complainant stated that he/she was complaining on behalf of a current employee of AbbVie UK, who was very concerned about the conduct of the senior management, in encouraging the salesforce to act in conduct which would clearly bring the industry into disrepute. Especially during the Covid-19 pandemic.

The complainant provided screenshots of an email sent by a representative to a senior manager and the response from the senior manager which was sent to the entire salesforce. The complainant alleged that these emails described how the representative circumvented the hospital security systems.

In addition, the complainant alleged that management had told representatives to meet in coffee shops, car parks, picnics and to text health professionals to offer ice creams/sandwiches.

The complainant stated that the originator of the complaint (current AbbVie employee) would be happy to discuss the matter further if contacted on the email address provided.

The AbbVie employee subsequently confirmed by email that he/she should be treated as the complainant and provided additional information.

The AbbVie employee confirmed that the email was shared as 'best practice' by two named senior managers to their sales teams. On weekly calls, examples of representatives buying ice creams and sandwiches were shared as best practice.

The sales teams across AbbVie were alleged to be currently targeted and incentivised to achieve 5 face to face calls with health professionals per week during a time when hospitals were not seeing many patients face to face.

The AbbVie employee subsequently provided further information that since the original complaint the sales team had received sales targets which were dependent on seeing 35 health professionals face to face during Q3. If the sales target was met but 35 health professionals were not seen, no bonus would be paid. Virtual calls no longer counted towards this target. This placed pressure on the sales team to circumvent trust policies still in place to restrict non-essential visitors within the acute setting.

When writing to AbbVie, the Authority asked it to consider the requirements of Clauses 2, 9.1, 15.2 and 15.4 of the 2019 Code.

## **RESPONSE**

AbbVie stated that it was fully committed to strict adherence to the Code and all applicable laws and regulations. As a member of the ABPI, AbbVie was dedicated to applying high standards at all times across all areas of its business and, similarly to the PMCPA, it took any complaint seriously.

### **1 Preliminary comments**

AbbVie stated that as the Panel would be aware, as of March 2020, significant restrictions had been introduced by the Government on individuals' and businesses' ability to carry out their normal activities, as a result of the Covid-19 global pandemic. While varying in geography and intensity over the last 16 months, nevertheless the Covid-19 restrictions had significantly impacted all industry sectors and social groups. For the pharmaceutical sector in particular, the restrictions had reflected in a significant reduction of in-person interactions between relevant stakeholders, including industry representatives and health professionals (HCPs), as well as in substantial backlogs of patient care.

As of July 2021, England had welcomed the so-called 'Freedom Day', ie the lifting of a significant proportion of Government restrictions starting with July 19, supported by a Government 'roadmap out of lockdown'. AbbVie submitted that, against this backdrop, ABPI members, much like all other companies operating in the UK, had had to make individual decisions about what the 'return to normal' ought to look like, in light of the evolving Government guidance on the matter and in a context that had been novel for everyone. Naturally one of the many aspects of such 'return to normal' had to do with the way company representatives interacted with health professionals. Through different communications to all employees AbbVie had ensured that its operations were always adjusted and in line with Government restrictions to continue ensuring high standards and compliance with all applicable Covid regulations, Code regulations and AbbVie policies. Several general manager (GM) communications issued to the UK affiliate, in October and December 2020 and January and May 2021, discussing AbbVie's approach to the various restrictions, both with respect to head office working and in-field activities, as well as the May 2021 edition of its internal compliance newsletter, discussing face-to-face engagements were provided.

AbbVie stated that it took its role very seriously and was committed to supporting patients, clinicians, and other relevant stakeholders to ensure patients in the UK had reliable and effective access to their therapies. In this context, AbbVie, alongside other businesses, individuals, and Government actors, had been undertaking phased endeavours to support the 'return to normal', aligned with the efforts of the entire UK economy. Therefore, AbbVie did not believe that its approach to gradually re-engage with health professionals, as set out in more detail below, could be regarded as unethical or as a breach of the Code.

### **2 Comments related to Clauses 15.2 and 15.4**

AbbVie noted that Clause 15.2 of the 2019 Code included that 'Representatives must at all times maintain a high standard of ethical conduct in the discharge of their duties and must comply with all relevant requirements of the Code'.

Clause 15.4 stated that 'Representatives must ensure that the frequency, timing and duration of calls on health professionals and other relevant decision makers in hospitals and NHS and other organisations, together with the manner in which they were made, did not cause inconvenience. The wishes of individuals on whom representatives wish to call and the arrangements in force at any particular establishment, must be observed'.

AbbVie provided a copy of the email chain at issue, with some sections redacted for reasons of privacy. The original email was from a member of the commercial field team (a sales representative) to their peers and managers. The response email was from a senior manager to that team.

Within the email, the sales representative described how they visited a hospital department in the hope of securing an appointment with a health professional. Owing to the audience in receipt of this email which were colleagues and managers, the tone was naturally positive and enthusiastic, which should not be unexpected considering in-field sales representatives had been one of the categories of employees that were most affected by the Covid-19 restrictions and were therefore unable to carry out their duties as before the pandemic for a significant period of time. The email did not suggest that, at any time, the sales representative would have concealed their identity or the reason for visiting the hospital. Additionally, given the context of the communication (ie the early days of AbbVie's phased return to normal commercial activity) and the intended audience (ie not only peers, but also managers), AbbVie stated that it could understand why the sales representative could have felt motivated to use language that over-emphasised some aspects of this in-field engagement. Nevertheless, AbbVie did not condone the sales representative's tone and style of communication, which was not aligned to AbbVie's practices, and therefore AbbVie was now addressing this internally with further guidance on responsible communication.

AbbVie stated that the manager's response email did not refer to the sales representative's description of the engagement as an example of best practice, nor did it encourage other members of the team to follow suit. The manager's response also reminded the team that they needed to stay within the bounds of the Code and AbbVie's internal Code of Business Conduct in the execution of their activities, as well as being respectful of local restrictions or policies regarding external visitors that individual trusts / departments might have put in place. The email contained no instructions to the sales team regarding product promotion and therefore was not considered to constitute briefing material for representatives. As such, this email was not required to be certified or otherwise subject to any prior review and/or approval process. This email exchange was merely an example of colleagues on a team sharing personal experiences during a time when they were experiencing potential unease around returning to a way of working they had been deterred from for a significant period. Noting the sales representative's point around the 'degree of normality' of returning to in-field work, the email was meant to convey a message of mutual support and reassurance between team members, rather than any unethical intent as alleged in the complaint.

In any case and in addition to the above, AbbVie clarified that it was not its expectation and no instructions had even been provided in a way that sales representatives would routinely try to access hospitals in the way described in the email at issue. To this end, AbbVie again referred to its enclosures and to the statement made in the line manager's email response with a reminder of the need to respect applicable rules and regulations.

AbbVie understood that the complaint referred to sales representatives being ‘told’ to meet (presumably HCPs) in coffee shops, car parks, picnics, and to offer ice creams / sandwiches. In relation to these aspects, AbbVie would like to briefly mention that:

- Per the Code, it was possible to provide hospitality at face-to-face meetings with health professionals, so long as it was limited to refreshments / subsistence and the hospitality was not the main purpose of the interaction. Pre-pandemic it would not have been unusual for refreshments such as coffee or sandwiches to be provided during a visit.
- AbbVie’s internal meeting policy, trained out annually and to any new hired employee, was clear that ‘hospitality must be moderate, incidental and secondary to the main purpose of the meeting’ and thus should not be a driver for an engagement. In addition to the annual certification on Code of Business Conduct completed in June 2021 for all AbbVie employees, another affiliate wide communication was sent in July 2021 by the compliance function in full alignment with leadership team, to reinforce the message on all those rules and also provided a clear sign that in no way these requirements and expectations were any different in the light of coming out of lockdown and restrictions easing.
- Assuming that it happened that during an interaction with a health professional, ice-cream was offered instead of coffee or any other refreshment – no evidence had been provided by the complainant in that sense – AbbVie expected this to have happened in the context of a legitimate business exchange in line with Code requirements.

AbbVie submitted that health professionals were increasingly interested in having face-to-face meetings with sales representatives (data provided); as a result, AbbVie was taking a respectful view of the health professional’s requests, in line with the Code, regulations and its policies.

The complaint (both the original communication and the additional follow-up) also referred to concerns about the alleged ‘targets’ set by AbbVie in relation to the number of face-to-face engagements that sales representative should aim to have with health professionals. In relation to these aspects, AbbVie stated that:

- Face-to-face interactions with health professionals constituted the norm in terms of AbbVie’s (and the industry’s, in general) promotional activities pre-pandemic. Details were provided regarding stretch targets and the number of face to face visits per week in Q2 2021 and the total number of face to face visits in Q3. AbbVie submitted that these targets were significantly lower than the typical pre pandemic call rates (provided).
- To date AbbVie had not received any complaints or challenges from trusts or individual health professionals, which gave AbbVie confidence that it was taking a responsible and respectful approach, in line with the ethical and compliance requirements set out by the Code and by the AbbVie Code of Business Conduct.
- AbbVie confirmed that it had reviewed, and its incentive scheme complied in full with the requirements of Clause 15.7 of the Code, which required sales representatives be paid a fixed basic salary and that any sales-related bonus did not constitute an undue proportion of their remuneration. AbbVie sales representatives were aware that relief / exemptions were provided by the company in circumstances where failure to achieve a component of the incentive scheme was outside an individual’s control. This implied that

the targets for face-to-face interactions with health professionals could be (and regularly were) adjusted to take into account individual constraints, thereby addressing any potential pressure that might be perceived by sales representatives. At the same time, the incentive scheme was a critical tool to support a gradual return to normal in line with the Code and with updates in Government guidance.

- Additionally, while the average number of health professionals in an area covered by a sales representative might vary, depending on the relevant therapeutic area, the promoted product etc., nevertheless AbbVie was confident that these targets were not capable of encouraging individual representatives to breach the requirements laid out in Clause 15.4 supplementary information in relation to calls exceeding three per year per health professional.

Given the above, AbbVie believed no breach of either Clause 15.2 or Clause 15.4 had occurred.

### **3 Comments related to Clauses 2 and 9**

Clause 2 of the Code stated that ‘Activities or materials associated with promotion must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry.’

Clause 9.1 of the Code stated that ‘High standards must be maintained at all times.’

In addition to the points highlighted in Section 2 above, which AbbVie respectfully asked the Panel to also consider in light of Clauses 2 and 9.1, AbbVie strongly refuted the allegation that AbbVie’s efforts to re-engage with the health professional community were inappropriate at a time when clinicians were not seeing their patients face-to-face.

Based on third party data (provided), the number of in-person face-to-face patient visits to GP surgeries showed the largest reduction in May 2020. The gap had been closing steadily since then; the upward trend was noticeable, and AbbVie expect that clinicians were currently seeing patients face-to-face in a primary care setting at comparable levels to those pre-pandemic. AbbVie submitted that it was not an outlier compared to other companies (details provided).

In this context, AbbVie was confident that its efforts to re-ignite face-to-face engagements between sales representatives and health professionals came at an appropriate time, in line both with clinicians’ expectations and industry endeavours, and reflected AbbVie’s commitment to serve its patients and live up to the critical role that industry had to play in supporting the healthcare community to overcome the impact of the pandemic. Therefore, AbbVie believed that no breach of either Clause 2 or Clause 9.1 had occurred.

AbbVie stated that it took its responsibility for compliance with the Code very seriously as it continuously endeavoured to maintain these high standards in all its activities. AbbVie stated that it remained available to answer any further questions the Panel might have but trusted that its response was sufficient for the Panel to confirm AbbVie was not in breach of the Code.

### **PANEL RULING**

The Panel noted that it was not clear whether the employee had raised his/her concerns with AbbVie. Companies should encourage employees with concerns to raise them directly in the first instance.



The Panel noted the complainant's concern that the conduct of senior management encouraged the salesforce to act in a way which would bring the industry into disrepute. In this regard, the complainant provided screenshots of an email outlining the representative's experience of a visit to a hospital sent to his/her peers and senior manager and the response from the senior manager which the complainant alleged was copied to the entire salesforce.

The Panel noted that Clause 15.9 stated, *inter alia*, that 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. This clause had not been raised by the case preparation manager and the Panel therefore considered this matter in relation Clause 9.1.

The Panel noted that the requirement for briefing material included both the training material used to instruct medical representatives about a medicine and the instructions given to them as to how the product should be promoted.

The Panel noted that the representative's email included, *inter alia*:

- 'The rheumatology department is located within a separate building with multiple entrances, although all have to be accessed using a security pass, (something I was aware of, so had prepared a simple reason as to why I should be let in when challenged) – following up a recent educational event with the nurses" + showed my business card as proof of I.D. – which proved to be sufficient to be let in by a member of staff, as they were exiting the building
- Once in the building, via a combination of strategic loitering & slow walking, I made my way to the nurses office, via a circuitous route past the consultant offices – where I struck lucky & met a consultant just as he was exiting his office
- With my elevator pitch & a number of other matters to discuss, I was able to engage him & his colleague in conversation – something they were happy to do (briefly) + secured a follow up VE call
- Moving onto the nurses office, using the information just gleaned from the consultant, I was able to have a few words with them & again arranged a follow up opportunity. Although they were less enthused to see me – read the signals & don't overstay your welcome
- Feeling very positive about the whole encounter, I thought I would see what security measures existed within the main hospital – there were none, patients were coming & going freely, the café was open & no-one challenged me
- Returning to my car, matters took a negative turn, when I received an email from one of the consultants that I had just seen, asking how I had got into the "locked" department – oh dear I thought, what rules have I broken? I replied, reiterating why I was there, the process of being let through the security door & checked with him that I believed I had done nothing wrong. He replied – "that's ok, thanks for clarifying" – matter resolved.'

The email then went on to list what the representative had learnt from his/her experience namely:

- It's ok to be apprehensive about calling on departments without an appointment
- A degree of normality is returning to our accounts – which only first hand experience will provide
- Plan ahead – why are you there, what do you want to achieve, scenario plan & be flexible
- Not everyone will be pleased to see you, but some will

- Be prepared to be challenged – have plans in place to mitigate
- Don't assume if challenged that it will be a big issue or COVID related
- The conversations had today provided significant information, that I have not been able to gather via other routes & will allow me to course correct my IAM plans
- I was able to positively position Rinvoq & secure follow up opportunities
- Today was challenging, I had to bury my pride, push myself & feel uncomfortable, but ultimately it was a rewarding experience.

The Panel was concerned at some of the language used in the email. Whilst the representative's reasoning to enter the hospital, when challenged, was to 'follow up a recent educational event with the nurses', it was not clear to the Panel whether this was so. It appeared to the Panel that this reasoning might have been inaccurate and only prepared by the representative to gain entry if challenged. The representative's reason for visiting the hospital, according to AbbVie, was the hope of securing an appointment with a health professional. The Panel was further concerned about the representative's reference to 'strategic loitering'.

The Panel noted AbbVie's submission that the representative's tone and style of communication was not aligned to AbbVie's practices and was being addressed. Further, it was not AbbVie expectations that sales representatives would routinely try to access hospitals in the way described in the email. The Panel, noting its comments above, considered that the representative had failed to maintain a high standard of ethical conduct in this regard and a breach of Clause 15.2 was ruled.

The Panel noted that the response from the representative's manager referred to the representative 'gaining promotional opportunities...which will help address the performance gap we are working to fix, deliver our ... messaging and win back dynamic opportunities from our competitor'. The manager also stated that 'Naturally we'd never deliberately go against any local policies but staying within the Code of Practice and AbbVie's Code of Business Conduct we will be able to find ways to reconnect, just as you have done here.'. The response ended with 'Thanks again for sharing and keep up the great work'.

With regard to AbbVie's submission that the manager's response email did not refer to the representative's description of the engagement as an example of best practice, nor did it encourage other members of the team to follow suit, the Panel considered that the circulation of the manager's response to his/her team would likely be seen as an endorsement that the representative's actions were acceptable to the company and were to be encouraged. In the Panel's view, it could thus be considered to be briefing material. The Panel noted that contrary to AbbVie's submission that the manager's response reminded the team that they needed to be respectful of local restrictions or policies regarding external visitors that individual trusts / departments might have put in place, the email actually stated 'Naturally, we'd never deliberately go against any local policies, but staying within the Code of Practice and AbbVie's Code of Business Conduct we will be able to find ways to reconnect, just as you have done here'. The Panel did not consider that the manager's reference to AbbVie's Code of Business Conduct was sufficient to discourage representatives to act in a similar manner; it would not be unreasonable for readers of the emails to assume that the actions were within the bounds of the Code and AbbVie's internal Code of Business Conduct. There was no reminder in the correspondence of the requirement in Clause 15.4 of the Code to observe the arrangements in force at any particular establishment.

The Panel accepted that a company would want to give positive messages to representatives for motivational purposes but such messages should be clear and ensure that in following them representatives were not encouraged to breach the Code.

The Panel noted its comments and ruling above and considered that the manager's email to his/her entire team, in response to the representative's email, endorsed a course of action which would likely lead to a breach of the Code. High standards had not been maintained in this regard and the Panel ruled a breach of Clause 9.1.

With regard to the allegation that management had told representatives to meet in coffee shops, car parks, picnics and to text health professionals to offer ice creams and sandwiches, there was an implication that representatives were using the provision of hospitality as the reason for the meeting rather than the hospitality being secondary to the main purpose of the meeting and were holding meetings in venues where members of the public might be able to overhear them. The Panel noted that the complainant had provided no evidence in this regard or that ice cream had been offered or provided as hospitality.

The Panel noted that in a Compliance Matters newsletter dated 21 May 2021, sent to staff, guidance was given around meeting venues and appropriate hospitality with the return of face to face engagements. The newsletter stated

'If engagements cannot be done within the HCPs hospital or clinics, thought must be given to your surroundings especially if in a public place. Restaurants/cafes or related venues must be moderate and conducive to a business/scientific discussion (e.g excluding theatres, boats, museums etc.). Consider: Can you be overheard by others? Is your device visible to others around you? Be cognisant of the Code requirements regarding promotion to the public, as well as privacy and company confidential information. Meals and Beverages: AbbVie can provide meals and beverages which are moderate, reasonable, and secondary to the main event. Coffee and meals (including on-site and off-site meals and snacks) can be provided as a business courtesy during legitimate business interactions'.

This advice was consistent with information sent as an attachment to staff on 12 July 2021 and the company's training.

The Panel was concerned that it appeared that AbbVie was encouraging the provision of coffee, meals etc as a business courtesy. There was an impression that hospitality could be provided at every meeting with a health professional and that this was a way of encouraging health professionals to see representatives. In addition to the requirement in the Code that hospitality should be strictly limited to the main purpose of the meeting, the level of subsistence must be appropriate and not out of proportion to the occasion.

Whilst the Panel was concerned about AbbVie's instructions, on balance, it did not consider that the instructions would encourage representatives to breach the requirements in the Code relating to the provision of hospitality. The Panel considered that the complainant had not established that high standards had not been maintained in relation to his/her allegation regarding the offering of hospitality or meeting venues. The Panel ruled no breach of Clause 9.1.

The Panel noted the complainant's further concern that the targets set by AbbVie placed pressure on the sales team to circumvent trust policies still in place to restrict non-essential visitors within the acute setting. In the absence of Clause 15.9 being raised by the case preparation manager, the Panel considered this matter under Clause 9.1.

With regard to the targets set by AbbVie, it was not necessarily a breach of the Code to set metrics for the number of visits representatives should make. Nor was it necessarily a breach of the Code for these to be deemed to be face to face rather than virtual visits. The Panel noted that trust policies were likely to vary.

The Panel considered that it was beholden on companies to make sure that such contact rates were placed within the context of the requirements of the Code including the requirement in Clause 15.4 of the Code to observe the arrangements in force at any particular establishment. In addition, it would be helpful if representatives were given guidance and training on how such increased contact rates could be achieved.

The Panel noted that a communication dated 14 October 2020 to AbbVie staff included:

'For in-field team colleagues – It remains critical to increase our level of access with customers. It is appropriate to engage customers and seek one-to-one interactions with face to face prioritised ensuring all risk reduction measures are taken. Remote 1:1 engagements should be utilised when face to face is not possible...'

The Panel noted that a communication dated 1 December 2020 to AbbVie staff included:

'Provided your stakeholder is willing and able to engage with you then it remains critical to have these discussions. Given the new regional tiers however, and out of an abundance of caution, we are advising remote-only engagements for those employees and customers in tier 3. For those in tier's 1 and 2, you should follow the rules applicable for that area, as defined here (Gov.uk outlining 'local restriction tiers: what you need to know'). Face to face engagement is permissible if all precautions are adhered to and with customer consent'.

A further communication dated 13 May 2021 included:

'As with Step 2, again all measures from Step 2 apply, but with an increased focus on customer face to face engagements, which from Monday 17th May, should take priority, where these can be done safely and where your stakeholder agrees'.

The Panel further noted AbbVie's submission regarding its phased 'return to normal', which included setting targets related to in-field employees' face-to-face interactions with health professionals following its assessment of health professionals' appetite to re-engage with the industry on a face-to-face basis. The Panel noted AbbVie's submission that this was done in a manner that ensured health professionals' preferences would be respected at all times without undue pressure on sales representatives related to their sales bonuses.

The Panel noted AbbVie's submission that starting with Q2/2021, the 'stretch target' of a defined number of face-to-face visits per week implied that, by reaching this goal, an employee would receive not only their base salary and a bonus related to their sales targets, but also an additional bonus. AbbVie submitted it introduced a target of a defined number of face-to-face

visits as a condition for the Q3/2021 bonus that sales representatives could receive which amounted to a lower number than set as a 'stretch target' for Q2/2021, in recognition of the summer holiday period, and was a reflection of the actual levels of face-to-face engagement identified in Q2/2021 and also highlighted by third party data. The Panel further noted AbbVie's submission that sales representatives were aware that relief/exemptions were provided by the company in circumstances where failure to achieve a component of the incentive scheme was outside an individual's control; this implied that the targets for face-to-face interactions with health professionals could be (and regularly were) adjusted to take into account individual constraints, thereby addressing any potential pressure that may be perceived by sales representatives. The Panel noted that it was unknown if local trust policies would have permitted access for all representatives in Q2 and Q3 when the above target and incentive schemes had been set by AbbVie. The Panel, however, noted AbbVie's submission that it remained respectful to individual challenges and local constraints in this regard.

The Panel noting its comments above did not consider that the complainant had established that the targets set by AbbVie encouraged a course of action which would likely lead to a breach of the Code as alleged. The Panel did not consider that high standards had not been maintained in this regard and therefore ruled no breach of Clause 9.1.

The Panel noted that Clause 15.4 stated that representatives must ensure that the frequency, timing and duration of calls on health professionals and other relevant decision makers in hospitals and NHS and other organisations, together with the manner in which they were made, did not cause inconvenience. The wishes of individuals on whom representatives wished to call and the arrangements in force at any particular establishment, must be observed.

The Panel did not know the specific arrangements and policies in place at the hospital visited by the representative, as referred to within the email in question. It appeared that access to the rheumatology department required a security pass, and the representative had been let in by a member of staff as they were exiting the building after showing his/her business card as proof of ID; the reasoning given was following up a recent educational event with nurses. Whilst the Panel queried the validity of that reason, it noted that a consultant had queried how the representative had got into the "locked" department and appeared satisfied with the representative's explanation.

Whilst the Panel was concerned with the representative's methods of entering the hospital department, it did not consider that the complainant had shown, on the balance of probabilities, that the representatives had called on the hospital in a way that caused inconvenience or did not observe the wishes of individuals and the arrangements in force at the hospital. The Panel, therefore, based on the complainant's allegation, ruled no breach of Clause 15.4.

The Panel noted its comments and rulings above and did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and was reserved for such use. No breach of Clause 2 was ruled.

## **APPEAL BOARD CONSIDERATION OF CASE REPORT**

AbbVie provided the requisite undertaking and assurance and as the case completed at Panel level the Appeal Board received the case report as set out in Paragraph 13.4 of the Constitution and Procedure.

The Appeal Board was very concerned about circulation of the manager's response email to his/her team which in effect endorsed 'strategic loitering' by sales representatives to contact health professionals.

The Appeal Board was of the view that consideration should be given to the imposition of additional sanctions under Paragraph 11.1 of the Constitution and Procedure. AbbVie should respond to these concerns in writing, and it was invited to attend the Appeal Board when this matter was considered. AbbVie was provided with a copy of the papers.

### **COMMENTS FROM ABBVIE**

AbbVie submitted that it was fully committed to strict adherence to the Code and all applicable laws and regulations. As a member of the ABPI, AbbVie was dedicated to applying high standards at all times across all areas of its business and took any concern raised regarding compliance with the Code very seriously. AbbVie confirmed that it had similarly taken this complaint, the decision of the PMCPA, as well as the obligations under the undertaking it had given, very seriously and set out below the corrective steps which AbbVie had taken and planned to take.

At the heart of this case was an AbbVie internal email exchange from May 2021 ('Email Exchange'), which AbbVie understood had caused the additional concerns of the Appeal Board. The original email (dated 27 May 2021) was from a sales representative, a member of AbbVie's commercial field team to his/her peers and managers. The response email (dated May 28, 2021) was from the representative's manager to that team.

AbbVie acknowledged that the over-excited language used by the representative could suggest an inappropriate standard of conduct and that the representative's manager's reply could be interpreted as an endorsement of that conduct. Nevertheless, AbbVie believed it was helpful to consider the Email Exchange and the particular words and phrases used in the full context and circumstances in which they appeared and respectfully asked the Appeal Board to take this into account. The internal Email Exchange was intended as a message of support and reassurance to encourage colleagues to overcome their anxiety and unease around their return to the field, after a difficult time which had impacted significantly their ability to work effectively, rather than as a factually accurate description of what would be considered acceptable conduct. The manager's reply focused on inspiring team members to overcome anxiety and reconnect with the health professional community and this was reflected in other wording such as 'things are returning to a degree of normality', telling colleagues that 'it's OK to be apprehensive', encouraging the representatives not to overstay their welcome, and referring to the overall 'rewarding experience' of seeing customers in person once again. AbbVie accepted that whilst expressly referring to the Code requirements in the email, the manager's reply should have been more specific in reinforcing the expected standards of conduct and calling out some of the inappropriate language and behaviours.

Whilst AbbVie agreed with the Panel's ruling that '[the Panel] did not consider that the complainant had shown, on the balance of probabilities, that the representatives had called on the hospital in a way that caused inconvenience or did not observe the wishes of individuals and the arrangements in force at the hospital' in this particular case, AbbVie would like to reassure the Appeal Board that it did not accept or condone behaviours such as 'strategic loitering' and such behaviours were not reflective of the high standards set by the AbbVie Code of Business

Conduct, in accordance with the ABPI Code. Robust corrective actions had been taken and would continue to be taken, by AbbVie in view of this case.

## **1 Summary of corrective actions taken**

In line with the undertaking and assurance that AbbVie was asked to provide, the company set out the steps taken to both correct any negative repercussions caused by the Email Exchange and to avoid similar breaches of the Code occurring again:

### **A. Corrective discussions with the manager and the relevant teams**

On receipt of the complaint in August 2021, an AbbVie director discussed the incident with a senior manager, who subsequently discussed the case with the representative's manager that circulated the response to his/her team and made it clear that AbbVie did not condone the sales representative's actions, tone and style of communication, that these were not aligned with the company's high standards and that the distribution of the email was not appropriate as it could be interpreted as an endorsement of those practices. Senior management reminded the representative's manager that he/she and his/her team must always adhere to the Code, AbbVie's Code of Conduct, its policies and to always respect trust and Government guidance.

At the time, senior managers from the relevant therapy division, also discussed this topic with relevant managers and reminded them that they, and their teams must always maintain the highest standard of ethical conduct in the discharge of their duties and must comply with all relevant requirements of the Code and AbbVie's internal Code of Business Conduct. The managers were also reminded that they must ensure that the frequency, timing and duration of calls and visits (to health professionals and other relevant decision makers in hospitals and NHS and other organisations) together with the manner in which they were made, (i) did not cause inconvenience, and (ii) respect Government and trust applicable rules and regulations.

### **B. Other corrective communications**

#### **Communication of the incident to the Affiliate Leadership Team**

On receipt of the complaint in August 2021, AbbVie UK's senior leadership, together with the Ethics and Compliance and the medical functions, discussed the case with the Leadership Team. It was made clear that AbbVie did not condone the sales representative's behaviour as described in the email, that such behaviour, as well as the tone and style of communication, were not aligned with AbbVie's practices, and that the distribution of the email was not appropriate as it could be interpreted as endorsement of those practices.

AbbVie submitted that it required all directors to remind all employees to always comply with the Code, AbbVie's Code of Conduct and to respect and follow the trusts' rules and regulations as they returned to the field.

#### **September In-field Conference**

In September 2021, all the AbbVie in-field teams met in-person for their annual workshops. In the opening session of this meeting, senior leadership reminded all the in-field teams as well as all the other employees that also attended this meeting (the vast majority of UK employees), that all employees must always maintain a high standard of ethical conduct in the discharge of

their duties and must comply with all relevant requirements of the Code, AbbVie's internal Code of Business Conduct and its local and global policies. This was also then reinforced by one of the therapy managers during the same opening session.

### **Case Follow-Up and Awareness – UK Affiliate and EU Compliance Meetings**

AbbVie submitted that since receipt of the complaint, the case had been discussed at the Affiliate Compliance Insight Forum (Compliance meeting with leadership team held to discuss compliance matters including adherence to legal and regulatory obligations and commitments, assessment of AbbVie's compliance programme, changes in the legal and regulatory environment, risk areas and best practices, and improvements to the programme) and at the Entity Compliance Insight Forum to ensure all leadership teams were aware of the case and to prevent and avoid similar breaches of the Code occurring again. The case was also discussed above country at the Area Compliance Insight Forum to ensure appropriate visibility of the case and consistent follow-up.

### **C. Ongoing Compliance Campaigns**

AbbVie submitted that in accordance with the AbbVie Code of Business Conduct, the company regularly rolled-out UK affiliate-wide campaigns to raise awareness of the high standards of conduct expected from employees and continuously reminded all employees of their obligations under the Code. These campaigns, alongside the annual training of all employees on the AbbVie Code of Business Conduct, were at the core of how AbbVie did business in the UK. AbbVie provided further detail on the most recent iterations of these campaigns.

#### **i) Acting with Integrity Campaign**

In February 2022, the AbbVie UK and Allergan UK senior leaders launched the Acting with Integrity Campaign. The campaign provided all employees with useful information on what integrity meant and why it was so important to AbbVie's success to drive ethical and compliant behaviours, the impact it made on the company's reputation, interactions with stakeholders and real examples of what could happen when acting unethically. The campaign included (i) video from AbbVie's vice-presidents outlining the importance of integrity and what it meant to them and the business, (ii) an email from the AbbVie UK senior leaders to all AbbVie UK employees on the importance to always act with integrity, (iii) an email from the AbbVie UK senior leaders to all AbbVie managers asking them to remind their teams of AbbVie's ethics and values, to hold individuals accountable for their conduct, to be a visible role model and example for ethical and compliant behaviour (iv) an article of the campaign in the company website and (v) a digital magazine with examples of what could happen when acting unethically. A copy was provided of the assets related to the Acting with Integrity Campaign.

In March 2022, a senior manager presented the Acting with Integrity Campaign to national and regional sales managers and reminded them of the importance of acting with integrity in all their interactions with their stakeholders and to hold their teams accountable for their conduct and to be a visible role model and example for ethical and compliant behaviour.

#### **ii) Speak-Up Campaign**



In March 2022, the Office of Ethics and Compliance (OEC) launched the Speak-Up campaign to remind all employees that AbbVie was a safe space and that the company encouraged employees to speak up with any questions or concerns about potential violations, including self-reporting. The campaign objective was to remind all employees of the many avenues to report a situation or to ask questions about a situation.

The campaign was communicated in the OEC newsletter for April and was visible in all the screens and meeting snap frames in AbbVie's company offices. The Speak-Up campaign was also part of the Acting with Integrity Campaign and was presented by a senior manager in the March 2022 meeting with all In-field team managers. A copy was provided of the OEC newsletter-Speak Up Campaign.

## **2 Further planned corrective and preventive actions**

In addition to the actions listed above, AbbVie was planning the following further actions once the case report was published:

- Detailed presentations of the facts in the Case, the Panel ruling, and further insights that could be embedded in current AbbVie practices and processes, to be delivered in key internal communications, forums and working groups, including:
  - A company-wide communication from the AbbVie UK senior leaders to all employees in the UK, presenting the Panel ruling and driving key messages related to the standards of behaviour and conduct expected by AbbVie and by the ABPI Code from all staff.
  - The AbbVie Business Leadership Forum, an AbbVie internal working group that met monthly to discuss matters of key strategic importance for the business and brought together all mid-to senior-level managers across all functions, including all in-field team managers.
  - The Entity Compliance Insights Forum, an AbbVie forum comprising of key members of the leadership teams across both the therapeutics and aesthetics divisions, that met on a quarterly basis to discuss key developments in Code compliance and ensure the high standards of the Code were understood and followed consistently across the business.
  - The AbbVie Code Club, an internal working group that met fortnightly to discuss recently PMCPA published cases and the learnings that Abbvie could take from these, bringing together a broad audience including medical reviewers, company signatories and compliance functions from all business divisions.
- Additional face-to-face training to the infield teams on (i) interactions with health professionals and (ii) examination and certification of briefing material.
- Additional communications reinforcing AbbVie's Acting with Integrity campaign messaging throughout the organization and the importance of Speaking Up.

AbbVie reiterated its continued commitment to ensure all employees operated consistently at the highest standards of Code compliance. AbbVie welcomed input from the Appeal Board on any particular points which the Appeal Board would like to see included in these communications to address the Appeal Board's specific concerns.

AbbVie submitted that it had consistently taken similar actions in the past in relation to all published cases that addressed novel or complex areas of the Code, irrespective of whether they involved AbbVie or not, in order to ensure that insights and learnings on all aspects of the Code were disseminated widely across the organisation and were embedded in the day-to-day work of field-based and office-based employees.

### **3 Conclusion**

AbbVie thanked the Appeal Board for the opportunity to respond and to demonstrate the seriousness with which it had taken this complaint and its obligations pursuant to the undertaking the company provided. AbbVie welcomed the opportunity to discuss further at the Appeal Board meeting the circumstances around the Email Exchange, the corrective actions taken and to provide reassurance to the Appeal Board that AbbVie had a full appreciation both of the seriousness of this case and AbbVie's obligations as members of the ABPI and in respect of the Code.

AbbVie submitted that it took its responsibility for compliance with the Code very seriously as it continuously endeavoured to maintain high standards in all its activities.

#### **APPEAL BOARD CONSIDERATION**

The Appeal Board was concerned about the case which had been ruled in breach of the Code. It was particularly concerned that none of the recipients of the email at issue raised any concerns about its content within the company nor had the complaint been addressed through any company whistleblowing procedure. It was only after AbbVie was notified of the complaint to the PMCPA that the company took action.

The Appeal Board noted the submission of the company representatives at the Appeal Board meeting that the email in question was sent when the field force was transitioning from virtual to face-to-face meetings and their acknowledgement that in retrospect the company should have highlighted the importance of Code compliance to the field force during this time.

The Appeal Board welcomed the actions taken by AbbVie as detailed in the response to the Appeal Board's decision to consider whether to impose additional sanctions and by the AbbVie representatives at the meeting. The Appeal Board did not consider that there was evidence to suggest that the emails at issue were symptomatic of wider problems within the company. The Appeal Board noted the apparent contrition and the extent of the remedial action undertaken. The Appeal Board remained concerned that the recipients of the email in question had not spoken up internally. The Appeal Board gave consideration to the use of additional sanctions but decided that none were required.

<b>Complaint received</b>	<b>7 July 2021</b>
<b>Case completed</b>	<b>23 March 2022</b>
<b>Appeal Board consideration</b>	<b>28 April 2022 and 26 May</b>