CASE AUTH/3292/12/19

EMPLOYEE v GE HEALTHCARE

Arrangements for a meeting and company culture

A GE Healthcare employee complained about the arrangements for a meeting and the company's culture.

The complainant provided email correspondence and a copy of his/her recent performance appraisal and alleged that the pressure put upon medical staff to push the limits of ethical practice was such, that despite their best efforts and those of compliance staff it became very difficult to adhere to the Code and within a short period of time, medical staff ended up leaving the company or being asked to leave.

The complainant explained that the email chain provided referred to a so called 'round table' held at a European Society of Radiology (ECR) conference in Vienna, which was not a round table, but just a dinner held in order to gain the favour of influential radiologists.

The complainant stated that although he/she rejected the meeting, a more senior employee approved it anyway.

There was no agenda, no slides and no discussion at the so-called round table. Guests sat down straight to dinner at a restaurant alongside other customers who had nothing to do with the GE Healthcare contingent.

The complainant stated that one of the things that he/she found very difficult at GE Healthcare was, that he/she was constantly told that the Code had 'Fifty shades of grey' and that the complainant's role was to support the commercial function in identifying 'opportunities within the loopholes'. The complainant had been told that he/she was too rigorous in applying the Code.

GE Healthcare encouraged sales representatives to prompt discussions with members of the medical affairs team, because they could speak about off-label use. The complainant stated that he/she reminded senior management that the medical affairs team were not an extension of the sales team and that it was not appropriate to solicit medical questions.

The detailed response from GE Healthcare is given below.

The Panel noted GE Healthcare's submission that the meeting was organised at the global HQ level by an employee in GE Healthcare's Pharmaceutical Diagnostics business based in mainland Europe. The Panel noted GE Healthcare's submission that GE Healthcare's headquarters was based in the UK and its Pharmaceutical Diagnostics business (PDx) was a global business that operated across many of GE Healthcare's

international subsidiaries and affiliates. The members of the PDx leadership team were located in a number of GE Healthcare's offices throughout USA and Europe, including the UK. The Panel noted that it appeared from the company website that the President and CEO of the Pharmaceutical Diagnostics business was UK-based and was also the President and CEO of GE Healthcare in the UK.

The Panel noted that it was an established principle under the Code that UK-based global or other such companies were subject to the Code. In the Panel's view, GE Healthcare UK was responsible for acts and omissions by UK-based GE Healthcare global which came within the scope of the Code regardless of whether the UK company had any role in such matters. To decide otherwise would allow UK-based affiliates to circumvent the requirements of the UK Code. The issue therefore was whether the UK based global company's meeting, held in Vienna, was within the scope of the UK Code. The Panel noted that GE Healthcare UK had not argued that it was not responsible for its UK-based global affiliate.

None of the invited radiologists (delegates at the ECR conference) were UK health professionals or other relevant decision makers. It was not known whether the UK company had suggested any delegates for invitation. Two UK-based global staff attended the meeting in question. The Panel further noted GE Healthcare's submission that it did not support any UK health professionals to attend the ECR conference in Vienna. Nonetheless, GE Healthcare did financially support certain non-UK health professionals to attend the ECR conference, it stated that such approval followed strict compliance approval and adherence to relevant local codes that applied to such attendees.

The Panel noted that GE Healthcare policy required any PDx materials relating to international congresses in Europe to be approved and certified under local regulations of the country where the congress took place and the ABPI Code regardless of whether the Code applied to the proposed activities or not. GE Healthcare's current policy stated that any scientific or promotional international meetings, scientific congresses and other such meetings in Europe must all be approved and certified under the ABPI Code regardless of their location and target audience (ie even for meetings outside of the UK with no involvement of UK health professionals or other relevant decision makers).

The Panel noted the example given in the supplementary information of the Code that a company located in the UK carrying out an activity outside the UK but within Europe such as in France must comply with the UK Code and the French Code, regardless of whether or not UK health professionals or other relevant decision makers are involved. The Panel considered that in these circumstances the UK Code applied to the meeting in question.

The Panel noted GE Healthcare's submission that the meeting arrangements were certified under the ABPI Code. GE Healthcare did not comment on whether the meeting had been approved over the head of the UK complainant, as alleged. The Panel queried whether the arrangements for the meeting required certification under the Code as it did not involve taking UK health professionals out of the UK. It was nonetheless at the very least good practice to do so. The Panel noted that the arrangements for the meeting in relation to the venue and subsistence had been certified and therefore no breach was ruled.

The Panel noted that GE Healthcare provided a copy of the invitation which stated that the purpose of the meeting was to discuss: Current & emerging clinical/diagnostics trends in oncology (including CIAKI risk and mitigations strategies); Understanding the changing paradigm in CT suite – personalized CT protocol including radiation and contrast media dose adaption; and the Role of emerging technologies in CT including Artificial Intelligence. The Panel noted GE Healthcare's submission that the meeting was held in a separate, reservable booth adjacent to the hotel lobby which was clearly private and separated from the general public. The Panel noted that an internal company email referred to the meeting as a non-promotional meeting whose main purpose was to create a forum for exchange of information between radiologists and GE Healthcare. The email stated that it was not as formal as an advisory board as this would require a different approach (less people, fees, etc). The email further stated that there was an agenda for the meeting and '[first name] would introduce the topics for discussion that would be held as a group and within each table during the dinner'. The Panel noted that it did not have a copy of a formal agenda but noted details appeared on the invitation. The Panel noted that within the same email trail a UK compliance employee stated that the previous year's similar event was done as a promotional one and was certified as such. The Panel noted that it appeared from the certificate that the current meeting at issue had also been certified as promotional despite it being described in the email trail referred to above as a non-promotional meeting. The Panel was concerned about certain aspects of the meeting including that there were no slides and the lack of formality of discussions during dinner at individual tables and the impression that would thereby be given to attendees. The Panel noted that in relation to the complainant's narrow allegation that the event was just a dinner to gain the favour of influential radiologists that the complainant bore the burden of proof and, on balance, given the clinical topics for discussion, its association with the first day of the scientific conference and that a note on the discussion appeared to have been produced for internal use, the Panel considered that the complainant had not discharged his/her burden of proof and ruled no breach of the Code.

The Panel noted the allegation that the event was just a dinner held in order to gain the favour of influential radiologists and, in this regard, considered that the level of expenditure was relevant. The cost of the dinner was €60 per attendee, including drinks which was in line with the local limit and therefore no breach of the Code was ruled in relation to the level of hospitality.

The Panel noted its rulings above and consequently ruled no breaches of the Code including Clause 2.

The Panel noted the complainant's allegation that GE Healthcare encouraged sales representatives to prompt discussions with members of the medical affairs team, because they could speak about off-label use. The Panel noted GE Healthcare's submission that the meeting did not involve any discussions about the off-label use of GE Healthcare products and the GE Healthcare commercial team at the ECR conference were specifically instructed to '[r]efer all medical-related questions to MA' (This instruction covered any questions about medicinal products, including those relating to off-label use).

The allegation appeared to the Panel to be a general allegation rather than particularly in relation to the ECR meeting. The Panel noted that the complainant bore the burden of

proof and did not consider that he/she had provided evidence to support his/her allegation and that, in any event, the allegation was unclear in this regard and therefore no breach of the Code was ruled.

The Panel noted the complainant made a general allegation about the pressure put upon medical staff and the company's compliance culture. The Panel noted GE Healthcare's submission that it had created an environment where medical staff were free to raise concerns and were ultimately able to say 'no' if they disagreed with materials or activities that fell under the Code. However, GE Healthcare expected its employees to work collaboratively to find ways to address and resolve such concerns. The Panel noted that the parties' accounts differed in this regard. Whilst the Panel had some concerns about the phrase 'Fifty shades of grey', context was important and the complainant had provided no detail about the discussion.

The Panel noted the difficulty in dealing with such complaints; it was difficult to establish where the truth lay. Whilst it had some concerns about the meeting at issue above and some of the company's approaches in relation to the Code as revealed in the documentation before it, the Panel, nonetheless, did not consider that the complainant had provided sufficient evidence to establish on the balance of probabilities that inappropriate pressure had been placed on medical staff and that the compliance culture was inappropriate as alleged. No breach of the Code was ruled in relation to each of these allegations.

A GE Healthcare employee complained about the arrangements for a meeting and the company's culture.

COMPLAINT

The complainant provided email correspondence and a copy of his/her recent performance appraisal and alleged that the pressure put upon medical staff to push the limits of ethical practice was such, that despite their best efforts and those of compliance staff, it became very difficult to adhere to the Code and within a short period of time, medical staff ended up either leaving the company or being asked to leave.

The complainant explained that the email chain provided referred to a so called 'round table' held at this year's European Society of Radiology (ECR) conference in Vienna, which was not a round table, but just a dinner held in order to gain the favour of influential radiologists.

The complainant noted that as seen from the correspondence, he/she rejected the meeting, but a named senior member of staff, decided to go over the complainant's head and approve it anyway.

There was no agenda, no slides and no discussion at the so-called round table. Guests sat down straight to dinner at a restaurant alongside other customers who had nothing to do with the GE Healthcare contingent.

The complainant had been told that he/she was too rigorous in applying the Code.

The complainant stated that one of the things that he/she found very difficult at GE Healthcare was, that he/she was constantly told that the Code had 'Fifty shades of grey' and that the

complainant's role was to support the commercial function in identifying 'opportunities within the loopholes'.

Another commercial strategy GE Healthcare encouraged sales representatives to pursue, was to prompt discussions with members of the medical affairs team, because they could speak about off-label use. Time and time again the complainant stated that he/she needed to remind senior management that the medical affairs team were not, as they saw it, an extension of the sales team and that it was not appropriate to solicit medical questions.

When writing to GE Healthcare, the Authority asked it to consider the requirements of Clauses 2, 9.1, 14.2, 15.9, 22.1 and 22.2 of the Code.

RESPONSE

GE Healthcare noted and denied the complainant's numerous allegations.

GE Healthcare provided some relevant background information about the complainant and his/her role and time at GE Healthcare.

GE Healthcare refuted all the complainant's allegations and considered that they had no basis in either fact or the Code.

GE Healthcare made two key points. Firstly, the meeting fell outside of the scope of the Code because it was held outside the UK and there were no UK healthcare professional invitees or attendees. Secondly, even if the meeting was subject to the Code, it fully complied with both the ABPI Code and the Austrian equivalent PHARMIG Code.

The meeting comprised of a round table meeting with dinner and was entitled 'Oncology CT Imaging Round Table'. It was held on 27 February 2019, at the end of the first day of the ECR conference in Vienna (which ran from 27 February 2019 until 3 March 2019). The meeting was organised at the global HQ level by an employee in GE Healthcare's Pharmaceutical Diagnostics business and radiologists who were delegates of the ECR conference were invited. None of the invitees were UK health professionals or other relevant decision makers, as defined under the Code.

GE Healthcare submitted that the meeting fell outside the scope of the Code because it was held outside the UK and GE Healthcare did not invite any UK health professionals or other relevant decision makers to the meeting, nor did any attend. The Code stated:

> Clause 1.1: 'This Code applies to the promotion of medicines to **members of the United Kingdom health professions and to other relevant decision makers**'.
>
> Supplementary Information Clause 1.1: 'The Code applies to the promotion of medicines to members of the health professions and to other relevant decision makers as specified in Clause 1.1. **This includes promotion at meetings for UK residents held outside the UK. It also applies to promotion to UK health professionals and other relevant decision makers at international meetings held outside the UK, except that the promotional material distributed at such meetings will need to comply with local requirements**' (emphasis added).

The principle that events held in countries outside of the UK that did not involve UK health professional delegates fell outside of the Code was well established both in the Code and in relevant PMCPA cases. The company referred in detail to Case AUTH/2880/10/16 and Case AUTH/1999/5/07.

GE Healthcare chose the venue because it was a reasonably priced, business-focused hotel in a central location. The cost was €60 per attendee, including drinks, which was less than the £75 limit under Clause 22.2 of the Code and €75 Limit under the PHARMIG Code. The meeting had a clear scientific and educational purpose. The purpose of the meeting was to discuss:

> Current & emerging clinical/ diagnostics trends in oncology (including CIAKI risk and mitigations strategies);
>
> Understanding the changing paradigm in CT suite – personalized CT protocol including radiation and contrast media dose adaption; and
>
> Role of emerging technologies in CT including Artificial Intelligence.

All of these were cutting edge issues of significant importance to GE Healthcare and its product development. A summary of the conclusions of the meeting was documented in the wider medical affairs summary report of the ECR 2019 conference and details were provided.

GE Healthcare were therefore surprised by the complainant's allegations that '[t]here was no agenda, no slides and no discussion'. While the format of the meeting did not necessitate slides, the rest of the allegations were self-evidently untrue.

There were a number of other allegations that were incorrect. The complainant contended that '[t]he fact that the meeting was being held in a restaurant created the wrong impression' and that '[g]uests sat down straight to dinner at a restaurant alongside other customers who had nothing to do with the GE contingent'. This was untrue. The meeting was not held in a restaurant and was not alongside other hotel guests, but in a separate, reservable booth adjacent to the hotel lobby which was clearly private and separated from the general public. Considering the modest number of attendees, such a venue was conducive to the discussion and sharing of ideas related to the agenda topics.

Therefore, the appropriate timing, venue, level of hospitality and discussion topics evidence the meeting's compliance with Clauses 22.1 and 22.2 of the Code. They contrast notably with cases where companies had been found in breach and an example was provided (Case AUTH/1827/4/06).

The timing of the meeting at the end of the first day of the ECR 2019 contrasted with Case AUTH/2603/5/13, which involved a meeting held on the day before the educational program of a conference.

GE Healthcare submitted that the complainant did not submit any evidence to suggest that the attendees did not maintain high standards at all times during the meeting (as required by Clause 9.1 of the Code) and there was clearly no breach of Clause 2.

The arrangements for the meeting were scrutinized and signed off by a medically qualified signatory (named) prior to the meeting (in compliance with Clause 14.2 and its supplementary

information. This sign-off process would have included prior input from local regulatory personnel in Austria as per GE Healthcare protocol. The fact that the complainant did not sign-off on the meeting, did not affect the validity of the approval.

GE Healthcare confirmed that it did not support any UK health professionals to attend the ECR conference in Vienna. Nonetheless, GE Healthcare did financially support certain non-UK health professionals to attend the ECR conference following strict compliance approval and adherence to relevant local codes that applied to such attendees.

GE Healthcare noted the Panel's request for copies of instructions to the field force about how they were to answer questions about off-label use and emphasized that the meeting did not involve any discussions of off-label use of GE Healthcare products. As in any event, the GE Healthcare commercial team at the ECR conference were specifically instructed to '[r]efer all medical-related questions to MA' . This instruction covered any questions about medicinal products, including those relating to off-label use (in compliance with Clause 15.9 of the Code).

GE Healthcare therefore denied any breaches of the Code, including Clauses 2, 9.1, 14.2, 15.9, 22.1 and 22.2. GE Healthcare stated that it had provided the information necessary for the PMCPA to conclude that GE Healthcare did not have a *prima facie* case to answer in respect of the meeting.

Response to allegations ii. and iii.

GE Healthcare noted that the majority of the allegations were vague assertions made by the complainant which GE Healthcare would endeavor to comment on as best it could, but it was difficult to do so seeing as the complainant did not provide any evidence.

As an initial comment, GE Healthcare drew attention to Paragraph 5.5 of the Constitution and Procedure of the PMCPA which stated that the case preparation manager must 'determine whether there is a *prima facie* case to answer under the Code'. Given the vague nature of such allegations, GE Healthcare did not acknowledge that there was a *prima facie* case to answer given the proof submitted by the complainant fell far below the required legal standard.

Allegation ii. (Medical staff were pressured to push the limits of ethical practice)

GE Healthcare vigorously refuted this allegation and highlighted the lack of evidence submitted with this allegation.

GE Healthcare submitted that it had created an environment where medical staff were free to raise concerns and were ultimately able to say 'no' if they disagreed with materials or activities that fell under the Code. However, GE Healthcare expected its employees to work collaboratively to find ways to address and resolve such concerns (which the complainant was repeatedly unwilling to do). In GE Healthcare's experience, GE Healthcare was a positive environment for an employee who expressed concerns but then was willing to engage with or discuss other perspectives. Employees who were unwilling to engage with such an environment might feel a degree of frustration and as a result might feel somewhat pressurised, even when no such pressure existed.

With respect to the reasons for departure of previous GE Healthcare medical staff, the complainant was incorrect. The competition for pharmaceutical companies to attract and retain

talented medical staff was very fierce in the UK. Details were provided including that none left due to the 'pressure' received at GE Healthcare.

Allegation iii. (GE Healthcare stated that the Code has 'Fifty shades of grey' and encouraged its sales representatives to prompt discussions with members of the medical affairs team regarding off-label use)

GE Healthcare again refuted this allegation. GE Healthcare submitted that the complainant's comments referring to the Code having 'Fifty shades of grey' arose from discussions during a Commercial Priorities & Expectations presentation from the GE Healthcare Global Medical Services Summit on 2 September 2019 which the complainant attended. During the discussion of slide 5 of the presentation, the concept of 'Fifty shades of grey' was raised as a reference to the fact that the interpretation of promotional activities under the Code was not always black or white. The complainant was strongly advocating that there were no grey areas and that this concept might represent an inducement to GE Healthcare medical affairs personnel to approve materials that might be at risk of complaint.

GE Healthcare refuted this characterization of the company's perception of the Code. Although GE Healthcare and pharmaceutical companies strove to work in full compliance with the Code, they would always look for opportunities to advance their commercial interests while remaining in compliance with the Code. There was, therefore, a necessary interaction and collaboration between medical affairs officers and commercial teams within pharmaceutical companies. As the PMCPA were aware, analysis of medicines advertising issues would always be subjective in nature. The Panel and others assessed whether, for example, something was misleading or if it was promotional or a scientific exchange, in light of the likely perception of the likely audience. What was a product claim to one person was legitimate scientific exchange to another. It was clear from the PMCPA cases that, just because the complainant claimed that an activity breached the Code did not mean that GE Healthcare had acted inappropriately

Finally, the complainant was incorrect in his assertion that GE Healthcare encouraged sales representatives to 'prompt discussions with members of the medical affairs team, because [they] could speak about off-label use'. Regardless of the complainant's lack of evidence in this assertion, such activities would be a clear violation of GE Healthcare's policies and procedures. GE Healthcare abided by the principle of separation of powers in its compliance with the Code and promotion of ethical activities. Specifically, GE Healthcare ensured that there was adequate separation between medical affairs and the commercial functions of the company. As evidenced by the ECR conference briefing materials, sales representatives were instructed to '[r]efer all medical-related questions to MA' and there was no distinction made between on-label versus off-label enquiries.

In response to a request for additional information from the case preparation manager ,GE Healthcare submitted that its Pharmaceutical Diagnostics business (PDx) was a global business that operated across many of GE Healthcare's international subsidiaries and affiliates. GE Healthcare's headquarters were based in UK. However, the members of the PDx leadership team were located in a number of GE Healthcare's offices throughout USA and Europe, including the UK. GE Healthcare policy therefore required any PDx materials relating to international congresses in Europe to be approved and certified under local regulations of the country where the congress took place and the ABPI Code , regardless of whether the Code applied to the proposed activities or not. GE Healthcare's current policy dictated that any scientific or promotional international meetings, scientific congresses and other such meetings

in Europe must all be approved and certified under the Code regardless of their location and target audience (ie, even for meetings outside of the UK with no involvement of UK health professionals or other relevant decision makers).

GE Healthcare stated that as emphasised in its initial response, it maintained that the Code did not apply to the meeting. GE Healthcare, nevertheless, ensured that the meeting met the requirements of the Code, and GE Healthcare maintained that this was the case.

GE Healthcare provided details of who organized, approved or attended the meetingAttendees based in the UK, had global roles.

GE Healthcare understood the PMCPA was still assessing whether the meeting fell within the scope of the Code. As discussed in more detail in its initial response, GE Healthcare asserted that the Code did not apply to the meeting. The meeting was held outside of the UK and GE Healthcare did not invite any UK health professionals or other relevant decision makers to the meeting, nor did any attend. No UK personnel were involved in its organisation or approval. As acknowledged above, PDx had a clear nexus with the UK, which is why it applied the Code as this was a widely recognized code in Europe. However, it did not therefore follow that all global PDx activities must fall under the scope of the Code – this would depend on the specific details of the activities themselves. In addition to the cases cited in its initial response, GE Healthcare noted Case AUTH/3088/9/18 and Case AUTH/2672/11/13.

In any event, GE Healthcare stated that it also made it clear in its initial response that the meeting was in full compliance with the requirements of the Code (including its certification).

PANEL RULING

Firstly, the Panel had to decide whether the meeting in question was subject to the Code.

The Panel noted that whether an activity came within the scope of the Code depended on a consideration of all the circumstances including Clause 1.1 and the supplementary information to Clause 1.11, Applicability of Codes.

The Panel noted GE Healthcare's references to and discussion of previous cases. The Panel noted that there were some differences between those cases and the current complaint. Each case under the Code had to be considered on its own merits.

The Panel noted GE Healthcare's submission that the meeting was organised at the global HQ level by a named employee in GE Healthcare's Pharmaceutical Diagnostics businesswho was based in mainland Europe. The Panel noted GE Healthcare's submission that GE Healthcare's headquarters was based in the UK and its Pharmaceutical Diagnostics business (PDx) was a global business that operated across many of GE Healthcare's international subsidiaries and affiliates. The members of the PDx leadership team were located in a number of GE Healthcare's offices throughout USA and Europe, including the UK. The Panel noted that it appeared from the company website that the President and CEO of the Pharmaceutical Diagnostics business was UK-based and was also the President and CEO of GE Healthcare in the UK.

The Panel noted that it was an established principle under the Code that UK-based global or other such companies were subject to the Code. If such entities were not members of the ABPI,

or on the list on non-member companies that otherwise complied with the Code, the UK company had to take responsibility for their acts and omissions under the Code. Thus, in the Panel's view, GE Healthcare UK was responsible for acts and omissions by UK-based GE Healthcare global which came within the scope of the Code regardless of whether the UK company had any role in such matters. To decide otherwise would allow UK-based affiliates to circumvent the requirements of the UK Code. The issue therefore was whether the UK based global company's meeting, held in Vienna, was within the scope of the UK Code. The Panel noted that GE Healthcare UK had not argued that it was not responsible for its UK-based global affiliate.

None of the invited radiologists (delegates at the ECR conference); were UK health professionals or other relevant decision makers. It was not known whether the UK company had suggested any delegates for invitation. Two UK-based global staff attended the meeting in question. The Panel further noted GE Healthcare's submission that it did not support any UK health professionals to attend the ECR conference in Vienna. Nonetheless, GE Healthcare did financially support certain non-UK health professionals to attend the ECR conference, it stated that such approval followed strict compliance approval and adherence to relevant local codes that applied to such attendees.

The Panel noted that GE Healthcare policy required any PDx materials relating to international congresses in Europe to be approved and certified under local regulations of the country where the congress took place and the ABPI Code regardless of whether the Code applied to the proposed activities or not. GE Healthcare's current policy stated that any scientific or promotional international meetings, scientific congresses and other such meetings in Europe must all be approved and certified under the ABPI Code regardless of their location and target audience (ie even for meetings outside of the UK with no involvement of UK health professionals or other relevant decision makers).

The Panel noted the example given in the Supplementary Information to Clause 1.11 that a company located in the UK carrying out an activity outside the UK but within Europe such as in France must comply with the UK Code and the French Code, regardless of whether or not UK health professionals or other relevant decision makers are involved. The Panel considered that in these circumstances the UK Code applied to the meeting in question.

The Panel noted GE Healthcare's submission that the meeting arrangements were certified under the ABPI Code prior to the meeting in compliance with Clause 14.2. It appeared from emails provided by the complainant that UK company staff had been involved in correspondence about the approval of the meeting. GE Healthcare did not comment on whether the meeting had been approved over the head of the UK complainant, as alleged. The Panel queried whether the arrangements for the meeting required certification under Clause 14.2 as it did not involve taking UK health professionals out of the UK. It was nonetheless at the very least good practice to do so. The Panel noted that the arrangements for the meeting in relation to the venue and subsistence had been certified as required by Clause 14.2 and therefore no breach was ruled.

The Panel noted that GE Healthcare provided a copy of the invitation which stated that the purpose of the meeting was to discuss: Current & emerging clinical/diagnostics trends in oncology (including CIAKI risk and mitigations strategies); Understanding the changing paradigm in CT suite – personalized CT protocol including radiation and contrast media dose adaption; and the Role of emerging technologies in CT including Artificial Intelligence. The

Panel noted GE Healthcare's submission that all of these were cutting edge issues of significant importance to GE Healthcare and its product development. The Panel further noted GE Healthcare's submission that the meeting was held in a separate, reservable booth adjacent to the hotel lobby which was clearly private and separated from the general public. The Panel noted that according to an internal company email dated 25 February 2019 the meeting was a non-promotional meeting whose main purpose was to create a forum for exchange of information between radiologists and GE Healthcare. The email stated that it was not as formal as an advisory board as this would require a different approach (less people, fees, etc). The email further stated that there was an agenda for the meeting and '[first name] would introduce the topics for discussion that would be held as a group and within each table during the dinner'. The Panel noted that it did not have a copy of a formal agenda but noted details appeared on the invitation. The Panel noted that within the same email trail the UK compliance officer stated that the previous year's similar event was done as a promotional one and was certified as such. The Panel noted that it appeared from the certificate that the current meeting at issue had also been certified as promotional despite it being described in the email trail referred to above as a non-promotional meeting. The Panel noted that the meeting took place on the first day of the ECR conference. The Panel was concerned about certain aspects of the meeting including that there were no slides and the lack of formality of discussions during dinner at individual tables and the impression that would thereby be given to attendees. The Panel considered that the arrangements and evidence before it implied a lack of understanding by GE Healthcare with regard to the requirements of the Code in relation to advisory boards and the like and the difference between promotional and non-promotional meetings. The Panel noted, however, that it had no allegation in this regard. The Panel noted that in relation to the complainant's narrow allegation that the event was just a dinner to gain the favour of influential radiologists that the complainant bore the burden of proof and, on balance, given the clinical topics for discussion, its association with the first day of the scientific conference and that a note on the discussion appeared to have been produced for internal use, the Panel considered that the complainant had not discharged his/her burden of proof and ruled no breach of Clause 22.1.

The Panel noted the allegation that the event was just a dinner held in order to gain the favour of influential radiologists and, in this regard, considered that the level of expenditure was relevant. The Panel noted the supplementary information to Clause 22.2, Maximum Cost of a Meal, which included that the maximum of £75 plus VAT and gratuities (or local equivalent) and that this would only be appropriate in very exceptional circumstances such as a dinner at a residential meeting for senior consultants or a learned society conference with substantial educational content. It also made it clear that the limit did not apply when a meeting was held outside UK in a European country where the national association was a member of EFPIA and thus covered by EFPIA Codes. In such circumstances, the limits in the host country code would apply. The Panel noted the limits in the Austrian Code were relevant. The Panel noted the Austrian limit of €75 Limit under the PHARMIG Code. The cost of the dinner was €60 per attendee, including drinks. This was in line with the local limit for a meal and therefore no breach of Clause 22.2 was ruled in relation to the level of hospitality.

The Panel noted its rulings above and consequently ruled no breach of Clauses 9.1 and 2.

The Panel noted the complainant's allegation that GE Healthcare encouraged sales representatives to prompt discussions with members of the medical affairs team, because they could speak about off-label use. The Panel noted that Clause 15.9 required that companies must prepare detailed briefing material for medical representatives on the technical aspects of each medicine which they will promote which must comply with the relevant requirements of the

Code and must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code.

The Panel noted GE Healthcare's submission that the meeting did not involve any discussions about the off-label use of GE Healthcare products and the GE Healthcare commercial team at the ECR conference were specifically instructed to '[r]efer all medical-related questions to MA' (This instruction covered any questions about medicinal products, including those relating to off-label use).

The allegation appeared to the Panel to be a general allegation rather than particularly in relation to the ECR meeting. The Panel noted that the complainant bore the burden of proof and did not consider that he/she had provided evidence to support his/her allegation and that, in any event, the allegation was unclear in this regard and therefore no breach of Clause 15.9 was ruled.

The Panel noted the complainant made a general allegation about the pressure put upon medical staff to push the limits of ethical practice, and the company's compliance culture. The Panel noted GE Healthcare's submission that it had created an environment where medical staff were free to raise concerns and were ultimately able to say 'no' if they disagreed with materials or activities that fell under the Code. However, GE Healthcare expected its employees to work collaboratively to find ways to address and resolve such concerns. The Panel noted that the parties' accounts differed in this regard. The Panel noted GE Healthcare's submission that the complainant's comments referring to the Code having 'Fifty shades of grey' arose from discussions of slide 5 of a Commercial Priorities & Expectations presentation from the GE Healthcare Global Medical Services Summit on 2 September 2019 which the complainant attended. The Panel noted that GE Healthcare had only provided it with the first three slides of this presentation and so the relevant slide, slide 5, was not before the Panel [see post consideration note below]. Nonetheless whilst the Panel had some concerns about the phrase 'Fifty shades of grey', context was important and the complainant had provided no detail about the discussion.

The Panel noted the difficulty in dealing with such complaints; it was difficult to establish where the truth lay. Whilst it had some concerns about the meeting at issue above and some of the company's approaches in relation to the Code as revealed in the documentation before it, the Panel, nonetheless, did not consider that the complainant had provided sufficient evidence to establish on the balance of probabilities that inappropriate pressure had been placed on medical directors and that the compliance culture was inappropriate as alleged. No breach of Clause 9.1 was ruled in relation to each of these allegations.

[Post consideration note. Upon being notified of the Panel's outcome, GE Healthcare clarified that with regards to the Commercial Priorities & Expectations presentation, it had submitted 3 slides of the presentation including the covering/title slide and slides 5 and 6.].

Complaint received **20 December 2019**

Case completed **12 February 2021**