

THE DAILY TELEGRAPH/DIRECTOR v STIRLING ANGLIAN

Arrangements for a meeting

The Daily Telegraph of Friday, 24 July 2015 carried a number of articles critical of the activities of pharmaceutical companies in relation to payments to senior NHS staff. An article in The Daily Telegraph on 25 July named Stirling Anglian in relation to a meeting held in Germany. In accordance with Paragraph 6.1 of the Constitution and Procedure the matter was taken up as a complaint under the Code.

When notified of the complaint Stirling Anglian was provided with a copy of two articles ('The NHS officials paid, wined and dined on spa trip', and 'Doctors may have to declare links to drug companies') and an editorial ('Health Worries') which were all published in The Daily Telegraph 25 July 2015. These articles formed the basis of the complaint.

When informed by the PMCPA case preparation manager that the article 'The NHS officials paid, wined and dined on spa trip' would be taken up under the Code, one of the authors confirmed that the reports spoke for themselves. The journalist was willing to be involved to the extent of considering any questions from the PMCPA.

The Daily Telegraph articles of 24 July stated that senior health officials who helped decide which medicines were used by GPs and hospitals were '... being paid to work as consultants to pharmaceutical companies that want the NHS to "switch" to medicines they produce'. The articles headed 'NHS bosses paid by drug firms' and 'Lavish trips laid on by drugs firms to "sway" NHS staff' referred to an undercover reporter's findings. One article named two pharmacists one of whom was head of medicines management at a named clinical commissioning group (CCG) who attended a meeting in Germany at which a company took 12 'payers' to 'one of the top 10 hotels in the world'.

One of the articles reported that the named pharmacist who was head of medicines management claimed that each delegate was paid £500 a day to attend and all of those invited 'switched' to the company's product after the trip. The named pharmacist was reported as stating the attendees were treated to dinner at a 'flashy' restaurant and up to '£1,000 worth of champagne'. The report stated that the named pharmacist did not consider the ABPI Code applied once 'you're outside the country'. The savings to the NHS and that there was a clinical benefit were also mentioned.

The Daily Telegraph of 25 July, which named Stirling Anglian in an article headed 'The NHS officials paid, wined and dined on spa trip', included details about the arrangements; it stated that health officials attended a luxury trip hosted by a pharmaceutical company lobbying to get its products used by the

NHS. It referred to a dozen senior staff, some of whom were named, who were taken to Baden-Baden, Germany. In the article a named pharmacist described the event as 'superb' and 'all the delegates came back with a glow'. They were paid £500 per day to attend and 'all the guests switched to the pharmaceutical company's products following the trip'. Three of the attendees were quoted as stating that 'no switches were made as a result of the meeting and decisions were made because drugs were cost effective or benefited the patient'. The article included photographs of the hotel which the named pharmacist described as 'one of the top 10 hotels'. The article stated that the PMCPA would be examining whether '... the trip had breached the rules' and that the Code stated that 'lavish, extravagant or deluxe venues must not be used'.

The second article 'Doctors may have to declare links to drug companies' and the editorial 'Health worries' referred to the meeting but discussed broader issues of NHS culture and disclosure of payments.

The detailed response from Stirling Anglian is given below.

The Panel noted that it was a well established principle under the Code that a pharmaceutical company was responsible for the actions of third party agents acting on behalf of that company. Stirling Anglian was responsible under the Code for the activities of its agents these being the third party named in the article and the manufacturer in relation to all the arrangements for the meeting in question.

The Panel noted that it was acceptable for companies to pay 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.

As stated in the supplementary information to Clause 22, Meetings and Hospitality, there had to be valid and cogent reasons for holding meetings at venues outside the UK.

The Panel noted Stirling Anglian's conflicting submissions regarding the selection criteria. Stirling Anglian submitted that selected delegates included those who, *inter alia*, had questions about its manufacturing facilities and supply chain and that the meeting gave attendees the opportunity to conduct due diligence on the supply chain and manufacturing partners. The Panel noted that those were not valid selection criteria for advisory boards which should address *bona fide* questions of the company, not of the attendees.

The Panel examined the agenda. The meeting appeared to have two distinct parts; the morning lasted 2 hours plus an hour for lunch. It started with an hour on 'Operating and Company History'. This was followed by an hour on 'Presentation SAP' by Stirling Anglian. Half the group then toured the 'Production and Laboratory' with 'Highlight Macrogol filling lines' followed by lunch and the remainder of the group had lunch then the tour.

The afternoon meeting started at 13.30 with 'Questions and discussions on what you have seen today'. This was followed by two group discussions each of 45 minutes on CosmoCol and theiCal-D3. 'The Pipeline: Innovation, Tackling specials, new products and technology' was discussed for 15 minutes. The last session was 30 minutes on 'What have we learned today?', 'What action will you undertake on your return to the UK as a consequence of this event?' and 'If I were SAP I would Please complete the sentence'. All the discussions were group discussions other than the last session which was 'delegates in turn' and all discussion were 'facilitated by [the third party]'. The meeting closed at 16:00.

The Panel noted that the dedicated time on the agenda for the attendees to provide advice was not clear and allowing time for group discussions did not appear to be sufficient. Even if it were, this amounted to less than 2 hours (13:45 – 15:30).

The Panel noted that the description of the accommodation and evening meal in The Daily Telegraph article was different to that submitted by Stirling Anglian. The Panel noted that a letter drafted by Stirling Anglian's lawyers and signed by the named pharmacist retracted comments in relation to certain elements of hospitality referred to in the article. The letter stated that the comments made to the undercover reporter 'were false or grossly exaggerated' and he wished to correct the public record. The letter referred to the role of the third party in identifying various health professionals and experts in medicines management to provide advice to Stirling Anglian about how best to raise awareness of the company, its manufacturing/supply chain credentials and its medicinal products. It referred to Stirling Anglian paying economy airfare and £500 per day for attending. Hotel accommodation, dinner

entertainment and ground transportation were paid by the manufacturer. The statement explained that delegates stayed in a straightforward business hotel near to Stirling Anglian's manufacturer's factory and a room at the hotel cost approximately £130 a night. He stated that he had grossly exaggerated when stating that the hotel was "probably the best in Baden Baden", that in the rooms "the waste bins were gold plated" and that the rooms of any delegate had a jacuzzi. There was no factual basis to state that the hotel "was top 10 in the world". The statement that a £1,000 was paid for champagne during the dinner entertainment on 2 July 2015 was inaccurate. The cost of the dinner (including any drinks) was approximately £70 per person. The statement concluded that the author had no reason to believe Stirling Anglian had breached the ABPI Code.

The Panel noted with concern Stirling Anglian's submission that advisory boards were a 'necessary and indeed entirely appropriate mechanism to engage with our customers and build awareness of our products'. Further that questions about the supply chain was a '*bona fide* reason for holding an advisory board in Germany'. The Panel noted that advisory boards were not an appropriate way to engage with customers and build awareness of products. The purpose must be for the company to obtain advice on *bona fide* questions.

The Panel examined the report on the meeting and was concerned that it, in parts, treated the entire meeting as an advisory board.

The meeting report noted that delegates all agreed that the trip was well executed, enjoyable and sociable. They did not feel, however, that the level of hospitality was in any way excessive. They appreciated the hospitality and enjoyed the presentations and factory tour. Some remarked that they were highly delighted to have been invited. There was unanimous agreement that every delegate would attend another advisory board of this type, if invited! The meeting report noted that the format of the advisory board was similar to the boards which were very successful. The manufacturer presented the history of the business, factory capacity and quality which produced a number of questions and comments. There was acknowledgement of good capacity for manufacturer and supply. There was a good degree of interest around twin dosing and resulting improved efficiency. One delegate mentioned use of calcium and vitamin D3 in caplet form, but stated the problem due to the total number of caplets per day. A third delegate stated at this point CosmoCol would be a particularly easy switch to make offering cost savings, improved flavour and improved range of flavours. Discussion around shelf life of CosmoCol was very positive.

The meeting report noted that a presentation was given by Stirling Anglian detailing pricing, product range and pipeline. Samples of theiCal-D3 were handed out. This prompted discussion round cost, savings and the advantage of once daily dosing. Discussion moved onto other pipeline products and

returned to Macrogol pricing. It was acknowledged that Stirling Anglian had driven down Macrogol prices in the UK. Certain other specific questions were raised at this point including on price, supply guarantee and questions on communications around pipeline products.

The factory tour of the plant was thought to be interesting and useful by all delegates.

The advisory board commenced after a buffet lunch and delegates were invited to respond to various questions including:

‘What do you think about the meeting so far?’

‘How important do you feel it is to visit the factory in Germany? Could this be achieved by an advisory board in the UK?’

‘Prior to this meeting had you heard of Cosmocol?’ and ‘What are your thoughts on action on return?’

The Panel was concerned that the questions and responses received indicated that this was not a *bona fide* advisory board. Responses referred to generous hospitality, that the visit to the factory in Germany was essential and switching to CosmoCol. Two of the delegates were not aware of CosmoCol prior to the meeting.

The discussion then switched to the theiCal-D3. Questions included: ‘What are your thoughts on theiCal-D3?’ and ‘What are your barriers to change?’

The Panel noted that responses included comments about the benefit of the once daily dosage regime and palatability. In general, delegates preferred this option to multiple doses of caplets. Comments around the favourable price point were received and widely acknowledged. Some delegates requested personal information around savings for their CCG, which Stirling Anglian agreed to provide.

The report then referred to a specific question from a delegate around future pipeline products from Stirling Anglian and their proposed costings. Stirling Anglian replied by giving approximate dates for proposed products which were desired by the delegates and their proposed costs were warmly anticipated.

The Panel noted that the question ‘What will your general actions be on return?’ was put to each delegate individually and according to the meeting report most of the answers included favourable comments about CosmoCol and switching and/or amending guidelines. There were also references to the theiCal-D3 switch programme. There was only one negative comment in relation to the prohibitive cost of a switch to CosmoCol.

The Panel noted the details of the presentations and discussions in the meeting report. The report appeared in parts to treat the whole meeting as an advisory board.

The Panel noted the company’s submission that the meeting arrangements combined a factory visit with an advisory board and that the payment was for the advice received. It appeared to the Panel that according to the report, more emphasis was placed on the visit to the manufacturers and building confidence in Stirling Anglian and its products and understanding what the attendees’ actions were on returning from the meeting rather than a genuine advisory board. Further, it was difficult to understand what advice was sought and would be obtained from the attendees, two of whom had attended another advisory board in another German city.

The Panel noted Stirling Anglian’s submission that this was the fifth such meeting held at the manufacturing site and five other advisory boards had been held. The Panel did not have the agendas or other information about these other meetings but considered that if there was any similarity in the agendas it was difficult to see how this number of meetings could be justified. In addition, 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 meeting for UK health professionals was held outside the UK and, as noted above, there had to be valid and cogent reasons for holding such meetings outside the UK. The Panel was concerned that the primary justification for holding the meeting outside the UK was the need for NHS staff to conduct due diligence on Stirling Anglian’s manufacturing facilities and supply chain. The Panel noted the tour of the manufacturing facilities lasted an hour and queried whether in the particular circumstances of this case it was really necessary for the health professionals to travel to Germany to be reassured about the products and their supply. It would have been preferable for the manufacturers to come to the UK or to present using remote technology.

The Panel considered that overall the arrangements were not a valid advisory board: It was of concern that payment was received for 2 days at £500 per day rather than just for that part of the meeting (one afternoon) that Stirling Anglian described as the advisory board element. On the material before the Panel there did not appear to be a clear unequivocal issue upon which Stirling Anglian had sought advice which necessitated an advisory board; nor had the role of the participants in relation to the advisory board been made clear in the email invitation and elsewhere. The Panel noted its general comments above about the arrangements for the meeting. The Panel was especially concerned that at the end of the advisory board participants addressed what they would do differently as a result of the meeting which, in the Panel’s view, demonstrated that the primary focus of the day was in providing information to and influencing participants rather than the provision of advice to the company. The time spent obtaining advice appeared to be extremely limited and further no preparation was needed. Taking all the factors into account the Panel did not consider that the arrangements either

for the whole day or just the afternoon were such that the UK health professionals had attended a genuine advisory board meeting. It therefore ruled a breach of the Code.

The Panel considered that, as it had ruled the arrangements did not meet the criteria for advisory boards, UK health professionals had been paid to attend a meeting where medicines were promoted including pipeline products. This was unacceptable. In addition, the payment was for two days and not limited to what Stirling Anglian described as the advisory body element. Further, it appeared that as a result of attending the meeting, health professionals' general actions indicated that switches to Stirling Anglian's products would be instigated. The Panel considered that the meeting was an inducement to recommend Stirling Anglian's medicines. A breach of the Code was ruled.

The Panel noted that the third party was providing services on behalf of Stirling Anglian. The Panel noted that under Clause 21 contracts under which institutions, organisations, or associations provided any type of service were only allowed if such services or other funding were, *inter alia*, not an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. The Panel noted its ruling above of a breach and thus considered that the service amounted to an inducement. The Panel noted that Stirling Anglian had not exercised due diligence over the service. A breach of the Code was ruled.

The Panel then considered the level of hospitality. It was concerned that irrespective of whether it was justifiable to visit the manufacturer, the arrangements were unacceptable. There was no need for the delegates to stay in Baden-Baden. Accommodation nearer to the manufacturer should have been used. The hotel used was not appropriate, it appeared to be a lavish and deluxe venue. The location and facilities were still more akin to leisure travel than business purposes. The Panel was also concerned about the cost of dinner. Stirling Anglian's submission was inconsistent in this regard. The Panel noted the receipts for the pre-dinner drinks at the hotel which cost €447. Stirling Anglian submitted that this was not for the UK invitees but for staff from Stirling Anglian, the manufacturers and the third party. The Panel noted that the latter submission appeared to be inconsistent with an earlier submission which clearly stated on an agenda '18.30 meet at the Hotel... welcome drink 19.30 Dinner at the Restaurant...'. Overnight accommodation cost €199.

The Panel noted that the bill for the evening meal, twenty four people attended the dinner at a cost per head (excluding tax and gratuities) of £71.43.

The Panel did not consider that the hospitality was secondary to the main purpose of the event ie subsistence only. The level was not appropriate and was out of proportion to the occasion. Further, the costs exceeded the level that recipients would normally adopt when paying for themselves. A breach of the Code was ruled.

The Panel noted the supplementary information to the code Maximum Cost of a Meal which included the financial 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 German Code were relevant. The Panel noted the German limit of €60 and that around €100 or £71.43 was spent per head for dinner (excluding tax and gratuities). This was in excess of the local limit for a meal and therefore a breach of the Code was ruled.

The Panel considered that, overall, high standards had not been maintained and a breach of the Code was ruled.

The Panel noted that Clause 2 was reserved for use as a sign of particular censure. The health professionals that attended the meeting had received a payment for two days at £500 per day in connection with the promotion of medicines including pipeline products. The Panel noted that unacceptable payments was listed in the supplementary information to Clause 2 as an example of an activity likely to be in breach of that Clause. The Panel was extremely concerned that the role of the participants had not been made clear in the invitation or elsewhere. The Panel was also extremely concerned about the poor impression given by all of the arrangements. It noted its rulings above regarding the hospitality. Given Stirling Anglian's ultimate responsibility for all of the arrangements including those parts organised by the third party and its manufacturing partner, the company did not appear to have exercised due diligence and ensured that third party activities met the requirements of the Code. The Panel considered that the arrangements brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel noted its comments and rulings above and considered that its concerns about the arrangements and the company's procedures warranted consideration by the Appeal Board. The Panel thus reported Stirling Anglian to the Appeal Board in accordance with Paragraph 8.2 of the Constitution and Procedure.

The Appeal Board was very concerned about the profound lack of Code expertise and oversight within Stirling Anglian that had allowed the meeting to go ahead. In the Appeal Board's view the arrangements for the meeting had been shambolic.

The Appeal Board noted that the company had accepted the rulings of breaches of the Code including a breach of Clause 2 and that it had stopped organising advisory boards until it was confident that it had appropriate oversight. The Appeal Board further noted the company's genuine contrition and that it had commissioned an external agency to audit its processes. Further the company had appointed a new general manager, was updating its procedures, training staff and considering employing compliance expertise.

Nonetheless, the Appeal Board was extremely concerned that UK health professionals had attended the meeting on the false understanding that it was an advisory board and had been paid to do so. This was unacceptable. Consequently, the Appeal Board decided, in accordance with Paragraph 11.3 of the Constitution and Procedure, to require Stirling Anglian to issue a corrective statement to all the UK attendees at the meeting. The corrective statement should refer to the case report. Under Paragraph 11.3 details of the proposed content and mode and timing of dissemination of the corrective statement must be provided to the Appeal Board for approval prior to use. [The corrective statement, which was agreed by the Appeal Board prior to use, appears at the end of this report].

The Appeal Board also decided, given its serious concerns about the conduct of Stirling Anglian as set out above, to require, in accordance with Paragraph 11.3 of the Constitution and Procedure, an audit of the company's procedures in relation to the Code, to take place in January 2016. On receipt of the audit report, the Appeal Board would consider whether further sanctions were necessary.

On receipt of the report of the audit and the company's comments in February 2016, the Appeal Board was encouraged by Stirling Anglian's willingness to improve its procedures and processes to comply with the Code, but noted from the report that significant progress was needed.

The Appeal Board was extremely concerned that despite a report that highlighted deficiencies in the company's knowledge and understanding of the Code and its failures with respect to compliance, Stirling Anglian had not provided any detail on when and how it would address those matters.

Stirling Anglian subsequently provided a further detailed response as requested. The Appeal Board was concerned that in an action plan some actions were marked as active with no indication of the expected date of completion. The Appeal Board decided that the company should be re-audited in June 2016 at which point it would be expected to demonstrate significant improvement.

Stirling Anglian was audited in June 2016 and although the Appeal Board was encouraged that the audit highlighted that Stirling Anglian had made meaningful improvements in compliance and that much work had been done, it also noted that there was still more to do. Stirling Anglian needed to ensure that its progress to date was maintained and built upon.

The Appeal Board decided that Stirling Anglian should be re-audited in April/May 2017 at which point the Appeal Board expected it to be able to demonstrate further and sustained improvement.

At its meeting in June the Appeal Board considered the report of the May 2017 re-audit and noted that the company's standard operating procedures (SOPs) were due to be reviewed and updated by August and it decided that Stirling Anglian should

provide the PMCPA with the outcome of its review, evidence of training and any new SOPs by early September.

On receipt of Stirling Anglian's response the Appeal Board considered that the PMCPA should ask Stirling Anglian to further amend its SOPs in light of certain concerns. On the basis that this work was completed promptly, the progress shown to date was continued and a company-wide commitment to compliance was maintained, the Appeal Board decided that, on balance, no further action was required.

The Daily Telegraph of Friday, 24 July 2015 carried a number of articles critical of the activities of pharmaceutical companies in relation to payments to senior NHS staff. An article in The Daily Telegraph on 25 July named Stirling Anglian in relation to a meeting held in Germany. In accordance with Paragraph 6.1 of the Constitution and Procedure the matter was taken up as a complaint under the Code.

When notified of the complaint Stirling Anglian was provided with a copy of two articles ('The NHS officials paid, wined and dined on spa trip', and 'Doctors may have to declare links to drug companies') and an editorial ('Health Worries') which were all published in The Daily Telegraph 25 July 2015. These articles formed the basis of the complaint.

When informed by the PMCPA case preparation manager that the article 'The NHS officials paid, wined and dined on spa trip' would be taken up under the Code, one of the authors confirmed that the reports spoke for themselves. The journalist was willing to be involved to the extent of considering any questions from the PMCPA.

The Daily Telegraph articles of 24 July stated that senior health officials who helped decide which medicines were used by GPs and hospitals were '... being paid to work as consultants to pharmaceutical companies that want the NHS to "switch" to medicines they produce'. The articles headed 'NHS bosses paid by drug firms' and 'Lavish trips laid on by drugs firms to "sway" NHS staff' referred to an undercover reporter's findings. One article named two pharmacists one of whom was head of medicines management of a named clinical commissioning group (CCG) who attended a meeting in Germany at which a company took 12 'payors' to 'one of the top 10 hotels in the world'.

One of the articles reported that the named pharmacist who was head of medicines management claimed that each delegate was paid £500 a day to attend and all of those invited 'switched' to the company's product after the trip. The Daily Telegraph reported that it had the names of the 12 attendees. The named pharmacist was reported as stating the attendees were treated to dinner at a 'flashy' restaurant and up to '£1,000 worth of champagne'. The report stated that the named pharmacist did not consider the ABPI Code applied once 'you're outside the country'. The savings to the NHS and that there was a clinical benefits were also mentioned.

A Daily Telegraph article of 1 August referred to 'Watchdog wants NHS whistleblowers to highlight fears over payments from drugs firms' and that the Director of the PMCPA called on 'industry figures to pass on complaints to help it "deal with these issues"'.

COMPLAINT

The Daily Telegraph of 25 July named the pharmaceutical company involved, Stirling Anglian, in an article headed 'The NHS officials paid, wined and dined on spa trip'. The article included details about the arrangements; it stated that health officials from across England attended a luxury trip hosted by a pharmaceutical company lobbying to get its products used by the NHS. It referred to a dozen senior staff, some of whom were named, who were taken to Baden-Baden, Germany. In the article a named pharmacist described the event as 'superb' and 'all the delegates came back with a glow'. They were paid £500 per day to attend and 'all the guests switched to the pharmaceutical company's products following the trip'. Three of the attendees were quoted as stating that 'no switches were made as a result of the meeting and decisions were made because drugs were cost effective or benefited the patient'. The article included photographs of the hotel which the named pharmacist described as 'one of the top 10 hotels'. The article stated that the PMCPA would be examining whether '... the trip had breached the rules' and that the Code stated that 'lavish, extravagant or deluxe venues must not be used'.

The second article 'Doctors may have to declare links to drug companies' and the editorial 'Health worries' referred to the meeting but discussed broader issues of NHS culture and disclosure of payments.

When writing to Stirling Anglian the Authority asked it to respond in relation to Clauses 2, 9.1, 18.1, 21, 22.1, 22.2 and 23.1 of the Code.

RESPONSE

Stirling Anglian stated that it took the issues raised very seriously and was disappointed that it had been associated with unfair, exaggerated and inaccurate reporting as depicted in The Daily Telegraph articles on 23 and 24 July 2015. It engaged external counsel and its manufacturer was also considering its legal position. The company was very surprised to see the comments of the Director of the PMCPA in an article on The Daily Telegraph website on 31 July which made specific reference to this case. Stirling Anglian submitted that such comments compounded the damage to its reputation.

As a recently formed small pharmaceutical company which aimed to grow in the face of fierce competition, Stirling Anglian submitted that conducting advisory boards in Germany was an entirely appropriate way to engage with health professionals, raise awareness of its products and build confidence in the supply chain. Stirling Anglian refuted any allegation that its actions were in breach of the Code. In particular, it could not

be held accountable under Clause 2 for bringing the pharmaceutical industry into disrepute on the basis of unfounded comments made by a third party. Under the principle established by the European Court of Justice in the Damgaard case (Case C-421/07), the third party was responsible under medicine advertising rules for its comments and respectfully suggested that the PMCPA took this specific matter up with the third party. Stirling Anglian did not see where its actions or those of its manufacturers had been such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry; it acted appropriately at all times and it was the subject of unfair, exaggerated and inaccurate reporting. This matter was taken up with the applicable editors and journalists of the journals that had reported this issue.

Stirling Anglian submitted it had no case to answer and therefore was not in breach of Clause 2. A recent email from the named pharmacist of the third party explaining his actions was provided.

Clause 9.1

Stirling Anglian submitted that it had conducted itself in accordance with the highest standards of professional conduct and had complied with the Code in all aspects of its advisory board meeting, factory visit and payments of honoraria to NHS personnel attending the event and providing expert advice.

The company was disappointed to be named in reports which it considered were unfair, exaggerated and inaccurate. Advisory board meetings were standard practice within the industry. The Code expressly allowed such meetings and factory visits to take place.

Furthermore, given that one of the manufacturing sites for CosmoCol was in Germany, it had valid and cogent reasons for holding such advisory boards in Germany. As a recently formed company, and in light of other companies failing to ensure continuity of supply at considerable cost to the NHS, potential customers continually asked its representatives about the supply chain arrangements including manufacturing partners, product quality and security of supply. For this reason, it arranged advisory boards at its manufacturing partner's factory, allowing customers to conduct due diligence as appropriate. This was a *bona fide* reason for holding an advisory board in Germany and allowable under the Code.

Stirling Anglian provided honoraria in line with advice on customary industry practice and economy class air fares. Again, these payments were within the Code and as far as it was aware, properly declared by delegates.

The German manufacturing partner provided hotel accommodation and an evening meal nearby together with ground transportation in Germany and meeting room facilities at its factory. Stirling Anglian was fully aware of its responsibilities under the Code. It discussed its obligations under the Code

with the German manufacturers, including the level and nature of the hospitality that was permitted and the details of the programme. Stirling Anglian and the German manufacturers understood that the hospitality provided was within both that guidance and the applicable German rules.

Clause 18.1

Stirling Anglian stated unequivocally that no gifts, pecuniary advantage or benefit was supplied, offered or promised to attendees at the advisory board, in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. Stirling Anglian strongly denied any such suggestion or allegation and further, there was no evidence whatsoever of such practices.

Hospitality was provided by its German manufacturer as explained above but there was never any expectation that this was in return for a recommendation to prescribe its medicines (as clearly stated in contracts with the attendees). The honoraria paid were in line with industry standards in recognition of delegates' expertise and advice provided during the advisory board. These payments were of course then subject to each individual providing a declaration of interest to their employing authority, a matter over which the company had no control.

Clause 21

Stirling Anglian submitted that in the context of the advisory board at issue, held on 3 July, it did not engage with any 'institutions, organisations or associations of health professionals under which such institutions, organisations or associations provide any type of services' on its behalf.

Stirling Anglian engaged only with a named third party (a private company which provided advisory board services) and 12 individual health professionals. Further details of these arrangements were given elsewhere, however, the modest honoraria paid was purely for the advice received and did not in any way constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. Stirling Anglian strongly refuted any such suggestion.

Clause 22.1

Stirling Anglian submitted that one of the primary reasons for the meeting was to provide delegates the opportunity to conduct due diligence as appropriate on Stirling Anglian's manufacturing facilities and supply chain. As the manufacturer's plants were in Germany, the advisory board had to be held there and given journey times from the UK, it was necessary to provide attendees with one night's hotel accommodation.

Accommodation, breakfast and an evening meal were provided and paid for by its manufacturer. The hotel in Baden-Baden was near to the factory and where the manufacturer usually hosted guests to the

facilities. The hotel was relatively small and did not have in-house leisure facilities, although facilities were available from third party providers nearby. Neither Stirling Anglian nor its manufacturer were aware of delegates' use of any such leisure facilities and did not pay for any. Further, due to the very tight timeline and the focus of the advisory board meeting and the factory visit, it would have been virtually impossible for the delegates to have engaged in leisure activities.

Stirling Anglian understood the costs incurred by its manufacturer were reasonable and within the Code. It was told that the accommodation cost was around £130 per room per night.

The manufacturer provided meeting room facilities at the plant (where the advisory board was held), together with a tour of the factory.

Twelve UK health professionals attended the advisory board, along with staff of Stirling Anglian (two), manufacturer's staff (eight for part of the meeting) and third party organisers (two). The names of the delegates and other attendees were provided.

Clause 22.2

Stirling Anglian did not host or pay for any meals or accommodation during the advisory board. Rather, it was hosted by its manufacturer which provided and paid for all meals and accommodation during the visit.

The manufacturer paid for modest drinks, which were ordered individually and dinner at a restaurant in Baden-Baden on 2 July 2015, ahead of the factory tour on 3 July 2015. The guests were provided with a preselected reduced menu with a main course price range of £13 – 24. The average overall costs of the dinner for the whole party including starters, main courses, desserts and all drinks amounted to approximately €70. Further details and a breakdown were provided.

Clause 23.1

Stirling Anglian submitted that a group of health professionals was invited to Germany to:

- give the attendees the opportunity to conduct due diligence on Stirling Anglian's supply chain and manufacturing partners;
- provide advice on how best to raise awareness of Stirling Anglian and its medicinal products within the NHS; and
- provide advice in identifying other medicine needs within the NHS which Stirling Anglian might help address, in line with its vision of driving down costs, reducing waste and improving patient experience.

Delegates were selected on the basis of their interest in Stirling Anglian medicines and questions raised in relation to its manufacturing facilities. The third party invited the delegates from various NHS regions. The number of invitees was set at 12 to ensure a useful

discussion during the advisory board, but also to facilitate factory tours where numbers were limited. Stirling Anglian entered into a consulting agreement with each delegate which was specifically designed to reflect Code requirements. For example, it clearly stated that:

‘Consultant shall carry out the Services to the best of the Consultant’s ability in a professional manner and in compliance with all applicable laws, rules and regulations including all applicable anti-bribery and anti-corruption laws, the [ABPI Code of Practice for the Pharmaceutical Industry (the “Code”)], the British Healthcare Business Intelligence Association (“BHBA”) Legal and Ethical Guidelines for Healthcare Market Research and/or any other codes of practice applicable in the country where the Services are being carried out.

Consultant shall provide the Services for the ultimate benefit of Stirling Anglian Pharmaceuticals Ltd., (the “Company”). Consultant agrees that he/she shall declare that he/she is a consultant of the Company whenever he/she writes or speaks in public about a matter that is the subject of this Agreement or any other issue relating to the Company.’

and

‘Stirling Anglian Pharmaceuticals Ltd. shall reimburse Consultant for travel and out-of-pocket expenses incurred by Consultant in performing the Services provided such expenses are reasonable and necessary in connection with the Services and have been approved in advance by Stirling Anglian Pharmaceuticals Ltd. The Parties acknowledge and agree that fees payable under this Agreement are intended to represent fair market value for the Services to be provided hereunder. For the avoidance of doubt the payment of fees under this Agreement shall impose no obligation upon Consultant to promote or otherwise encourage the prescription, recommendation, purchase, supply, sale or administration of the products of the Company nor is it intended to reward past practices.’

Stirling Anglian stated that where a CCG added Stirling Anglian products to its formulary, this was done entirely on an arm’s length basis and purely on considerations of cost/benefit and in particular of patient care. Reports in the press to the contrary were inaccurate and without foundation.

Stirling Anglian engaged a third party private company to organise advisory boards on its behalf. Its services were limited to:

- recruitment of attendees;
- logistical support;
- chairing of advisory board meetings and
- provision of post-meeting review and summary of discussions.

In consideration for these services, Stirling Anglian paid a fee per advisory board. The letter confirming the terms of the engagement was provided.

Stirling Anglian stated that the third party invited a range of delegates from various NHS regions who expressed an interest in its products and had questions on its manufacturing facilities, supply chain etc, given it was a recently-formed company.

Stirling Anglian submitted that it was wholly legitimate for Stirling Anglian to raise its profile and seek guidance from health professionals on how best to raise awareness of its products with key staff. It was important that cost-effective and quality medicines were brought to the attention of key staff to allow decisions to be made to benefit patients.

It was also important to demonstrate to key NHS personnel the reliability of manufacturers and distributors of medicines provided by Stirling Anglian, so that there could be confidence in the continuity of the supply chain ie confidence that a patient prescribed one of Stirling Anglian’s medicines would not experience any difficulty in obtaining a supply. Stirling Anglian also took advice from these advisory boards on the sorts of products to be developed and how existing products might be improved.

Copies of correspondence between Stirling Anglian and the third party were provided and copies of contracts that Stirling Anglian had with the third party and with each delegate. In spite of reminders signed contracts were not received back from three of the delegates.

The meeting was initiated by Stirling Anglian in response to feedback and questions from customers and potential customers. The delegates were identified (based on the selection criteria above) and invited by the third party. The advisory board setting allowed Stirling Anglian to gather together a number of key NHS medicines management personnel in a single venue. As such this was seen as efficient time management as opposed to organising a number of separate meetings with individuals.

Stirling Anglian submitted this format was perfectly acceptable to the ABPI and it was common practice within the pharmaceutical industry and the NHS. The setting also allowed an open and frank discussion and sharing of ideas amongst NHS colleagues. As a result Stirling Anglian gained a much better insight into the needs of the NHS and patients which would be put to use in developing its product portfolio.

One of the sites where CosmoCol was manufactured was in Germany. As such it was appropriate to hold advisory board meetings in Germany at the plant where customers could conduct due diligence as appropriate. For NHS colleagues the factory visit and the chance to meet key people from the manufacturer and from Stirling Anglian were all viewed as being crucial in providing reassurance about the continuity of the supply chain for Stirling Anglian’s medicines.

In response to a question, Stirling Anglian stated that no materials were provided to the delegates during the meeting or afterwards. The only presentation slides used were those of the manufacturer, which comprised a company overview, details of its

capabilities and a description of the manufacturing process. A copy of the manufacturer's presentation was provided.

Stirling Anglian provided detailed account of the two day programme to include leisure time

2 July:

Travel from UK to Baden-Baden

18.30 Meet at the hotel in Baden-Baden.
Welcome drink

19.30 Dinner at the restaurant

3 July:

09:00 Travel to manufacturer plant

09:30 Introduction and presentation
by manufacturer

10:30 Presentation by Stirling Anglian

11:30 Group 1: Production & Laboratory Tour

11:30 Group 2: Lunch

12:30 Group 2: Production & Laboratory Tour

12:30 Group 1: Lunch

13:30 Advisory board discussion and questions

16:00 Shuttle back to the airport

It was an approximately two hour drive between Frankfurt Airport and the meeting venue and so it was impossible to schedule the event and travel into one day. The advisory board was held in a meeting room at Stirling Anglian's manufacturer's factory at Appenweier with lunch in a separate room.

In response to a question about certification, Stirling Anglian submitted that there were no materials which required certification.

In response to the request for a complete and comprehensive breakdown of all the hospitality provided to include incidental costs together with a copy of the receipted invoices and credit card receipts to show where bills were settled, Stirling Anglian submitted that as it did not provide the accommodation or sustenance it was unable to provide receipts. However, it was told by the manufacturer which met these costs that the hotel was €199 (around £130) per person per night and that the meal including starters, desserts, coffee and all drinks did not exceed £70 per guest. The meal was selected from a restricted menu with a main course price range of €13 -24 and given the heat and the long journey to reach the venue most guests retired early having mainly consumed soft drinks. Regarding the drinks, 26 bottles of mineral water, 32 aperitifs, 1 Coke, 4 bottles of red wine, 9 bottles of white wine, 1 glass of beer and 3 digestives were consumed by the group as a whole only half of whom were members of the advisory board, the rest of the group being representatives of the manufacturer, Stirling Anglian and the third party.

In response to a question about fees and travelling expenses an honoraria of £500 per day was paid by Stirling Anglian to each delegate in recognition of their expertise and advice provided during the advisory board.

Stirling Anglian also paid for economy class air travel between the UK and Frankfurt together with

out-of-pocket expenses. Details of the cost of each delegate's airfare and expenses were provided.

Stirling Anglian stated that it had held ten advisory boards since June 2013, five of which had been at the manufacturing site in Appenweier/Baden-Baden.

FURTHER INFORMATION FROM STIRLING ANGLIAN

In response to a request for further information Stirling Anglian reiterated that it took its compliance obligations very seriously. The company submitted that it had complied with the letter and spirit of the Code (as interpreted by various PMCPA cases on these matters) in relation to the advisory board meeting itself and this was reflected in the documents between participants and the third party. However, the company was infuriated by the untrue comments made by the named pharmacist about the arrangements and rationale for the meeting. The company referred to his email dated 13 August 2015 in which a retraction was made stating that 'a number of over enthusiastic and exaggerated comments' had been made.

Stirling Anglian also understood from the press reports that the relevant CCGs were checking to see whether the NHS officials who attended the meeting had complied with NHS standards of business conduct. Stirling Anglian submitted that the primary responsibility for ensuring that the delegates made the appropriate disclosures and obtained the right consents to work with Stirling Anglian rested with the individual delegates. Each CCG had its own guidance. The delegates represented and warranted to Stirling Anglian that they had complied with their NHS and other professional obligations.

Procedural comments/observations

Stirling Anglian asked that a number of procedural queries were addressed prior to the final determination. These included confirmation of the context in which the PMCPA provided comments to The Daily Telegraph in relation to the newspaper's article on 31 July 2015 ('Medicines watchdog calls for whistleblowers') whether The Daily Telegraph had provided a copy of the full video of the applicable interview with the named pharmacist and/or whether the PMCPA would be asking for a submission from the journalist responsible for the story. If so, it asked for a copy of the correspondence so that it had an opportunity to respond. Stirling Anglian stated it was seeking a retraction/clarification from The Daily Telegraph.

Stirling Anglian submitted that it (and no doubt other pharmaceutical companies using the third party's services) had been very badly let down by the untrue comments reported in The Daily Telegraph.

Stirling Anglian was fully aware of the PMCPA's position 'that a company was responsible for the actions of third parties employed on the company's behalf even if that third party acted outside the instructions from the pharmaceutical company'. However, without shirking its compliance obligations for the meeting itself, this principle could not

extend to situations where the agent/third party was genuinely 'off on a frolic of their own'. In this regard, Stirling Anglian referred to two reasons. Firstly, in making untrue comments to The Daily Telegraph (or anyone for that matter) the third party acted outside the terms of its engagement with Stirling Anglian. The company did not endorse the comments and nor did it authorize them. Secondly, nothing Stirling Anglian had seen from the reporting suggested that the comments were made to meet contractual obligations. Rather, Stirling Anglian understood that the comments were made to a journalist who pretended to represent an Indian pharmaceutical company which wanted to organize an advisory board on the Greek islands. This had nothing remotely to do with Stirling Anglian and the comments were not made to potential delegates attending Stirling Anglian advisory boards.

Stirling Anglian submitted that the second point above was a key issue from a vicarious liability perspective and it wanted to ensure that the PMCPA was aware of this nuance since it reflected the legal case law on this principle and therefore a body like the PMCPA exercising a public function must adhere to it during its decision-making process. Also, extending liability to situations where a third party was off on a frolic (as defined by the two factors above) was neither fair nor just and would result in an unreasonable interpretation of the Code.

For this reason, Stirling Anglian respectively suggested that the PMCPA also wrote to the third party in relation to the untrue comments made. There was a clear basis for the PMCPA to do this under the principle established in Damgaard and Stirling Anglian did not see any reason why the PMCPA could not invoke it (separately or in parallel to this complaint). However, the PMCPA might decide that the evidence provided to date to demonstrate that the comments were untrue was sufficient.

In response to additional questions from the Panel, Stirling Anglian accepted responsibility for the arrangements of the meeting but it could not be held liable or responsible under Clause 2 for the subsequent comments made by the named pharmacist and reported in The Daily Telegraph. It submitted that it had been very badly let down in this matter as had anyone using the third party to assist with advisory boards.

Stirling Anglian stated that the third party identified and proposed potential candidates who would be willing in principle to work with Stirling Anglian based on its knowledge and experience and in particular its healthcare contacts across the UK. As stated above, delegates were selected if they expressed an interest in Stirling Anglian's products and had questions about the company's manufacturing facilities, supply chain and so forth since Stirling Anglian was a recently formed company. The third party confirmed the delegates.

Stirling Anglian then invited delegates to the meeting enclosing a copy of the consultancy agreement and requesting certain information to make travel reservations. Copies of expense reports and

invoice of the delegates, which were filled out and sent to the third party were also provided. Copies were then emailed or posted to Stirling Anglian for reimbursement.

Stirling Anglian was not aware of any other communications between Stirling Anglian and the delegates or between the third party and the delegates.

Stirling Anglian stated that it emailed travel details and a copy of the two-day agenda to the delegates. This was followed up by two emails with further advice on weather conditions and dress code. A more detailed agenda was later provided to delegates by the third party. There was no pre-reading.

Stirling Anglian stated that the consultancy agreement was drawn up by the company to ensure all its engagements with consultants were properly regulated. The services were defined in paragraph 1 to describe the advisory board meeting, which included a tour of the manufacturing facility, presentations on the manufacturing issues as well as the products and how Stirling Anglian planned on positioning them, before group discussion, questioning and the rendering of advice. The agenda for the meeting set out the scope of the meeting in more detail.

As previously stated, the consultants were engaged for their experience and expertise in medicines management. The services provided included:

- advice on how best to raise awareness of Stirling Anglian, its manufacturing/supply chain credentials (hence the factory tour and presentation by Stirling Anglian's manufacturer on the various manufacturing techniques), and Stirling Anglian's medicinal products within the NHS; and
- advice in identifying other medicine needs within the NHS which Stirling Anglian might help address, in line with its vision of driving down costs, ensuring supply chain integrity and manufacturing excellence, reducing waste and improving patient experience.

Copies of the contracts had already been provided to the PMCPA. Stirling Anglian had also included certain provisions regarding compliance with the Code that it wished to highlight. However, additional provisions that Stirling Anglian submitted were important in light of apparent investigations by the NHS into transparency and declarations, could be found in clause 6 which made it clear that the delegates confirmed that their attendance and services complied with applicable NHS and professional rules governing outside employment.

There was no obligation on any participant to conduct market research within any other role on behalf of Stirling Anglian.

Stirling Anglian provided a copy of the final meeting report. As stated previously, no slides were used at the afternoon meeting. The objectives for the meeting as a whole were clearly stated previously.

There were no separate objectives for each separate session. The format of the report reflected the objectives. The report constituted the final record of the meeting as produced by the third party. Stirling Anglian held no further records of the discussion.

The report gave a detailed account of the meeting including comments on the hospitality, presentations in the morning, including the visit to the factory and the afternoon advisory board meeting. It detailed the delegates' opinions on Stirling Anglian, its products both licensed and pipeline and what attendees would do on their return. The report also referred to discussion about switches. The report concluded that '... this was a useful and fruitful event. Many positive actions should result directly from the discussions'. Attendees would all 'attend another advisory board of this type if invited'.

Stirling Anglian submitted that given its longstanding relationship with the manufacturer, Stirling Anglian handled interactions with it on behalf of the third party, including, for example, provision of delegates' names and other details (eg arrival times). The manufacturer then arranged local logistics, accommodation and meals. A detailed breakdown of the costs for the hotel and dinner was provided previously and receipts were now provided. The lunch was a light buffet with soft drinks (primarily water) and was hosted in the main office of the manufacturing facility. According to the manufacturer, the cost of the lunch per head was €20.80.

In relation to Stirling Anglian's policies and procedures prior to the company joining the list of non members that comply with the Code and accept the jurisdiction of the PMCPA in May 2015 Stirling Anglian submitted that it had interacted with colleagues in a manner compatible with the Code and would always endeavour to do so. Material and meetings were co-approved by senior members of Stirling Anglian's staff. Advisory boards were documented as complying with the Code and the company expected delegates and third parties also to comply with the Code (the company referred to the contract with the third party and also the consultancy agreement with delegates) as well as their own NHS codes and professional codes of conduct. Stirling Anglian reviewed a number of PMCPA rulings on various advisory boards over the last several years and firmly believed that its approach was consistent with the letter and spirit of those rulings. In that connection, Stirling Anglian cited three cases where the PMCPA found no breach; Case AUTH/2527/8/12, Case AUTH/2454/11/11 and Case AUTH/2113/3/08.

Stirling Anglian also cited one example of advisory boards that the PMCPA considered on balance did not stand up to scrutiny, eg because delegates were being promoted to more than advice being sought; Case AUTH/2290/12/09. Stirling Anglian believed that the manner in which it conducted its meeting was far removed from such examples and delegates had not complained in this regard. Any suggestion or impression that the purpose of the meeting was promotional could only be the result of the untrue reporting.

Stirling Anglian provided a copy of a letter signed by the named pharmacist who wished to correct the public record.

In response to a second request for further information Stirling Anglian submitted that its response detailed below was based on its recollection of events at the time and this did not always fit with the particulars of the restaurant bill because the bill was mixed with beverages enjoyed by representatives from the manufacturer after the UK delegates had left.

Stirling Anglian stated that the hotel bill was not for pre-dinner drinks but for drinks and snacks in relation to a separate and distinct meeting of representatives of the manufacturer who arrived early to discuss the details of the organisation of the evening and the arrangements for the following day and to make sure that all were present by the time the delegates arrived. This was held in a meeting room at the hotel and included representatives from Stirling Anglian and the third party who joined that group for a meeting to co-ordinate the activities for the following day and also to decide the seating plan for dinner.

Stirling Anglian stated that there were 24 attendees at the dinner and that it had provided as complete a list of attendees as it had. The restaurant bill of €3,164.30 was for the meal and accompanying drinks, including pre-dinner drinks/aperitifs and water. However, Stirling Anglian noted that several UK attendees left the dinner early and a number of the drinks were consumed by representatives from the manufacturer who stayed at the restaurant later. In reality, the UK delegates in the main (as well as Stirling Anglian representative [sic]) drank water or soft drinks given the extreme heat and humidity which people from the UK were not used to. Most of the wine was ordered 'for the table' by the manufacturer (as host) but left untouched. Therefore, the restaurant bill simply did not reflect the arrangements for the UK attendees. Rather, it included drinks consumed mostly by the 8 representatives from the manufacturer at the end of the meal which was entirely separate from the hospitality provided to the UK attendees. Also, the bill did not seem to include all the bottles of water consumed. In addition, Stirling Anglian recalled several of the UK delegates asking for soft drinks yet only one was billed.

For these reasons, Stirling Anglian submitted it was impossible to tell which items on the bill were attributable to the UK attendees and those which were consumed by representatives from the manufacturer who stayed on at the restaurant after the meal and paid the bill at the end of the evening. Stirling Anglian stated its original letter merely included the crude cost per head breakdown based on the figures it had at the time. Since reviewing the items on the bill in detail it was clear that there were some irregularities and that a large proportion of it related to drinks consumed after dinner by employees of the manufacturer. Details of the £70 cost per head calculation was provided.

Stirling Anglian understood that a house special aperitif was provided which was available as an alcoholic or non-alcoholic beverage. Thirty-two aperitifs were listed on the bill and Stirling Anglian assumed that the restaurant calculated this on the basis of the number of jugs ordered by the manufacturer. Not everyone had a glass (most had coffee or more water). Stirling Anglian did not see anything excessive or lavish about the house aperitif.

Stirling Anglian stated that its German manufacturer considered that the level of hospitality provided to the UK delegates at the restaurant was reasonable and what one would typically expect to receive in Germany. The German Code applied to members of the "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." (FSA) ("Voluntary Self-regulation for the Pharmaceutical Industry"). The manufacturer was not a member of the FSA but the position under the Code was the same in that hospitality must be reasonable and within socially-acceptable bounds. When arranging the menu for the dinner, the manufacturer restricted the menu to reasonable choices. This was also consistent with the feedback from the meeting itself (report) and supported by the fact that no UK attendees complained about the hospitality (or any aspect of this advisory board for that matter). This was also consistent with Stirling Anglian's interpretation of events. With the benefit of hindsight, it would have been preferable to have a completely separate bill for the dinner and a separate tab for drinks ordered by the manufacturer so that the cost could be clearly broken down.

Stirling Anglian stated that the only slides used during the morning presentation were those by the manufacturer (previously provided). No slides were used and there were no speaker's notes for the Stirling Anglian speaker who articulated the company's corporate vision and values. This was a relatively informal, scene-setting introduction to the company followed by an interactive discussion.

Stirling Anglian appreciated that the Panel thought that pre-reading might be useful but it simply was not necessary for every advisory board particularly when the company was asking for advice on matters that were well within their expertise. Also the most valuable advice was an expert's instant reaction to a series of questions put to them individually and as a group. In a small session scenario, this advice worked very well for Stirling Anglian and allowed the company to fine tune its positioning so that it had the robust messages in place when meeting commissioners, who often had an instant reaction to what Stirling Anglian told them. This approach might be in contrast to a situation where a clinician was asked to digest detailed clinical trial information with a view to advising on clinical trial design etc. In such circumstances, Stirling Anglian could appreciate the potential need for pre-reading but much depended on the circumstances.

In addition, Stirling Anglian emphasised that there were just 12 consultants as opposed to a situation where hundreds of consultants were present in an advisory board. This approach would have a traditional "meeting" environment and Stirling

Anglian would expect a Q&A session to be less useful since it would be general and non-specific. Stirling Anglian made these points because it noted the Panel's comments in Case AUTH/2747/1/15. Stirling Anglian emphasised that its arrangements for the meeting were very different to the situation in that case in various ways as described above. The company wanted to make it clear that it did not think there was a one-size-fits all approach to advisory boards in terms of precise time spent providing background information, the time spent in obtaining advice, how the advice was rendered and how the advice was digested by the company.

PANEL RULING

The Panel noted that Stirling Anglian had signed the form agreeing to join the list of non member companies that have agreed to comply with the Code and accept the jurisdiction of the PMCPA on 18 May 2015. The meeting at issue was held nearly 7 weeks after this agreement on 3 July. The Panel noted that the company's activities from 18 May 2015 including the meeting in question had to comply with the Code. The Panel also noted that in response to a question about what policies etc the company adhered to before 18 May 2015 to ensure such meetings met high ethical standards the company submitted that it had and would always endeavor to ensure that it interacted with colleagues in a manner compatible with the Code. There was no evidence that Stirling Anglian had reviewed activities and materials including the meeting arrangements on joining the non members list. In addition, the Panel noted that even before 18 May 2015 Stirling Anglian would have had to ensure that the arrangements complied with relevant UK legal requirements.

The Panel noted that Stirling Anglian had raised a number of procedural matters which the Panel considered in the usual way as part of its ruling.

The Panel noted Stirling Anglian's concern about another article on The Daily Telegraph website (31 July) which referred to this case and comments made by the Director of the PMCPA. The Daily Telegraph article referred to the Director calling upon 'industry figures to pass on complaints to help it [the PMCPA] "deal with these issues and problems"'. The article explained that the PMCPA had dealt with cases about advisory board meetings and if anyone had evidence of activities that they were concerned about in relation to the Code they should submit complaints to the PMCPA to be dealt with. The article then went on to refer to its recent coverage of advisory board meetings and that the PMCPA was 'currently carrying out an inquiry into a trip for NHS officials funded by ... Stirling Anglian to the German spa town of Baden-Baden'.

The Panel noted that in accordance with established procedure the Director provided a factual response to press enquiries. The ABPI had organised a press briefing to discuss disclosure of transfers of value and the development of the ABPI central platform for such disclosure. The Director of the PMCPA had been invited to present about the Code in general and a Daily Telegraph journalist at the meeting had asked relevant questions. The Panel did not accept that

very general factual comments by the Director that there had been breaches of the Code ruled in relation to advisory boards and the discrete factual comment that the PMCPA was taking action in the present case would be prejudicial or compounded the damage to Stirling Anglian's reputation as submitted by the company. As in the present case, the PMCPA never publicly commented on the merits of an ongoing case. The present case would be considered in the normal way in accordance with the Constitution and Procedure.

The PMCPA Constitution and Procedure was clear that when it appeared from media reports that a company might have breached the Code the matter was treated as a complaint. Like all complaints the matter would be judged on the evidence provided by the parties.

The Panel noted that in accordance with Paragraph 6.1 of the Constitution and Procedure one of the authors of The Daily Telegraph articles (25 July) was asked whether he/she wanted to be involved in the case and whether they had any additional information to submit. In response the journalist stated that the reports spoke for themselves but was willing to be involved to the extent that the journalist would consider any questions. If any further information was received from the journalist it would be sent to Stirling Anglian for comment prior to any consideration by the Panel.

The Panel noted that it was a well established principle under the Code that a pharmaceutical company was responsible for the actions of third party agents acting on behalf of that company and in this regard, it considered that Stirling Anglian was responsible under the Code for the activities of its agents these being the third party named in the article and the manufacturer in relation to all the arrangements for the meeting in question. The Panel also noted that even if Stirling Anglian did not consider the manufacturer to be its agent for the purpose of the meeting, Stirling Anglian was still responsible under the Code for ensuring that all of the meeting arrangements including those elements organised by the manufacturer complied with the Code. In addition, the Panel noted that it was in Stirling Anglian's commercial interest for the NHS to be confident in the supply chain for Stirling Anglian's medicines irrespective of which company manufactured those medicines.

The Panel noted Stirling Anglian's submission that it could not be held liable or responsible under Clause 2 for the subsequent comments made by the named pharmacist and reported in The Daily Telegraph. The Panel noted its comments above about Stirling Anglian's responsibility for its agents and third parties and noted Stirling Anglian's responsibility under the Code for the third party including Clause 2 matters was limited to its role in relation to organising the meeting. Subsequent comments as published in The Daily Telegraph were only relevant in so far as they formed part of the complaint to which Stirling Anglian could respond under the Constitution and Procedure.

The Code applied to pharmaceutical companies. The PMCPA had no jurisdiction with regard to taking matters up with third parties directly as mentioned by Stirling Anglian.

The Panel noted the allegations as set out in the articles and editorial in The Daily Telegraph of 25 July 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 facility, including their overseas location and the level of hospitality.

The Panel noted that it was acceptable for companies to pay 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.

As stated in the supplementary information to Clause 22, Meetings and Hospitality, there had to be valid and cogent reasons for holding meetings at venues outside the UK.

The Panel noted Stirling Anglian's conflicting submissions regarding the selection criteria. Stirling Anglian submitted that selected delegates included those who, *inter alia*, had questions about its manufacturing facilities and supply chain and that the meeting gave attendees the opportunity to conduct due diligence on the supply chain and manufacturing partners. The Panel noted that those were not valid selection criteria for advisory boards which should be to address *bona fide* questions of the company, not of the attendees.

The Panel examined the agenda. Participants were not required to do any pre-reading or other preparation and the Panel noted Stirling Anglian's submission on this point. The meeting appeared to have two distinct parts; the morning lasted 2 hours plus an hour for lunch. It started at 09.30 with an hour on 'Operating and Company History'. This was followed by an hour on 'Presentation SAP' by Stirling Anglian. At 11:30 half the group then took a tour of the 'Production and Laboratory' with 'Highlight Macrogol filling lines' followed by lunch and the remainder of the group had lunch then the tour.

The afternoon meeting started at 13.30 with 'Questions and discussions on what you have seen today'. This was followed by two group discussions each of 45 minutes on CosmoCol and theiCal-D3. 'The Pipeline: Innovation, Tackling specials, new products and technology' was discussed for 15 minutes. The last session was 30 minutes on 'What have we learned today?', 'What action will you undertake on your return to the UK as a consequence of this event?' and 'If I were SAP I would Please complete the sentence'. All the discussions were group discussions other than the last session which was 'delegates in turn' and all discussion were 'facilitated by [the third party]'. The meeting closed at 16:00.

The Panel noted that the dedicated time on the agenda for the attendees to provide advice was not clear and allowing time for group discussions did not appear to be sufficient. Even if it were, this amounted to less than 2 hours (13:45 – 15:30).

The Panel noted that the description of the accommodation and evening meal in The Daily Telegraph article was different to that submitted by Stirling Anglian. The Panel noted that a letter drafted by Stirling Anglian's lawyers and signed by the named pharmacist retracted comments in relation to certain elements of hospitality referred to in the article. The letter stated that the comments made to the undercover reporter 'were false or grossly exaggerated' and he wished to correct the public record. The letter referred to the role of the third party in identifying various health professionals and experts in medicines management to provide advice to Stirling Anglian about how best to raise awareness of the company, its manufacturing/supply chain credentials and its medicinal products. It referred to Stirling Anglian paying economy airfare and £500 per day for attending. Hotel accommodation, dinner entertainment and ground transportation was paid by the manufacturer. The statement explained that delegates stayed in a straightforward business hotel near to Stirling Anglian's manufacturer's factory and a room at the hotel cost approximately £130 a night. He stated that he had grossly exaggerated when stating that the hotel was "probably the best in Baden Baden", that in the rooms "the waste bins were gold plated" and that the rooms of any delegate had a jacuzzi. There was no factual basis to state that the hotel "was top 10 in the world". The statement that a £1,000 was paid for champagne during the dinner entertainment on 2 July 2015 was inaccurate. The cost of the dinner (including any drinks) was approximately £70 per person. The statement concluded that the author had no reason to believe Stirling Anglian had breached the ABPI Code.

The Panel noted with concern Stirling Anglian's submission that advisory boards were a 'necessary and indeed entirely appropriate mechanism to engage with our customers and build awareness of our products'. Further that questions about the supply chain was a '*bona fide* reason for holding an advisory board in Germany'. The Panel noted that advisory boards were not an appropriate way to engage with customers and build awareness of

products. The purpose must be for the company to obtain advice on *bona fide* questions.

The Panel examined the report on the meeting and was concerned that it, in parts, treated the entire meeting as an advisory board.

The meeting report noted that delegates all agreed that the trip was well executed, enjoyable and sociable. They did not feel, however, that the level of hospitality was in any way excessive. They appreciated the hospitality offered by the manufacturer and enjoyed the presentations and factory tour. Some remarked that they were highly delighted to have been invited. There was unanimous agreement that every delegate would attend another advisory board of this type, if invited! The meeting report noted that the format of the advisory board was similar to the boards which were very successful. The manufacturer presented the history of the business, factory capacity and quality which produced a number of questions and comments. There was acknowledgement of good capacity for manufacturer and supply. There was a good degree of interest around twin dosing and resulting improved efficiency. One delegate mentioned use of calcium and vitamin D3 in caplet form, but stated the problem due to the total number of caplets per day. A third delegate stated at this point CosmoCol would be a particularly easy switch to make offering cost savings, improved flavour and improved range of flavours. Discussion around shelf life of CosmoCol was very positive.

The meeting report noted that a presentation was given by Stirling Anglian detailing pricing, product range and pipeline. Samples of theiCal-D3 were handed out. This prompted discussion round cost, savings and the advantage of once daily dosing. Discussion moved onto other pipeline products and returned to Macrolog pricing. It was acknowledged that Stirling Anglian had driven down Macrolog prices in the UK. Certain other specific questions were raised at this point including on price, supply guarantee and questions on communications around pipeline products.

The factory tour of the plant was thought to be interesting and useful by all delegates.

The advisory board commenced after a buffet lunch and delegates were invited to respond to various questions including:

'What do you think about the meeting so far?'

'How important do you feel it is to visit the factory in Germany? Could this be achieved by an advisory board in the UK?'

'Prior to this meeting had you heard of Cosmocol?' and 'What are your thoughts on action on return?'

The Panel was concerned that the questions and responses received indicated that this was not a *bona fide* advisory board. Responses referred to generous hospitality, that the visit to the factory in

Germany was essential and switching to CosmoCol. Two of the delegates were not aware of CosmoCol prior to the meeting.

The discussion then switched to the theiCal-D3. Questions included: 'What are your thoughts on theiCal-D3?' and 'What are your barriers to change?'

The Panel noted that responses included comments about the benefit of the once daily dosage regime and palatability. In general, delegates preferred this option to multiple doses of caplets. Comments around the favourable price point were received and widely acknowledged. Some delegates requested personal information around savings for their CCG, which Stirling Anglian agreed to provide.

The report then referred to a specific question from a delegate around future pipeline products from Stirling Anglian and their proposed costings. Stirling Anglian replied by giving approximate dates for proposed products which were desired by the delegates and their proposed costs were warmly anticipated.

The Panel noted that the question 'What will your general actions be on return?' was put to each delegate individually and according to the meeting report most of the answers included favourable comments about CosmoCol and switching and/or amending guidelines. There were also references to the theiCal-D3 switch programme. There was only one negative comment in relation to the prohibitive cost of a switch to CosmoCol.

The Panel noted the details of the presentations and discussions in the meeting report. The report appeared in parts to treat the whole meeting as an advisory board.

The Panel noted the company's submission that the meeting arrangements combined a factory visit with an advisory board and that the payment was for the advice received. It appeared to the Panel that according to the report, more emphasis was placed on the visit to the manufacturers and building confidence in Stirling Anglian and its products and understanding what the attendees' actions were on returning from the meeting rather than a genuine advisory board. Further, it was difficult to understand what advice was sought and would be obtained from the attendees, two of whom had attended another advisory board in another German city.

The Panel noted Stirling Anglian's submission that this was the fifth such meeting held at the manufacturing site and five other advisory boards had been held, giving a total of 10 since 2013. The Panel did not have the agendas or other information about these other meetings but considered that if there was any similarity in the agendas it was difficult to see how this number of meetings could be justified. In addition, 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 meeting for UK health professionals was held outside the UK and, as noted above, there had to be valid and cogent reasons for holding such meetings outside the UK. The Panel was concerned that the primary justification for holding the meeting outside the UK was the need for NHS staff to conduct due diligence on Stirling Anglian's manufacturing facilities and supply chain. The Panel noted the tour of the manufacturing facilities lasted an hour and queried whether in the particular circumstances of this case it was really necessary for the health professionals to travel to Germany to be reassured about the products and their supply. It would have been preferable for the manufacturers to come to the UK or to present using remote technology.

With regard to the acceptability of meetings held outside the UK, the Panel noted the supplementary information to Clause 22.1 gave two examples including that 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. The supplementary information also stated that 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. In any event, in the Panel's view, the acceptability of the visit to the manufacturing facilities 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. This was especially so given that in parts of its response Stirling Anglian applied advisory board criteria to the entire day.

The Panel considered that overall the arrangements were not a valid advisory board: It was of concern that payment was received for 2 days at £500 per day rather than just for that part of the meeting (one afternoon) that Stirling Anglian described as the advisory board element. On the material before the Panel there did not appear to be a clear unequivocal issue upon which Stirling Anglian had sought advice which necessitated an advisory board; nor had the role of the participants in relation to the advisory board been made clear in the email invitation and elsewhere. The Panel noted its general comments above about the arrangements for the meeting including the selection criteria, content, feedback and fee for service payments. The Panel was especially concerned that at the end of the advisory board participants addressed what they would do differently as a result of the meeting which, in the Panel's view, demonstrated that the primary focus of the day was in providing information to and influencing participants rather than the provision of advice to the company. The Panel was concerned that the time spent obtaining advice appeared to be extremely limited and further no preparation was needed. Taking all the factors into account the Panel

did not consider that the arrangements either for the whole day or just the afternoon 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 considered that, as it had ruled the arrangements did not meet the criteria for advisory boards, UK health professionals had been paid to attend a meeting where medicines were promoted. The Panel queried whether it was ever acceptable to combine two company meetings such that products were promoted at part of the meeting and another part was a genuine advisory board. The Panel considered that UK health professionals had received payment to attend a meeting which the Panel considered promoted medicines including pipeline products. Any payment received for an advisory board that did not meet the requirements of Clause 23.1 was contrary to the requirements of Clause 18.1. In addition, the payment was for two days and not limited to what Stirling Anglian described as the advisory body element. Further, it appeared that as a result of attending the meeting health professionals' general actions indicated that switches to Stirling Anglian's products would be instigated. The Panel considered that the meeting was an inducement to recommend Stirling Anglian's medicines. A breach of Clause 18.1 was ruled.

The Panel noted that the third party was providing services on behalf of Stirling Anglian. One of the staff members was head of medicines management. The report referred to comments made by the named pharmacist 'on the zero switchback rate on [his area]'. The Panel noted that under Clause 21 contracts under which institutions, organisations, or associations provided any type of service were only allowed if such services or other funding were, *inter alia*, not an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. The Panel noted its ruling above of a breach of Clause 18.1 and thus considered that the service amounted to an inducement. The Panel noted that Stirling Anglian had not exercised due diligence over the service. A breach of Clause 21 was ruled.

The Panel then considered the level of hospitality. It was concerned that irrespective of whether it was justifiable to visit the manufacturer, the arrangements were unacceptable. There was no need for the delegates to stay in Baden-Baden. Accommodation nearer to the manufacturer should have been used. The hotel used in Baden-Baden was not appropriate, it appeared to be a lavish and deluxe venue. In this regard, the Panel noted the retraction statement regarding the reported comments in the articles signed by the named pharmacist and the Panel's comments above in this regard. Regardless of the retraction statement, the location and facilities were still more akin to leisure travel than business purposes. The Panel was also concerned about the cost of dinner. Stirling Anglian's submission was inconsistent in this regard. One part stated that dinner and drinks cost €70 another part stated it did not exceed €70. The latest response confirmed that the cost per head (without tax (€400.52) and gratuities (€280)) was €100.99 around £71.43. The Panel noted the receipts

for the pre-dinner drinks at the hotel which cost €447. Stirling Anglian submitted that this was not for the UK invitees but for staff from Stirling Anglian, the manufacturers and the third party. The Panel noted that the latter submission appeared to be inconsistent with an earlier submission which clearly stated on an agenda '18.30 meet at the Hotel... welcome drink 19.30 Dinner at the Restaurant...'. Overnight accommodation cost €199.

The Panel noted that the bill for the evening meal listed a number of main courses which cost more than £13-24, for example, €34-38. The bill included an additional bottle of wine to that listed by Stirling Anglian. Twenty four people attended the dinner at a cost per head (excluding tax and gratuities) of £71.43.

Some of the delegates commented positively on the hospitality in their expense claims. The report stated that 'the trip was well executed, enjoyable and sociable' and that the level of hospitality was not excessive.

The Panel did not consider that the hospitality was secondary to the main purpose of the event ie subsistence only. The level was not appropriate and was out of proportion to the occasion. Further, the costs exceeded the level that recipients would normally adopt when paying for themselves. A breach of Clause 22.1 was ruled.

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 German Code were relevant. The English translation of the FSA (Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V.) Code of Conduct on the Collaboration with Healthcare Professionals (December 2014) and Guidelines (effective 27 January 2015) were relevant. Sections 9.2 and 14.2 of the Guidelines were similar and Section 9.2 stated:

'The "hospitality arrangement" is "reasonable" and does not exceed "reasonable bounds" as long as it is socially acceptable. An amount of roughly EUR 60.00 is a benchmark for what is still considered a reasonable hospitality arrangement in Germany, under consideration of price increases and the value-added tax increase since the Code of Conduct took effect in 2004 (effectively: July 2008).'

Section 9.2 of the Guidelines related to Section 20 of the FSA Code, 'Invitation to job-related, science-oriented training events'. Section 14.2 of the Guidelines referred to Section 22 of the FSA Code, 'Hospitality'.

The Panel noted the German limit of €60 and that around €100 or £71.43 was spent per head for dinner (excluding tax and gratuities). This was in excess of the local limit for a meal and therefore a breach of Clause 22.2 was ruled.

The Panel considered that, overall, high standards had not been maintained and a breach of Clause 9.1 was ruled.

The Panel noted that Clause 2 was reserved for use as a sign of particular censure. The health professionals that attended the meeting had received a payment for two days at £500 per day in connection with the promotion of medicines including pipeline products. The Panel noted that unacceptable payments was listed in the supplementary information to Clause 2 as an example of an activity likely to be in breach of that Clause. The Panel was extremely concerned that the role of the participants had not been made clear in the invitation or elsewhere. The Panel was also extremely concerned about the poor impression given by all of the arrangements. It noted its rulings above regarding the hospitality. Given Stirling Anglian's ultimate responsibility for all of the arrangements including those parts organised by the third party and its manufacturing partner, the company did not appear to have exercised due diligence and ensured that third party activities met the requirements of the Code. The Panel considered that the arrangements brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel noted its comments and rulings above and considered that its concerns about the arrangements and the company's procedures warranted consideration by the Appeal Board. The Panel thus reported Stirling Anglian to the Appeal Board in accordance with Paragraph 8.2 of the Constitution and Procedure.

During the consideration of this case the Panel was concerned that the arrangements had not been certified. In this regard, it requested that Stirling Anglian be reminded of the requirements of Clause 14.2. The Panel was also concerned at the informal and unprofessional nature of some of the emails from Stirling Anglian to the pharmacist attendees. Some of these were headed 'Baden Baden Ad Board', reference was also made to 'the trip' this week, 'enjoying yourselves' and were signed off 'Take care'. The Panel requested that its concerns in this regard were drawn to the company's attention. It also requested that Stirling Anglian be reminded of the requirements of the Code in relation to disclosure of transfers of value.

COMMENTS FROM STIRLING ANGLIAN ON THE REPORT FROM THE PANEL

Stirling Anglian formally apologised for the impact caused by recent events related to this case, particularly the unwelcome publicity for the industry. The company recognised both the serious nature of the matters at issue and the effect that the public reporting of these events had both within the pharmaceutical industry and for the wider public.

Stirling Anglian submitted that when it was first told about an interview between an undercover reporter from The Daily Telegraph and a director of a company with whom it was engaged, it was surprised and dismayed by the way in which the company director presented both himself and the activities of his company in support of Stirling Anglian. Stirling Anglian continued to believe that the account given was exaggerated and did not represent the instructions and understanding it had given. However, Stirling Anglian accepted that the report in The Daily Telegraph reflected the statements made by the named pharmacist and that this, in turn, raised legitimate concerns which required investigation by the PMCPA.

Stirling Anglian submitted that as a relatively new company, it had endeavoured to abide by the principles of the Code. The company had trained its staff in this area and Code compliance had featured strongly in discussions at board meetings. Stirling Anglian honestly believed that it had acted within industry norms and in line with the Code. However, the company had read the Panel's ruling and now accepted that things could have, and should have, been done differently. It analysed the position as follows:

- 1 Stirling Anglian should have ensured continuous monitoring of its advisory board activities to determine that they met the requirements of the Code and that there was a legitimate need for the services and also for an onsite factory tour (as opposed to video-conferencing).
- 2 The level of oversight of the activities of the third party was deficient. This was finally manifested in the meeting report which clearly showed a level of performance far removed from Stirling Anglian's original intent and instruction. While Stirling Anglian contended that the third party moved away from its original brief, it accepted the principle of responsibility for the actions of this third party provider.
- 3 By allowing the combination of the various components of the meeting – the factory tour, raising awareness of the company and discussing the needs of the NHS over a full-day, the company did not maintain the level of separation of activity that was expected under the Code for advisory boards. Stirling Anglian accepted that the impression given was that the event was not a genuine advisory board.
- 4 The selection criteria for attendees was not clear, transparent and robust.
- 5 While attempting to facilitate arrangements for the meeting by liaison with regard to travel and other arrangements, there was not the correct degree of separation between Stirling Anglian and the attendees. Stirling Anglian also accepted that some communications with attendees, while intended to be polite and convivial, could be seen as unprofessional when seen in the context of other concerns.
- 6 Stirling Anglian had never intended to provide lavish or excessive accommodation or hospitality. This aspect was arranged by its manufacturer which used local services and providers with whom it had previous business relationships. Stirling Anglian should have been more directive

as to the standard of accommodation arranged – a hotel that a manufacturer used to accommodate normal business visitors might be less suited to an advisory board. A clear separation between various activities at that time should have been maintained and that a far clearer trail of expenditure should have been recorded. The company was deficient in not providing clearer guidance to its German partners in this regard. This was amplified by the third party's poor interpretation of the Code. Stirling Anglian was let down by the third party on this point, but it accepted responsibility for that.

Stirling Anglian stated that it had carefully reflected on the Panel's rulings and accepted them in full; it had provided the required undertaking and ceased this form of activity entirely. Such activity would not be used by Stirling Anglian in the future.

Stirling Anglian had also commissioned an external audit of its processes which would take place in November 2015, which would take the form of a gap analysis of current processes and include an action plan to correct any remaining deficiencies. A formal report would be submitted to the Stirling Anglian board.

Stirling Anglian recognised that most of this could have been prevented had it sought advice from the PMCPA before embarking on this course of action. Stirling Anglian was resolved to seeking such advice more proactively in future.

Stirling Anglian concluded that these events had a profound effect on the company both collectively and at a personal level. Stirling Anglian was a new company, founded by people who believed strongly in the values of the NHS. Stirling Anglian was trying to make a difference in a highly adversarial environment. To find that it had fallen short of the standards expected of it was intensely distressing. The company was deeply sorry that this had happened, and was resolved to put things right.

APPEAL BOARD CONSIDERATION OF THE REPORT FROM THE PANEL

The Appeal Board was very concerned about the profound lack of Code expertise and oversight within Stirling Anglian that had allowed the meeting to go ahead. In the Appeal Board's view the arrangements for the meeting had been shambolic. The Appeal Board noted, from Stirling Anglian at the consideration of the report, that the company had relied on the third party provider to ensure that the meeting complied with the Code. The Appeal Board was further concerned that in its comments on the report from the Panel Stirling Anglian stated that it had '...accepted that the impression given was that the event was not a genuine advisory board'. The Appeal Board noted that it was much more than the impression of the meeting which was wrong; the arrangements were such that the meeting was in fact a promotional event, clearly in breach of the Code. That it was more than the impression was accepted by the company representatives at the consideration of the report.

The Appeal Board noted that the company had accepted all the Panel's rulings of breaches of the Code including a breach of Clause 2 and that it had stopped organising advisory boards until it was confident that it had appropriate oversight. The Appeal Board further noted the company's genuine contrition and that it had commissioned an external agency to audit its processes. Further, the Stirling Anglian representatives at the consideration of the report stated that the company had appointed a new general manager, was updating its procedures, training staff and considering employing compliance expertise.

Nonetheless, the Appeal Board was extremely concerned that UK health professionals had attended the meeting on the false understanding that it was an advisory board and had been paid to do so. This was unacceptable. Consequently, the Appeal Board decided, in accordance with Paragraph 11.3 of the Constitution and Procedure, to require Stirling Anglian to issue a corrective statement to all the UK attendees at the meeting. The corrective statement should refer to the case report. Under Paragraph 11.3 details of the proposed content and mode and timing of dissemination of the corrective statement must be provided to the Appeal Board for approval prior to use. [The corrective statement, which was agreed by the Appeal Board prior to use, appears at the end of this report].

The Appeal Board also decided, given its serious concerns about the conduct of Stirling Anglian as set out above, to require, in accordance with Paragraph 11.3 of the Constitution and Procedure, an audit of the company's procedures in relation to the Code, to take place in January 2016. On receipt of the audit report, the Appeal Board would consider whether further sanctions were necessary.

APPEAL BOARD FURTHER CONSIDERATION

Stirling Anglian was audited in January 2016 and on receipt of the report of the audit and the company's comments in February, the Appeal Board was encouraged by Stirling Anglian's willingness to improve its procedures and processes to comply with the Code, but noted from the report that significant progress was needed.

The Appeal Board was extremely concerned that despite a report that highlighted deficiencies in the company's knowledge and understanding of the Code and its failures with respect to compliance, Stirling Anglian had not provided any detail on when and how it would address those matters.

Stirling Anglian subsequently provided a further detailed response as requested. The Appeal Board was concerned that in an action plan some actions were marked as active with no indication of the expected date of completion. The Appeal Board decided that the company should be re-audited in June 2016 at which point it would be expected to demonstrate significant improvement.

Stirling Anglian was audited in June 2016 although the Appeal Board was encouraged that the audit

highlighted that Stirling Anglian had made meaningful improvements in compliance and that much work had been done, it also noted that there was still more to do including continuing issues regarding third party interactions. Stirling Anglian needed to ensure that its progress to date was maintained and built upon.

The Appeal Board decided that Stirling Anglian should be re-audited in April/May 2017 at which point the Appeal Board expected it to be able to demonstrate further and sustained improvement.

Stirling Anglian was re-audited in May 2017 and the report was considered by the Appeal Board in June.

The Appeal Board noted that there had been numerous staff changes at Stirling Anglian and it used a contract sales force and a third party marketing agency. The Appeal Board considered that the company needed to be vigilant about the effective governance of using third parties and maintaining compliance. The Appeal Board was encouraged by the progress made which needed to be built on and then maintained. Given the company's history it should ensure that compliance was at the forefront of everything it did. Training on the Code and attention to detail still needed to be improved.

The Appeal Board noted that the companies standard operating procedures (SOPs) were due to be reviewed and updated by August 2017 and it decided that Stirling Anglian should provide the PMCPA with the outcome of its review, evidence of training and any new SOPs by early September.

On receipt of Stirling Anglian's response the Appeal Board considered that the PMCPA should ask Stirling Anglian to amend further its SOPs in light of certain concerns. On the basis that this work was completed promptly, the progress shown to date was continued and a company-wide commitment to compliance was maintained, the Appeal Board decided that, on balance, no further action was required.

Complaint received	27 July 2015
Undertaking received	21 October 2015
Appeal Board consideration	12 November 2015, 25 February 2016, 17 March, 21 July, 22 June, 12 October 2017
Corrective statement issued	16 December 2015
Interim case report published	16 December 2015
Case completed	12 October 2017

On 16 December 2015 Stirling Anglian sent the following corrective statement to all UK delegates at the meeting.

'Corrective statement

On 2/3 July, you attended a meeting organised by Stirling Anglian Pharmaceuticals Ltd, held in Baden-Baden. The meeting was described as an "Advisory Board".

An article in The Daily Telegraph on 25 July raised concerns about the excessive hospitality provided at the meeting and the matter was taken up by The Prescription Medicines Code of Practice Authority as a complaint under the ABPI Code of Practice for the Pharmaceutical Industry (Case AUTH/2783/7/15). The Code of Practice Panel ruled that the arrangements did not meet the criteria for an advisory board and that UK health professionals had thus been paid to attend a promotional meeting. The Panel also considered that the meeting was an inducement to recommend Stirling Anglian's medicines and that the hospitality provided was not appropriate, was out of proportion to the occasion and that the costs exceeded the level that recipients would normally adopt if paying for themselves. The Panel considered that Stirling Anglian had failed to uphold high standards and had brought discredit upon, and reduced confidence in, the pharmaceutical industry. The Panel considered that its concerns warranted further consideration and thus reported Stirling Anglian to the Code of Practice Appeal Board. The Appeal Board was extremely concerned that health professionals had attended the meeting on the false understanding that it was a genuine advisory board. The Appeal Board required Stirling Anglian to send you this corrective statement and a copy of the published report for the case which contains full details. This is enclosed.

Details of this case (Case AUTH/2783/7/15) are also available on the PMCPA website (www.pmcpa.org.uk).'
