CASE AUTH/2820/2/16

MEDIA/DIRECTOR v HOSPIRA

Arrangements for an overseas meeting

The Daily Telegraph of Wednesday, 17 February 2016 carried an article criticising pharmaceutical companies in relation to payments to senior NHS staff ('NHS officials with second jobs at drugs firms' which continued under the heading 'How drugs firms give NHS officials trips abroad at top hotels for £1000 a day'). Hospira was named in relation to the arrangements for a meeting held at a five-star hotel in Zagreb which had a spa and casino. In accordance with Paragraph 6.1 of the Constitution and Procedure the matter was taken up as a complaint under the Code.

Hospira submitted that the trip included a manufacturing site visit and an advisory board. The company's detailed response is below.

The Panel noted that it was acceptable for companies to contract health professionals and others for advice. Nonetheless, the arrangements for such meetings had to comply with the Code. To be considered a legitimate advisory board the choice and number of participants should stand up to independent scrutiny with each chosen according to their expertise such that they would be able to contribute meaningfully to the purpose and expected outcomes. The number of participants should be limited to allow active participation by all. The agenda should allow adequate time for discussion. The number of meetings and the number of participants should be driven by need and not the invitees' willingness to attend. Invitations to participate should state the purpose of the advisory board meeting, the expected advisory role and the amount of work to be undertaken. If an honorarium was offered it should be made clear that it was a payment for such work and advice. Honoraria must be reasonable and reflect the fair market value of the time and effort involved.

Turning to the meeting at issue the Panel noted that it was wholly for UK health professionals (five pharmacists); two were from the same hospital's NHS trust. The Panel noted that the delegates were not paid any honoraria. In addition three Hospira staff attended and an employee of its communications agency. The Panel queried whether the ratio of Hospira staff to delegates was appropriate. The Panel noted Hospira's submission that the delegates were selected because they were UK pharmacists with a role in quality assurance and procurement of biologic/biosimilars. In the Panel's view the primary aim of trying to recruit 10-12 delegates for the meeting appeared to be driven by an attempt to maximise the number who could visit the manufacturing site rather than the number necessary to achieve the identified need of the advisory board. Hospira initially invited 17 potential delegates. The Panel queried, however, why no-one from Wales or Northern Ireland was invited given Hospira's submission that the purpose of the advisory board was, *inter alia*, to seek advice on how to further facilitate the uptake of biosimilar products in the UK. The Panel further noted Hospira's submission that five delegates was sufficient to achieve the identified need of the advisory board and that if there had been 10-12, the additional input would have been welcomed but the feedback from five was useful.

The Panel noted Hospira's submission that the meeting would combine a site visit to Hospira's Zagreb biologics manufacturing site and an advisory board associated with Hospira's biosimilars. The Panel noted that it was in Hospira's interest for the NHS to be confident in the manufacture of its medicines. The Panel queried whether it was ever acceptable to combine two company meetings such that one part was promotional and the other part was an advisory board. The Panel noted that the invitation was to a site visit of the manufacturing facility, Monday to Wednesday (3 nights). The invitation further stated 'You will have a tour of the Hospira manufacturing facility and you will also take part in an advisory board during your visit'. The Panel noted that the agenda was entitled 'Agenda and Plan for Hospira UK, Zagreb Manufacturing Site Tour'. The expenses claim forms were entitled 'Hospira Manufacturing Facility Site Visit Expenses Form'. It appeared to the Panel that the visit to the manufacturing site and gaining confidence in the quality of that site was emphasised more than the advisory board.

The Panel noted that meetings which involved UK health professionals at venues outside the UK were not necessarily unacceptable provided there were valid and cogent reasons for holding meetings at such venues. As with meetings held in the UK, in determining whether such a meeting was acceptable or not, consideration must also be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience, subsistence provided and the like. As with any meeting it should be the programme that attracted delegates and not the associated hospitality or venue.

The Panel was concerned that the primary justification for holding the meeting outside the UK appeared to be to allow UK pharmacists to conduct due diligence on Hospira's manufacturing facilities. In any event, in the Panel's view, the acceptability of the visit to the manufacturing site could not be considered separately to the rest of the meeting. The two elements were inextricably linked and the acceptability of the arrangements had to be considered in the round.

The Panel noted Hospira's submission that it manufactured and marketed a number of biosimilars. The Panel queried whether there was a *bona fide* need for advice such as to justify the advisory board meeting in question. The Panel noted that the advisory board ran from 2.30 – 6pm on Monday, 13 July. It was stated that the advisory board would focus on key issues including gaining advice and insights to uptake of biosimilars in the UK, including the recently licensed Inflectra; examining current challenges and perceived benefits of biosimilars that pharmacists experience; discussing educational and communication needs around biosimilars in the UK (eg new materials, communication, raising physician awareness and confidence in biosimilars etc); additional areas of interest to Hospira; and sharing what they hoped to achieve from the site tour the following day including questions that they would like to be answered. The Panel did not consider that sharing what delegates hoped to achieve from the site tour was a legitimate objective for an advisory board which should address *bona fide* questions of the company, not of the attendees. There did not appear to be a clear *bona fide* issue upon which Hospira had sought advice which necessitated an advisory board, nor had the anticipated role of the participants in the advisory board been made sufficiently clear in the invitation and elsewhere. In the Panel's view, despite the subheading 'Advisory Board planned agenda' some of the bullet points beneath including 'Discussing educational and communication needs ...' and 'sharing what you hope to achieve from the Zagreb tour …' did not make it sufficiently clear that the company was seeking advice. Some recipients might have considered that they were being invited to participate in a discussion forum or such like. The Panel noted that the advisory board meeting notes listed no further actions for Hospira and there was an emphasis on finding out the position of delegates' NHS bodies in relation to switching to Inflectra. There appeared to be little substantive discussion of all of the stated objectives. In addition, the Panel noted Hospira's submission that in error the delegates had not been provided with a contract setting out the nature of the services to be provided as required by the Code. The Panel was concerned that the time spent obtaining advice appeared to be limited and further no preparation was needed. Hospira had not argued that this element of the meeting was anything other than an advisory board. Taking all the factors into account the Panel did not consider that the arrangements were such that the UK health professionals had attended a genuine advisory board meeting. A breach of the Code was ruled.

The Panel noted that whilst the manufacturing site visit took the whole day, it only included approximately three and a half hours of educational content. The Panel queried whether it was really necessary for the health professionals to travel to Croatia to be reassured about the manufacturing quality of Hospira products. In the Panel's view detailed information about the manufacturing facility could have been incorporated into a meeting held in the UK. The Panel considered that Hospira had effectively organised an overseas promotional meeting for UK health professionals.

The Panel noted that the average total cost of hospitality was approximately £450 per person plus economy airfares. The cost of the two evening meals in Croatia were £24.14 and £37.18 per head.

The hotel used was not appropriate. The Panel noted Hospira's submission that it understood that at the time, the hotel was a four-star hotel and there was no longer nor at the time of the meeting a casino; the only complimentary guest facilities were a gym and swimming pool/spa. The hotel was described in material provided by Hospira as 'the finest hotel in Zagreb' and that it was until recently a member of the 'Leading Hotels in the World'. The hotel was a 45 minute transfer from the manufacturing site; accommodation nearer to the manufacturer should have been used. In the Panel's view, the location and facilities were more akin to leisure travel than business purposes and would have attracted delegates to attend. The Panel was very concerned that the venue had been chosen without further assessment of its acceptability in the context of UK requirements.

The Panel considered that whilst the subsistence alone had not been excessive, the total hospitality provided was out of proportion to the occasion (ie overseas location, the venue and three nights' accommodation). The total educational content was approximately 7 hours including three and a half hours for the advisory board. The Panel noted its comments on the content of the meeting above. The Panel considered that hosting UK delegates for a two day promotional meeting in Croatia, in circumstances where the Panel did not consider that there was any clear and cogent reason for holding the meeting outside the UK was unacceptable and an inducement to prescribe or recommend Hospira products. A breach of the Code was ruled.

The Panel considered that, as it had ruled the arrangements did not meet the criteria for advisory boards, UK health professionals had been invited to attend a two day promotional meeting in Croatia, the primary objective of which appeared to be to increase their confidence in the manufacturing quality of Hospira products. The Panel noted its comments above and given the lack of a clear and cogent reason to hold the meeting outside the UK, ruled a breach of the Code.

The cost of the two dinners were each within the limits in the Croatian Code (HRK500 (£52)) and therefore no breach of the Code was ruled.

The Panel noted its criticisms of the meeting and rulings set out above and ruled a breach as high standards had not been maintained.

The Panel was very concerned to note that although the meeting (and materials) were approved and certified by Hospira at a European level, the meeting including the venue, the decision to take UK health professionals overseas and the majority of the materials were not reassessed and certified in the UK. The Panel noted that overall the company had exercised poor governance in relation to the arrangements including the failure to issue contracts and failure to certify an overseas meeting for health

professionals. In addition health professionals had been taken overseas without there being valid and cogent reasons for so doing. This was compounded by the inclusion of an advisory board which failed to meet the requirements of the Code. The Panel considered that the overall arrangements was such as to bring discredit upon and reduce confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

The Daily Telegraph of Wednesday, 17 February 2016 carried an article critical of the activities of pharmaceutical companies in relation to payments to senior NHS staff ('NHS officials with second jobs at drugs firms' continued under the heading 'How drugs firms give NHS officials trips abroad at top hotels for £1000 a day'). The article named Hospira in relation to the arrangements for a meeting held in Croatia. In accordance with Paragraph 6.1 of the Constitution and Procedure the matter was taken up as a complaint under the Code.

COMPLAINT

The Daily Telegraph article at issue named Hospira and stated that it hosted officials in a five-star hotel in Zagreb which had a spa and casino.

When writing to Hospira, the Authority provided it with a copy of The Daily Telegraph article at issue and asked it to respond in relation to Clauses 2, 9.1, 18.1, 22.1, 22.2 and 23.1 of the 2015 Code. The 2016 Constitution and Procedure applied.

RESPONSE

Hospira submitted that the trip to Zagreb encapsulated a manufacturing site visit and an advisory board.

Hospira stated that with regard to the meeting in question it had engaged third party service providers in connection with its interactions with health professionals and/or corporate travel requirements:

- a healthcare communications agency, to assist with the logistical arrangements for the meeting including travel arrangements for delegates and paying for travel, accommodation, food and beverages and other reasonable expenses for the delegates (in accordance with Hospira's policy on interactions with health professionals) on Hospira's behalf. These costs and expenses were then reimbursed by Hospira.

- a corporate travel agent, to book the Zagreb hotel.

- a company signatory, to assist with the review and approval of the interactions with health professionals and the associated materials. In particular the agency acted as business signatory from a Code perspective. The named signatory notified to the PMCPA and the MHRA, was a licensed medical practitioner.

Hospira submitted that, neither it nor its communications agency paid any fees or honoraria to the delegates; the only transfers of value to the delegates were the payment of travel, accommodation and food/beverage costs and other reasonable expenses. Although the Daily Telegraph referred to a five-star luxury spa hotel with casino, Hospira noted that there was no longer, nor at the time of the meeting, a casino at the hotel and the only complimentary guest health facilities were a gym and swimming pool/sauna. The agreed bed and breakfast rate was €130/night. The hotel currently described itself as a five-star venue (there was no longer an independent international star classification for hotels) but when the meeting was held Hospira understood that the hotel was a four-star hotel and it was still assessed as a four-star hotel by some booking websites.

Hospira explained that it held the meeting in Zagreb because one of its key biosimilar product manufacturing sites was located there. Biosimilar products were relatively novel and so awareness of, and confidence in them was still being established amongst health professionals. Hospira therefore generally considered it was an important and valuable educational opportunity (for all stakeholders) for the prescribers and procurers of these products in different countries to have the opportunity to gain confidence as to the quality of Hospira's biosimilar manufacturing sites (such as that in Zagreb). Likewise, with respect to the advisory board element of the meeting, it was helpful to Hospira to further understand the professional barriers and/or challenges health professionals might have with respect to the purchasing and/or prescription of biosimilar products. The discussions during the manufacturing site visit generally focussed on Hospira as a manufacturer of biosimilar products, the manufacturing processes for those products and biosimilars as a class of products as a whole.

Clause 23.1

Hospira submitted that due to an employee's misunderstanding of the relevant corporate policy, no contracts were agreed with the delegates in connection with this meeting. The employee mistakenly considered that as no fee and/or honorarium was paid, no contract was required. Hospira accepted that this was not in compliance with Clause 23.1, however it emphasised that it had a clear corporate policy requiring appropriate written contracts to be entered into with all health professionals who acted as consultants to the company. Template contracts for this purpose were readily available to all Hospira employees on an easy to use self-service website.

Hospira submitted that its internal policy on advisory boards required a legitimate need to be identified in advance and approved by the applicable country manager as part of the overall approval process for advisory boards. In this case the legitimate need was for Hospira, which manufactured and marketed of a number of biosimilars to gain insight from key stakeholders within significant NHS trusts with respect to challenges facing biosimilars and ways to facilitate their future uptake.
Hospira submitted that given the above identified

need the selected consultants were chosen based on their standing as NHS procurement/ logistics pharmacists with a significant role in the commissioning process for biosimilar products.

Hospira submitted that it intended to have 10 to 12 delegates and so assuming that some invitations would be declined, 17 were issued (a list of invitees was provided). Ultimately 5 delegates (names provided) attended the meeting which was sufficient to achieve the identified need with respect to the advisory board. Also at the meeting were three Hospira employees and one employee from the healthcare communications agency.

Hospira submitted that the meeting notes it took with respect to the delegates' discussions and comments had been retained for future reference (copy provided).

Hospira submitted that the invitation to each delegate (copies provided) made it clear that the invitation was not offered as an inducement, furthermore the delegates were not paid for their participation in the advisory board or manufacturing site visit. The hospitality provided to the delegates was not excessive, it was in accordance with the Code and not an inducement to prescribe.

Hospira submitted that its written contracts contained a provision regarding the obligation of the consultant to declare that he/she was a consultant to the company whenever he/she wrote or spoke in public about a matter that was the subject of the agreement or any other issue relating to that company (template contract provided). However, as stated above, due to an employee's error, no contracts were put in place in this instance. Moreover, the consultants who participated in the meeting at issue were not retained to write or speak in public with regard to the meeting.

Clause 22

As further detailed below Hospira accepted that there was an omission in terms of the approval and certification process for the meeting at issue (and the associated materials used in connection with it) in that the meeting (and materials) were approved and certified by Hospira at a European level in accordance with the principles of the EFPIA Code of Conduct, however, the majority of the materials were not reassessed and recertified under the UK Code. However, Hospira submitted that the requirements of the Code as set out in Clause 22.1 were nevertheless met with respect to this event.

All hospitality provided to the delegates (who were all health professionals) was in association with the advisory board and manufacturing site visit. The venues for the meeting were a meeting room within the hotel for the advisory board and Hospira's Zagreb manufacturing facility for the site visit. Hospira noted that careful consideration was given at a European level to the selection of an appropriate hotel for this event (in accordance with Hospira's policy on interactions with health professionals). As noted above, at the time, Hospira's understood that the hotel was a four-star hotel and was both the most centrally located and offered the cheapest bed and breakfast rate of the three hotels considered at €130/ night. Hospira listed two other hotels considered in planning for the meeting and stated that one was rejected from further consideration as it was a five-star hotel. The hotel used was then selected by the Hospira UK team without further assessment of its acceptability in the context of UK requirements.

Hospira noted that the timing of the single Zagreb/ UK return flight each day (12.30pm) was such that a second night of accommodation was required as it would not have been possible to conclude the second day's planned activities in time for that day's return flight. The UK departure flight at 8.35am required delegates to stay overnight (Sunday) at a Heathrow hotel. The Heathrow hotel was a four-star hotel and the room rate for the delegates was £110 a night. Hospira considered this further supported the company's appropriate approach to the provision of hospitality to health professionals.

Hospira noted that advisory boards and manufacturing site visits were described in the supplementary information to Clause 22.1 in the Code as being appropriate meetings for a company to have with health professionals.

Hospira confirmed that the costs of meals provided to the delegates at the Zagreb hotel did not exceed the amount referred to in Clause 22.1 as evidenced by the hotel invoice (copy provided). With respect to the two evening meals at restaurants in Zagreb, the healthcare communications agency confirmed payments to the two restaurants of £217.30 and £302.25. Hospira confirmed that the costs per person for those meals (£24.14 and £37.78 respectively) did not exceed the amount referenced in Clause 22.2 of the Code.

Clause 18

Hospira submitted that no gifts, pecuniary advantages or benefits were supplied, offered or promised to the delegates other than the value of the travel, accommodation and expenses in connection with the meeting which were paid for by Hospira – none of which were supplied, offered or promised as an inducement to prescribe, supply, administer, recommend, buy or sell any medicines. In particular no fees or honoraria were paid to the delegates in connection with any aspect of the meeting.

Clause 9

Hospira submitted that while it always strove to maintain high standards, it recognised that there were some specific compliance errors that had occurred. Nevertheless Hospira submitted that it maintained high standards with respect to its interactions with health professionals in general and specifically with respect to this meeting as a whole as evidenced in part by Hospira's detailed policies and procedures which were established to maintain those high standards.

Clause 2

Hospira submitted that with a few specific exceptions it had generally organised and undertaken the advisory board and manufacturing site visit in accordance with the Code. It took compliance with the Code (and other applicable laws, regulations and industry codes of practice) very seriously and had implemented systems and procedures and trained its employees to ensure that it was compliant. By way of example, Hospira provided attendance records for an external training session on the Code for UK employees in September 2015.

Hospira submitted that the meeting did not prejudice patient safety or public health, the hospitality offered was not excessive, there were no inducements to prescribe, delegates were not paid and the conduct of its employees and agents was generally competent.

Hospira submitted that The Daily Telegraph article was misleading in that it mistakenly stated that the hotel had a casino when the meeting was held, it implied that the Hospira delegates were paid fees when they were not and that the delegates might have had spa treatments at Hospira's expense which they did not; the article ignored the fact that manufacturing site visits and advisory boards were entirely legitimate interactions between industry and health professionals and in this case the manufacturing site provided a rare and valuable opportunity for the delegates to further their scientific and professional understanding of biosimilar products which would have an important role to play in the UK healthcare system. Hospira thus denied a breach of Clause 2.

Hospira submitted that the delegates were selected on the basis of their status as pharmacists in the UK whose roles encompassed quality assurance and procurement of pharmaceutical products, and in particular biologic/biosimilar products.

Hospira submitted that the meeting was held for two reasons, to combine a site visit to Hospira's biologics manufacturing site and an advisory board about Hospira's biosimilar products. Hospira intended that the delegates would share the training received during the site visit on the high standards of the manufacturing of Hospira biologics with their peers and communicate Hospira's adherence to those high standards. Hospira's intention was that the advisory board would enable it to obtain advice from the delegates about how to further facilitate the uptake of biosimilar products in the UK and allow it to understand the challenges these pharmacists faced in daily practice, the likely challenges relating to biosimilar use and educational and communication needs related to biosimilar use in the UK.

Hospira submitted that no contracts were entered into with the delegates on the basis that no honorarium or fee was paid to any delegate. Hospira explained that its policy on interactions with health professionals was very clear in its absolute requirement for detailed contracts to be entered into with attendees at advisory boards (Hospira had template contracts for this purpose which were readily available to all employees). Accordingly the decision not to implement contracts with these delegates was a mistaken interpretation of the policy by the individual who arranged this aspect of the advisory board and site visit.

Hospira submitted that it was 'valid and cogent' to invite the delegates to its Zagreb manufacturing site in order that they could be directly exposed to, and experience the high standards of the manufacturing of Hospira biologics, which could then be shared with their peers to communicate Hospira's adherence to those high standards.

Hospira submitted that no materials were sent out to the delegates after the event – internal notes of the advisory board which were distributed in-house were provided.

Hospira noted that the meeting (and the associated materials shared with the delegates – copies provided) was fully approved and certified at a European level but only partially approved and certified from a UK Code perspective.

The programme was as set out in an agenda (copy provided). Hospira submitted that there was minimal leisure time for the delegates and there were no Hospira organised leisure activities.

Hospira reiterated that no fees or honoraria were paid to the delegates. All airfares, accommodation and meals in-country were paid for by the communications agency and subsequently reimbursed by Hospira. The only expenses incurred directly by the delegates (and subsequently reimbursed by the communications agency on behalf of Hospira) were train tickets, taxi or personal mileage and airport parking costs to cover the delegates' journeys to and from the UK airport from their home address.

Hospira reiterated that no fees were paid and economy airfare was provided. The advisory board was held in a private meeting room at the hotel and the manufacturing site visit was held in private at Hospira's Zagreb manufacturing site. Dining was in public in a quiet section of the relevant restaurant. Neither Hospira nor the communications agency paid for any services from the hotel on behalf of the delegates (or reimbursed any expenses to delegates in connection with the hotel) other than room and food/beverage costs as detailed in the hotel invoice and expenses spreadsheet.

Hospira submitted that in accordance with typical market practices certain aspects of the hotel leisure facilities were complimentary to all guests (in particular use of gym facilities and swimming pool/sauna), however Hospira did not know if any of the delegates made use of any of the hotel leisure facilities. Hospira understood that use of the hotel leisure facilities or services other than the gym or swimming pool/sauna (ie spa treatments or similar) required payment by guests and was not included in room rates.

Hospira submitted that it had not organised any other similar Zagreb manufacturing site visits and advisory boards meetings.

In response to a request for further information, Hospira submitted that the advisory board produced a productive and valuable discussion which might have slightly over-run the allocated time; Hospira attendees recollected that it might have finished closer to 7pm than 6pm. Hospira did not have a breakdown of timings for each of the topics however the advisory board was a roundtable discussion in which each of the topics received approximately equal discussion. The meeting started with a short 30 minute presentation to the delegates (copy provided) and the remaining time was spent receiving feedback from the delegates.

Whilst two delegates attended from the same NHS trust, they had very different roles and so it was valid and cogent reasons for both to attend. One attendee was a deputy director of pharmacy with an over-arching role and able to provide feedback from a more strategic perspective. In contrast, the other delegate was a pharmacist who focused on more operational issues.

The primary rationale for holding the meeting in Zagreb was the manufacturing site visit for which Hospira approached 17 potential delegates on the assumption that, following the likely decline of some invitees (due to prior commitments, potential lack of interest etc), approximately 10-12 would be able to attend, which would allow for two groups of up to 6 at the manufacturing site. In certain parts of the facility (ie viewing windows onto clean rooms etc) a group of more than 6 was impractical. Similarly, due to the sterile nature of the manufacturing facility, all visitors had to change in and out of protective clothing which was time-consuming. Therefore, there was a maximum number of visitors for whom this was practical. The primary aim of trying to recruit 10-12 delegates for the meeting was therefore to attempt to maximise the number of individuals who could participate in this educational opportunity. Ultimately 6 delegates accepted the invitation although one subsequently dropped out.

Separately, Hospira considered five delegates was sufficient to achieve the identified need of the advisory board; if 10-12 had accepted, the additional perspectives in the advisory board meeting would have been welcomed but the feedback from the five who attended was useful. As stated above, no fees were paid to any of the advisory board participants.

Hospira noted that differences in timings noted in the documentation provided related to the agenda set out on the initial delegate invitation and the final updated agenda (copy provided) which was produced once delegates had responded to the invitation and (given the number of acceptances) it was confirmed that the manufacturing site tour would be undertaken by a single group.

Hospira understood that the delegates arrived back at the hotel on Tuesday, 17 July approximately in accordance with the final agenda (ie at around 4.15pm). The intention was that between 4.15-7pm, delegates could catch up with work commitments (ie check and respond to emails, take telephone calls etc). Hospira did not arrange any additional services at the hotel or any tours of Zagreb.

Hospira noted that the final agenda confirmed that the time allotted for lunch during the factory tour was 1 hour 15 minutes. This time was necessary because the lunch was served in an office building onsite but separate to the manufacturing facilities. Additionally, the delegates had to have time to take off protective clothing before lunch. The lunch menu was exactly the same as the staff lunch (this was not an out of pocket cost paid to a third party as the delegates were simply offered a staff meal that was paid for as part of the manufacturing site's normal operating expenses). Hospira could not state what was specifically provided to the delegates but there was usually a salad or vegetable choice and a meat and vegetarian option, bread and fruit or cake as dessert with water, soft drinks, tea or coffee.

Hospira was unable to retrospectively state what other flight times were available to it – however as stated above, the only realistic return flight time was 12.30pm. It appeared that there were currently two carriers operating directly between London Heathrow and Zagreb. One of these appeared to offer a later daily return flight at 5.50pm, however, in Hospira's view, this would be unworkable in terms of ensuring the manufacturing site visit could be completed and an airport transfer undertaken in time to check-in and board for this flight on the same day as the manufacturing site visit; and if this flight was available at the time of the meeting it would have meant returning with a different carrier to the outbound journey which would have significantly increased the delegate travel costs.

Hospira stated that no subsistence was provided to the delegates during the overnight stay at Heathrow and no Hospira or communications agency personnel met the delegates on the Sunday night. The first interactions between Hospira/ communications agency personnel and the delegates were during the hotel check-out and/or airport check-in on the Monday morning.

Hospira stated that the Croatian Code was not specifically considered during the approval process for the meeting. However, having now reviewed the Croatian Code, Hospira considered that it had complied with its provisions in relation to subsistence. The Croatian Code required the use of 4-star (rather than 5-star) hotels, but as explained above, Hospira colleagues believed that the hotel at issue was a 4-star hotel when it was selected.

Hospira stated that it had not arranged any other such meetings for UK health professionals and has not arranged any similar standalone advisory boards either in the UK or elsewhere.

Hospira stated that it realised in September 2015 that no consultancy agreements had been issued to the delegates.

Hospira stated that no breakdown of beverage costs was available, however the only bar beverages purchased for delegates (ie drinks provided to delegates not directly in association with a meal or the advisory board or manufacturing site visit) were those on the hotel invoice on 13 July and these were just hot and cold soft drinks purchased for the delegates and Hospira/communications agency attendees on arrival at the hotel. The only drinks provided to delegates during the advisory board and/or manufacturing site visit were hot and cold soft drinks.

Hospira submitted that the hotel was primarily chosen on the basis of a pre-planning visit by Hospira regional personnel who considered different Zagreb hotels against various criteria including suitability from the perspective of Hospira's compliance with applicable regulations and codes, location (for example convenience for walking to evening meal venues rather than incurring taxi costs and off-road parking facility for bus transfer drop-off/pick-up) and quality of meeting room/business facilities.

Hospira stated that having considered these criteria and ensured that they were satisfied, the final selection of the hotel was based on price (vs other options) however, as stated above, this was not the only criteria involved in its selection. There was a mistaken assumption by the Hospira UK team that because the acceptability of the hotel had already been considered at a European level (in relation to EFPIA Code requirements) there was no need to undertake a further assessment of its acceptability in the context of UK-specific requirements (such as the Code).

In conclusion, Hospira reiterated that with a few specific exceptions it generally organised and undertook this advisory board and manufacturing site visit in accordance with the Code. Hospira took its compliance with the Code (and other applicable laws, regulations and industry codes of practice) very seriously and had implemented systems and procedures and trained its employees to ensure that it was compliant.

PANEL RULING

The Panel noted the allegations as set out in The Daily Telegraph article of 17 February and the company's responses. In the Panel's view, it had to consider the acceptability of the advisory board and tour of the manufacturing site, including their overseas location and the level of hospitality.

The Panel noted that it was acceptable for companies to contract health professionals and others for relevant advice. Nonetheless, the arrangements for such meetings had to comply with the Code, particularly Clause 23. To be considered a legitimate advisory board the choice and number of participants should stand up to independent scrutiny; each should be chosen according to their expertise such that they would be able to contribute meaningfully to the purpose and expected outcomes of the advisory board. The number of participants should be limited so as to allow active participation by all. The agenda should allow adequate time for discussion. The number of meetings and the number of participants should be driven by need and not the invitees' willingness to attend. Invitations to participate should state the purpose of the advisory board meeting, the expected advisory role and the amount of work to be undertaken. If an honorarium was offered it should be made clear that it was a payment for such work and advice. Honoraria must be reasonable and reflect the fair market value of the time and effort involved.

Turning to the meeting at issue the Panel noted that it was wholly for UK health professionals; the delegates comprised five pharmacists. Two delegates were from the same hospital's NHS trust. The Panel noted that the delegates were not paid any honoraria. In addition three Hospira staff attended and an employee of the healthcare communications agency. The Panel queried whether the ratio of Hospira staff to delegates was appropriate. The Panel noted Hospira's submission that the delegates were selected on the basis of their status as UK pharmacists with a role in quality assurance and procurement of medicines, and in particular biologic/biosimilars. In the Panel's view the primary aim of trying to recruit 10-12 delegates for the meeting appeared to be driven by an attempt to maximise the number of individuals who could participate in the visit to the manufacturing site, rather than the number of consultants necessary to achieve the identified need of the advisory board. The Panel noted that in making allowance for the possibility that some invitations would be declined, Hospira initially invited 17 potential delegates. The Panel queried, however, why no-one from Wales or Northern Ireland was invited given Hospira's submission that the purpose of the advisory board was to seek advice on how to further facilitate the uptake of biosimilar products in the UK, the challenges these pharmacists faced in daily practice and the likely challenges relating to biosimilar use, and educational and communication needs related to biosimilar use in the UK. The Panel further noted Hospira's submission that five delegates was sufficient to achieve the identified need of the advisory board and that if 10-12 delegates had accepted, the additional perspectives in the advisory board meeting would have been welcomed but the feedback from the five who attended was useful. The Panel noted its general comments on the acceptable number of participants in an advisory board above.

The Panel noted Hospira's submission that the purpose of the meeting was to combine a site visit to Hospira's Zagreb biologics manufacturing site and an advisory board associated with Hospira's biosimilars. The Panel noted that it was in Hospira's commercial interest for the NHS to be confident in the manufacture of Hospira medicines. The Panel queried whether it was ever acceptable to combine two company meetings such that a company's products were promoted at part of the meeting and another part was a genuine advisory board. The Panel noted that the invitation for the meeting invited the reader to a site visit of the manufacturing facility at Zagreb, Croatia, on Monday 13 July to Wednesday

15 July. The invitation further stated 'You will have a tour of the Hospira manufacturing facility and you will also take part in an advisory board during your visit'. The Panel noted that the agenda was entitled 'Agenda and Plan for Hospira UK, Zagreb Manufacturing Site Tour'. All of the expenses claim forms were also entitled 'Hospira Manufacturing Facility Site Visit Expenses Form'. It appeared to the Panel that more emphasis was placed on the visit to the manufacturing site and gaining confidence in the quality of that site rather than the advisory board.

The Panel noted that the supplementary information to Clause 22 stated that meetings organised by pharmaceutical companies which involved UK health professionals at venues outside the UK were not necessarily unacceptable. There had, however, to be valid and cogent reasons for holding meetings at such venues. These were that most of the invitees were from outside the UK and, given their countries of origin, it made greater logistical sense to hold the meeting outside the UK or, given the location of the relevant resource or expertise that was the object or subject matter of the meeting, it made greater logistical sense to hold the meeting outside the UK. As with meetings held in the UK, in determining whether such a meeting was acceptable or not, consideration must also be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience, subsistence provided and the like. As with any meeting it should be the programme that attracted delegates and not the associated hospitality or venue.

The Panel was concerned that the primary justification for holding the meeting outside the UK appeared to be to allow UK pharmacists to conduct due diligence on Hospira's manufacturing facilities. In any event, in the Panel's view, the acceptability of the visit to the manufacturing site could not be considered separately to the rest of the meeting. The two elements of the meeting were inextricably linked and the acceptability of the arrangements had to be considered in the round.

The Panel noted Hospira's submission that it manufactured and marketed a number of biosimilars. The Panel queried whether there was a *bona fide* need for advice such as to justify the advisory board meeting in question. The Panel noted that the advisory board ran from 2.30-6pm on Monday, 13 July. It was stated that the advisory board would focus on key issues including gaining advice and insights to uptake of biosimilars in the UK, including the recently licensed Inflectra; examining current challenges and perceived benefits of biosimilars that pharmacists experience in daily practice; discussing educational and communication needs around biosimilars in the UK (eg new materials, communication, raising physician awareness and confidence in biosimilars etc); additional areas of interest to Hospira; and sharing what they hoped to achieve from the site tour the following day including questions that they would like to be answered. The Panel did not consider that sharing what delegates hoped to achieve from the site tour the following day was a legitimate objective for an advisory board which should address *bona fide* questions of the company, not of the attendees. On the material before the Panel there did not appear to be a clear *bona fide* issue upon which Hospira had sought advice which necessitated an advisory board, nor had the anticipated role of the participants in the advisory board been made sufficiently clear in the invitation and elsewhere. In the Panel's view, despite the subheading 'Advisory Board planned agenda' some of the bullet points beneath the subheading including 'Discussing educational and communication needs ...' and 'sharing what you hope to achieve from the Zagreb tour ...' did not make it sufficiently clear that the company was seeking advice. Some recipients might have considered that they were being invited to participate in a discussion forum or such like. The Panel noted that the advisory board meeting notes listed no further actions for Hospira and there was an emphasis on finding out the position of delegates' NHS bodies in relation to switching to Inflectra. There appeared to be little substantive discussion of all of the stated objectives. In addition, the Panel noted Hospira's submission that in error the delegates had not been provided with a contract setting out the nature of the services to be provided as required by Clause 23.1. The Panel was concerned that the time spent obtaining advice appeared to be limited and further no preparation was needed. Hospira had not argued that this element of the meeting was anything other than an advisory board. Taking all the factors into account the Panel did not consider that the arrangements were such that the UK health professionals had attended a genuine advisory board meeting. It therefore ruled a breach of Clause 23.1.

The Panel noted that delegates departed for the manufacturing site at 9.15am on Tuesday, 14 July and arrived back at the hotel at 4.15pm. The Panel noted that the tour of the manufacturing facility lasted two hours following a half hour introductory video which described the tour and a half hour welcome. After lunch on-site there was a 1 hour discussion about the development of the manufacturing facility and production in Zagreb and other feedback/queries following the tour. The Panel noted that whilst the manufacturing site visit took the whole day, it only included approximately three and a half hours of educational content. The Panel queried whether it was really necessary for the health professionals to travel to Croatia to be reassured about the manufacturing quality of Hospira products. In the Panel's view detailed information about the manufacturing facility could have been incorporated into a meeting held in the UK. The Panel considered that Hospira had effectively organised an overseas promotional meeting for UK health professionals.

The Panel noted that the average total cost of hospitality was approximately £449.40 per person plus economy airfares. The cost of the two evening meals in Croatia were £24.14 and £37.18 per head. The Panel noted Hospira's submission that it had not provided any subsistence on the night of Sunday, 12 July.

The hotel used was not appropriate. The Panel noted Hospira's submission that it understood that at the

time, the hotel was a four-star hotel and there was no longer nor at the time of the meeting a casino and the only complimentary guest facilities were a gym and swimming pool/spa. The hotel, however, was described in material provided by Hospira as 'the finest hotel in Zagreb' and that it was until recently a member of the 'Leading Hotels in the World'. The hotel was a 45 minute transfer from the manufacturing site; accommodation nearer to the manufacturer should have been used. In the Panel's view, the location and facilities were still more akin to leisure travel than business purposes and would have attracted delegates to attend. The Panel was very concerned that the venue had been chosen without further assessment of its acceptability in the context of UK requirements.

The Panel considered that whilst the subsistence alone had not been excessive, the total hospitality provided was out of proportion to the occasion (ie overseas location, the venue and three nights' accommodation). The total educational content was approximately 7 hours including three and a half hours for the advisory board for which three nights' accommodation was provided. The Panel noted its comments on the content of the meeting above. The Panel considered that hosting UK delegates for a two day promotional meeting in Croatia, in circumstances where the Panel did not consider that there was any clear and cogent reason for holding the meeting outside the UK was unacceptable in relation to the requirements of Clause 18.1 and an inducement to prescribe or recommend Hospira products. A breach of Clause 18.1 was ruled.

The Panel considered that, as it had ruled the arrangements did not meet the criteria for advisory boards, UK health professionals had been invited to attend a two day promotional meeting in Croatia, the primary objective of which appeared to be to increase their confidence in the manufacturing quality of Hospira products. The Panel noted its comments above and given the lack of a clear and cogent reason to hold the meeting outside the UK, ruled a breach of Clause 22.1.

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 Croatian Code were relevant. The Panel noted the Croatian limit of HRK500 (£52) and that £24.14 and £37.18 was spent per head for dinner (excluding tax and gratuities) on the two evening meals. This was in line with the local limit for a meal and therefore no breach of Clause 22.2 was ruled.

The Panel noted its criticisms of the meeting and rulings set out above and considered that high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel was concerned to note that although the meeting (and materials) were approved and certified by Hospira at a European level against the principles of the EFPIA Healthcare Professional Code the meeting including the decision to take UK health professionals overseas and the majority of the materials were not reassessed and certified at a UK-specific level in accordance with the UK Code. The Panel was very concerned to note that the hotel used was selected by the Hospira UK team without further assessment of the acceptability of that hotel in the context of UK requirements. The Panel noted that overall the company had exercised poor governance in relation to the arrangements including the failure to issue contracts and failure to certify an overseas meeting for health professionals. In addition health professionals had been taken overseas without there being good and cogent reasons for so doing. This was compounded by the inclusion of an advisory board which failed to meet the requirements of the Code. The Panel noted that the supplementary information to Clause 2 stated that, *inter alia*, one activity likely to be in breach of Clause 2 was an inducement to prescribe. The Panel noted its comments above and its ruling of a breach of Clause 18.1 and thus considered that the overall arrangements including holding the meeting in question in Croatia was such as to bring discredit upon and reduce confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel was very concerned about the arrangements and the apparent lack of governance as set out above. Nonetheless, the Panel also noted that the meeting happened some seven and a half weeks before the company was acquired by Pfizer Inc and approximately nine months before Hospira joined the list of non member companies that have agreed to comply with the Code. In the exceptional circumstances of this case, and on balance, the Panel decided not to report Hospira to the Code of Practice Appeal Board for it to consider in accordance with Paragraph 8.2 of the Constitution and Procedure.

During its consideration of this matter the Panel requested that Hospira be reminded of the disclosure requirements as set out in the Code.

Complaint received **17 February 2016**

Case completed **5 July 2016**