

ANONYMOUS HEALTH PROFESSIONALS v ASTELLAS, ALLERGAN, BAXTER, FERRING, IPSEN, JANSSEN, ORION, PFIZER, RECORDATI AND TAKEDA

Sponsorship of a meeting

An anonymous non-contactable group describing themselves as NHS health professionals complained that a number of companies had breached the Code when supporting the annual meeting organised by the Irish Society of Urology (ISU), and held in Belfast in September 2012.

The complainants noted that the meeting was held in the UK and UK health professionals attended. Most of the employees from the companies were based in the UK. The first page of the scientific programme featured photographs of the very luxurious, 5 star venue and nearby attractions; this placed undue emphasis on non-scientific aspects of the meeting. The welcome message on the first page of programme read 'The social aspect of this meeting is extremely important and the two evening events promise great enjoyment. The unique opportunity to have our gala dinner in Stormont was one that we couldn't pass over!' Most of a second day of the meeting was dedicated to playing golf and leisure activities as clearly marked in the programme.

The complainants alleged that the pharmaceutical companies that supported this meeting seriously breached the Code on the grounds of excessive hospitality.

The detailed responses from Astellas, Allergan, Baxter, Ferring, Ipsen, Janssen, Orion, Pfizer, Recordati and Takeda are given below.

The Panel noted that the meeting had been held in Northern Ireland and thus the ABPI Code applied. The Panel also noted that it was an established principle that UK pharmaceutical companies were responsible for the activities of overseas affiliates if such activities related to UK health professionals or were carried out in the UK.

The 'programme at a glance' stated that the meeting started on the Friday with registration followed by scientific/educational sessions from 9am. The conference dinner was held at 7pm. On the Saturday scientific/educational sessions ran from 9am after the annual general meeting until 12.10pm when the meeting closed with lunch. The programme stated '12.50 Departure for Golf, [named golf club]' and '18.45 Departure for Gala Dinner, Parliament Buildings, Kindly sponsored by [a Northern Ireland named politician]. The more detailed programme stated that the conference dinner on 21 September included a 'Drinks reception

kindly sponsored by Astellas Pharma Co Ltd'. The notes page of the programme (penultimate page) stated 'An educational grant was provided by Allergan Ltd to the Irish Society of Urology to support this independent course. Allergan [sic] has had no involvement in the logistics, design or content of the course'. On the back page of the programme was a list of companies (including the ten at issue in these cases) which the ISU thanked for their support.

The Panel noted that the Immediate Past President of the ISU (who was President when the meeting took place and who appeared to have received a copy of the complaint) had written to the companies to address some of the inaccuracies in the complaint and clarify the role of the pharmaceutical companies. The past president stated that he chose the meeting venue and the venue for the gala dinner. Golf was arranged as a courtesy for delegates by the ISU. Anyone who played golf paid for it themselves and no pharmaceutical company was involved in this in any way. The golf was arranged for after the scientific meeting had finished and when the trade exhibitors and indeed some attendees had already left. The letter stated that no pharmaceutical company had any hand, act or part in any of the issues raised in the complaint, which, in the past president's view, was, by definition, spurious as it was unsigned and mischievous. The meeting was solely organised by the ISU and pharmaceutical companies were invited to exhibit. Delegates were responsible for their own expenses during the meeting, including registration fees, meals and accommodation. The letter finished by stating that the ISU would continue to organise its own meeting and at a venue of its choosing.

The Panel noted that pharmaceutical companies could be involved in meetings organised by third parties including by way of general sponsorship, sponsoring a specific part of the meeting, sponsoring delegates to attend or paying to exhibit. Further details are given in the Panel's general comments below. Each case would be considered on its own merits bearing in mind all the relevant circumstances. The overall impression of the arrangements was an important consideration.

The Panel noted that the ISU could organise whatever meetings it wanted to for its own members but the involvement of pharmaceutical companies with various activities meant the meeting at issue was covered by the Code. Most of

the pharmaceutical companies had only exhibited at the meeting. Two of the companies had provided sponsorship.

The Panel considered that the scientific content was not unreasonable. It consisted of one and a half days of education. The programme stated '9 CPD [continuing professional development] credits'. The Panel noted that a number of companies paid for exhibition space and considered that the amount charged did not appear unreasonable. The Panel noted that the exhibitor's fee included 3 tickets for the conference dinner. (The Panel noted that the ISU had informed some of the companies that the cost of the exhibition stand at €1,850 represented around 2% of the total cost of hosting the scientific programme. Nineteen companies had supported the meeting thus covering 38% of the costs. The ISU stated that the sponsorship from exhibitors did not assist with the expense of the social functions including golf, conference dinner, gala dinner or accommodation). The exhibitor registration form included a section headed 'social programme' which stated that tickets for the conference dinner and gala dinner were €60 and €70 respectively. There was no mention of golf on this form. The Panel did not know how much the ISU charged for the golf. The Panel noted that the meeting programme referred to the golf and the gala dinner. The Panel considered that in this regard the two events were part of the formal proceedings of the meeting albeit that they occurred after the medical/scientific sessions had finished and had to be paid for by the delegates themselves.

The Panel further noted that the declaration of pharmaceutical company sponsorship on the back page of the programme was not clear as to exactly what had been supported. It was not unreasonable to assume that the companies listed had supported everything in the programme including the golf and gala dinner.

The Panel was also mindful of the established principle that a pharmaceutical company could not support a third party activity if that activity was itself in breach of the Code.

The Panel noted that the venue was a 5 star conference hotel and would thus be seen as luxurious. In that regard the Panel queried whether the venue met the requirements of the Code. It noted the companies' submissions regarding the hotel's conference facilities but considered that other non-luxurious venues would have had adequate conference facilities.

Taking all the circumstances into account it appeared that the pharmaceutical companies listed on the back page of the programme had supported all the arrangements for the two-day meeting held at a luxurious venue with golf and a gala dinner. There was no indication that the majority of companies listed had only paid to exhibit. The conference programme stated that without participation from the pharmaceutical and medical equipment industries the meeting would not be possible. The Panel considered that the arrangements for the meeting as described in the

programme and the impression given were unacceptable. In this regard, high standards had not been met. The Panel ruled Astellas, Baxter, Ferring, Ipsen, Janssen, Orion, Pfizer, Recordati and Takeda in breach of the Code.

The Panel noted that in addition to paying to exhibit, Astellas Ireland had paid for what was described in the programme as a drinks reception. The itemised bill was paid at 1.15am. The receipt recorded 125 covers and 265 items. Astellas UK stated that the drinks reception was immediately before dinner. The Panel noted that attendees were given two tickets which allowed them to obtain two drinks of their choice; Astellas had no control over what was provided. In the Panel's view this was unacceptable. The itemised bill showed that a number of spirits had been ordered as well as 2 Irish coffees, 3 liqueurs and other drinks which were more likely to be consumed after dinner than before. There was no way of knowing at what time the drinks were provided.

Astellas Ireland had also supported the attendance of 6 delegates from the Irish Republic. Some of these delegates had their accommodation paid for, one dinner had been paid for and some registration fees.

The Panel considered that by paying the accommodation, subsistence and registration costs of some delegates and its lack of control at the drinks reception rendered the level of hospitality provided by Astellas inappropriate; high standards had not been maintained. Breaches of the Code were ruled.

Allergan had not exhibited at the meeting and its support was for the venue hire and AV costs. The company had clearly stated its terms of support in a letter to the Royal College of Surgeons in Ireland (RCSI).

The penultimate page of the programme referred to the educational grant provided by Allergan. It was for the same amount as that paid for an exhibition stand. There was no indication that the majority of companies listed on the back page had only paid to exhibit at the meeting. The conference programme stated that without participation from the pharmaceutical and medical equipment industries the meeting would not be possible. The Panel considered that the arrangements for the meeting as described in the programme and the impression given were unacceptable. In this regard, high standards had not been met by Allergan and the Panel ruled a breach.

The Panel noted that Baxter, Ferring, Ipsen, Janssen, Orion, Pfizer, Recordati and Takeda had not sponsored any health professional to attend the meeting by paying for accommodation, subsistence or registration fees. Allergan, Baxter, Ferring, Ipsen, Janssen, Orion, Pfizer, Recordati and Takeda had supported the venue hire and AV costs of the meeting. The Panel considered that the venue was on the limits of acceptability given its 5 star rating but nonetheless ruled no breach of the Code.

The Panel noted that Ferring did more than pay to exhibit; one employee had attended the gala dinner.

The Panel considered that purchasing a ticket for the gala dinner was inappropriate. Although health professionals paid for their own tickets it was not acceptable for a company to be involved in such an event. The educational content of that day (3 hours 40 minutes in the morning) did not justify the gala dinner in the evening which appeared to be a social event; high standards had not been met in this regard. Breaches of the Code were ruled.

The Panel noted that in addition to paying to exhibit, Janssen had purchased a ticket for the gala dinner. Although the dinner ticket had not been used the Panel considered that its purchase showed an intent to attend. It noted its previous rulings that the education content did not justify the gala dinner which appeared to be a social event and that high standards had not been met in this regard. Breaches of the Code were ruled.

The Panel noted that a ruling of a breach of Clause 2 was a sign of particular censure and was reserved for such circumstances. The Panel noted its rulings above and decided that, on balance, the circumstances did not warrant such a ruling and no breach of Clause 2 was ruled in relation to all the companies referred to in this case report.

An anonymous non-contactable group describing themselves as NHS health professionals complained that a number of companies had breached the Code when supporting the annual meeting organised by the Irish Society of Urology (ISU) and held at the Culloden Estate and Spa, Holywood, Belfast in September 2012.

COMPLAINT

The complainants noted that:

- The meeting was held within the UK and significant numbers of attendees were UK health professionals. Most of the employees from the companies named by the complainants were based in the UK.
- The meeting was held at a very luxurious, 5 star venue, described on its website as:

***'Built for a Bishop, Fit for a King
This is 5 star. This is red carpet romance. Platinum standard pleasure. This is something very special indeed.*** [emphasis added]

Nestled high in the Holywood hills and overlooking Belfast Lough, is the Hastings Group's most luxurious hotel, The Culloden Estate & Spa. Originally built as an official palace for the Bishops of Down, this stunning spot, set in 12 acres of secluded gardens, is the jewel in the crown of County Down. [emphasis added]

Come for business. Indulge in an ESPA Spa treatment. Head for Royal Belfast Golf Club. [emphasis added]

- The first page of the scientific programme featured photographs of the venue and nearby attractions; this placed undue emphasis on non-scientific aspects of the meeting.
- The welcome message from the President of the ISU on the first page of programme read 'The social aspect of this meeting is extremely important and the two evening events promise great enjoyment. The unique opportunity to have our gala dinner in Stormont was one that we couldn't pass over!'
- A significant part of a second day of the meeting (the majority of it indeed!) was dedicated to playing golf and leisure activities and that was very clearly marked in the programme:

'12.50 Departure for Golf; Blackwood Golf Club' [emphasis added]

The complainants alleged that all of the pharmaceutical companies that supported this meeting seriously breached the Code on the grounds of excessive hospitality.

The complainants submitted that this was of the upmost importance in times where NHS budgets were cut across the board and where the public increasingly scrutinised their profession.

When writing to the companies named, the Authority asked each to respond in relation to Clauses 2, 9.1 and 19.1 of the Code.

CASE AUTH/2546/11/12 ASTELLAS

RESPONSE

Astellas Pharma Ltd (UK Affiliate) stated that it had good processes for meetings review and approval. Astellas took particular care to ensure that the Code was upheld in both letter and spirit and so it was dismayed to realise that an Astellas organisation supported a meeting in the UK without its knowledge. In this case it was the Irish affiliate, Astellas Pharma Co Ltd, however Astellas Pharma Ltd accepted that it was responsible for ensuring compliance with the Code for meetings which involved UK health professionals and/or took place in the UK.

Astellas submitted that the ISU was a respected academic society which covered the whole of Ireland. Its annual scientific meeting was sometimes held in Northern Ireland although most of the delegates were from the Republic of Ireland. It was regrettable that the Irish affiliate forgot that this would have to be approved by the UK although in mitigation there was a growing tendency in academia to treat the whole of Ireland as a single country. However, the Irish affiliate had recognised the need to further raise the awareness of its procedures in this regard and a compliance manager for Astellas Europe had already emailed a reminder to all affiliates as a result of this complaint.

The meeting was approved by the Irish affiliate in line with the Irish Pharmaceutical Healthcare Association (IPHA) Code of Practice. Astellas Ireland received the exhibitor booking from ISU on 18 May 2012 and approved the meeting on 11 September 2012. Astellas UK understood that a final programme was available on 11 September for inspection.

Astellas did not advertise the event and therefore no materials were produced. Astellas's sponsorship of the event was acknowledged on the last page of the programme.

All sponsoring companies were charged a flat exhibitor's fee of €1,850 which entitled them to three places at the conference dinner on the Friday evening. Astellas Ireland paid for an additional dinner place (€60). A letter from the President of the ISU at the time, confirmed that the venue, post-meeting golf and post-meeting gala dinner were entirely organised by the ISU and that the monies raised were not used to pay for any of these events.

Astellas UK noted that six delegates from the Irish Republic had some of their costs paid by Astellas Ireland. Five delegates had their registration paid for and five had accommodation paid for. This was considered by the Irish affiliate to be consistent with the IPHA Code. No UK delegates were sponsored to attend by either Astellas Ireland or Astellas UK.

The ISU meeting was a main event for urologists in the whole of Ireland. The programme was academic and the meeting itself was the main attraction and not the venue, golf or gala dinner. No pharmaceutical company was involved in choosing the venue. While accepting that this was a 5 star venue and therefore would not normally be approved, it was a well known and highly convenient conference venue in Northern Ireland; it was close to road and air links and so it made logistical sense for such a meeting to be held there. In addition Astellas noted that the hotel had no golf course. Bearing in mind that no UK delegate was sponsored by Astellas to attend and that Astellas had no input into the choice of this venue, Astellas did not believe that there had been a breach of Clause 19.1.

The Astellas stand had no promotional materials available to hand out and there were only clinical papers approved for use which could be distributed on request.

The Friday evening conference dinner took place at the meeting venue and was attended by four Astellas Ireland personnel. A drinks reception, which the ISU invited Astellas to sponsor, was held immediately before the dinner in the hotel. Itemised bar receipts were provided. Delegates were given two tickets which allowed them to have two soft or alcoholic drinks; they had to pay for any further drinks themselves. Astellas did not know how many delegates attended but assumed that the vast majority of the 132 registered delegates were present, bearing in mind the delegate geographical breakdown (95 from the Republic of Ireland, 23 from Northern Ireland and 14 from mainland Britain). The

bill for drinks was £1012.40 which was, on average, around £7.60 to £9 per person which Astellas did not consider excessive or beyond anything the delegates would reasonably have paid for themselves. Astellas did not provide any funding for drinks at the main conference dinner. The supplementary information to Clause 19.1 of the Code stated that 'The provision of hospitality is limited to refreshments/subsistence (meals and drinks), accommodation, etc...' and therefore Astellas did not consider that this in itself was a breach of the Code.

With regard to the golf organised after the official close of the meeting, Astellas UK submitted that it had been reassured by its Irish colleagues that no Astellas employee played golf and that Astellas did not subsidise the golf in any way. The programme made it very clear that golf took place after the meeting had officially closed and was therefore, in Astellas' view, not part of the meeting which again made this not necessarily unacceptable, although Astellas questioned the wisdom of advertising it on the programme itself rather than in a separate communication unrelated to the scientific programme.

Similarly, Astellas had no input into the choice of the venue for the gala dinner (Stormont Buildings) and no Astellas employee attended this dinner. No subsistence was given by Astellas towards the costs of this dinner and therefore Astellas UK did not believe, despite its lack of knowledge of this event, that it would have found this to be unacceptable had it had the chance to review this before the event, given that this dinner also occurred after the official close of the meeting. The ISU clearly retained the right to organise its own meetings and the lack of attendance by Astellas employees and of any subsidy of social activities by Astellas in its opinion meant that this was not in breach of Clause 19.1.

In summary, although Astellas UK was unaware of this meeting taking place and had not approved it under its procedures it was confident that the meeting could have been approved in principle as no pharmaceutical company had any input into the meeting content or venue or to any social activity, except for the sponsorship of the Friday evening pre-dinner drinks by Astellas. The supplementary information to Clause 19.1 stated that it was unacceptable for companies to sponsor meetings which were 'wholly or mainly of a social or sporting nature'. The programme clearly demonstrated that the meeting was mainly scientific in nature with one 'social event' – the conference dinner occurring during the meeting and two other social activities – golf and the gala dinner – taking place clearly after the meeting had officially finished and the pharmaceutical companies had dismantled their stands and left. Astellas submitted that as delegates had to eat somewhere, a dinner occurring during the scientific part of the meeting was not unreasonable and would provide further networking opportunities for delegates. In Astellas UK's view it was regrettable that undue emphasis was placed on the social events in the programme. This would have concerned Astellas UK and it would have wished to see the balance of the welcome message focus on the

scientific content. Astellas UK submitted, however, that the hospitality provided by Astellas was not excessive and it therefore denied a breach of Clause 19.1.

Astellas UK stated that it was regrettable that its Irish affiliate forgot to get UK approval for this meeting but bearing in mind the unusual situation in Ireland it was perhaps an understandable mistake and Astellas did not consider it merited a ruling that high standards had not been maintained by the UK affiliate (Clause 9.1). The Irish affiliate had improved the awareness of its procedures in this regard and a reminder from Astellas Europe was sent to all affiliates. Similarly Astellas submitted that, given the findings of its investigation, it had not brought discredit upon or reduced confidence in the industry's reputation (Clause 2

GENERAL COMMENTS FROM THE PANEL (apply in all cases)

The Panel considered the complaint in relation to the ABPI Code only. The meeting had been held in Northern Ireland and thus the ABPI Code applied. The supplementary information to Clause 1.8 made it clear that an activity carried out in the UK must comply with the UK Code regardless of whether or not UK health professionals attended. The Panel also noted that it was an established principle that UK pharmaceutical companies were responsible for the activities of overseas affiliates if such activities related to UK health professionals or were carried out in the UK.

Before considering each individual case, the Panel reviewed relevant requirements of the Code in relation to meetings, hospitality and sponsorship.

Clause 19.1 stated that meetings must be held in appropriate venues conducive to the main purpose of the event. Hospitality must be strictly limited to the main purpose of the event and must be secondary to the purpose of the meeting ie subsistence only. The level of subsistence offered must be appropriate and not out of proportion to the occasion. The costs involved must not exceed that level which the recipients would normally adopt when paying for themselves. The supplementary information to Clause 19.1 made it clear that the provision of hospitality was limited to refreshments/subsistence, accommodation, genuine registration fees and the payment of reasonable travel costs which a company might provide to sponsor a delegate to attend a meeting. The venue must not be lavish, extravagant or deluxe and companies must not sponsor or organise entertainment such as sporting or leisure events. In determining whether a meeting was acceptable or not consideration needed to be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience, subsistence provided and the like. It should be the programme that attracted delegates and not the associated hospitality or venue. The supplementary information also stated that a useful criterion in determining whether the arrangements for any meeting were acceptable was to apply the question 'would you and your company be willing to have

these arrangements generally known?' The impression that was created by the arrangements for any meeting must always be kept in mind.

The Panel noted that the welcome message from the ISU President, printed in the meeting programme, referred to the fact that the ISU was an all island society and that the annual meeting was more usually held in the Republic of Ireland. It also referred to a record number of abstracts being submitted for consideration but the ISU was unable to accommodate a significant number in the programme. The ISU hoped that this trend of increased numbers of submissions would continue in the future and in so doing raise the scientific profile and standard of the meeting which was already high. The welcome referred to three speakers before a short paragraph which described the social aspect of the meeting as 'extremely important and the two evening events promise great enjoyment. The unique opportunity to have our gala dinner in Stormont was one that we couldn't pass over!'. The President also referred to the participation of 'our colleagues from the pharmaceutical and medical equipment industries' without which 'a meeting such as this would not be possible and we are very grateful for their involvement'. The President thanked all who would be presenting at the meeting or chairing parts of it, hoped the meeting proved to be educational and enjoyable and that delegates enjoyed 'this beautiful area of County Down'. The President's message concluded by inviting attendance at the 2013 meeting which would be held at a named venue in Wicklow.

The 'programme at a glance' stated that the meeting started on Friday 21 September 2012 with registration followed by scientific/educational sessions from 9am. The conference dinner was held at 7pm. On Saturday 22 September scientific/educational sessions ran from 9am after the annual general meeting until 12.10pm when the meeting closed with lunch. The programme stated '12.50 Departure for Golf, [named golf club]' and '18.45 Departure for Gala Dinner, Parliament Buildings, Kindly sponsored by [a Northern Ireland named politician]'. The more detailed programme stated that the conference dinner on 21 September included a 'Drinks reception kindly sponsored by Astellas Pharma Co Ltd'. The notes page of the programme (penultimate page) stated 'An educational grant was provided by Allergan Ltd to the Irish Society of Urology to support this independent course. Allergan (sic) has had no involvement in the logistics, design or content of the course' on the back page of the programme was a list of companies (including the ten at issue in these cases) which the ISU thanked for their support.

The Panel noted that the Immediate Past President of the ISU (who was President when the meeting took place and who appeared to have received a copy of the complaint) had written a letter to the companies in which he stated that he would address some of the inaccuracies in the complaint and clarify the role of the pharmaceutical companies in the conduct of the meeting. The past president stated that the venue was chosen solely by him. No pharmaceutical company had any part in the choice of venue. Stormont Castle was also chosen by him as the location for the gala

dinner. No pharmaceutical company had any input into this event. The golf was arranged as a courtesy for delegates by the ISU. Anyone who played golf on that day paid for it themselves and again no pharmaceutical company was involved in this in any way. The golf was arranged for a time after the scientific meeting had finished and when the trade exhibitors and indeed some attendees had already left. The letter stated that no pharmaceutical company had any hand, act or part in any of the issues raised in the complaint, which, in the past president's view, was, by definition, spurious as it was unsigned and mischievous. The meeting was solely organised by the ISU and pharmaceutical companies were invited to exhibit at the trade exhibition during the course of the meeting in a room provided for this purpose. All delegates were responsible for all of their own expenses during the meeting, including registration fees, meals and accommodation. The letter finished by stating that the ISU would continue to organise its own meeting and at a venue of its choosing.

The Panel noted that there were a number of ways that pharmaceutical companies could be involved in meetings organised by third parties. This included general sponsorship of such a meeting, sponsoring a specific part of it, sponsoring delegates to attend or paying to exhibit.

With regard to the implications of a pharmaceutical company paying to exhibit at a third party meeting, the Panel considered that if a company only paid for an exhibition stand then this would not necessarily be in breach of the Code even if aspects of the meeting did not meet the requirements of the Code. In the Panel's view certain conditions were relevant. Firstly, the exhibition must be a formal part of a genuine scientific or medical meeting independently organised, for example by a learned society. The meeting overall must not be of a wholly or mainly social or sporting nature. Secondly, the amount paid for the exhibition space must cover the genuine costs of putting on the exhibition and not be used to pay for or subsidise activities that did not meet the requirement of the Code. Thirdly, preferably a number of other companies must also be exhibiting. Fourthly, it should be made clear to all attendees that the pharmaceutical company had only paid for a trade stand. Fifthly, the venue must be appropriate and broadly in line with the requirements of the Code. Finally, apart from paying for an exhibition stand the company must have no other involvement in the meeting or in the arrangements for it. This would include sponsoring delegates to attend or sponsoring other aspects of the meeting. Each case would be considered on its own merits bearing in mind all the relevant circumstances. The overall impression of the arrangements was an important consideration.

With regard to the meeting in question, the Panel noted that it was organised by the ISU. The ISU was of course free to organise whatever meetings it wanted to for its own members. If there had been no involvement from pharmaceutical companies then the meeting would not have been covered by the Code. The involvement of the pharmaceutical companies with various activities meant the matter was covered by the Code. Most of the pharmaceutical companies

had only exhibited at the meeting. Two of the companies had provided sponsorship.

The Panel considered that the scientific content was not unreasonable. It consisted of one and a half days of education. The programme stated '9 CPD [continuing professional development] credits'. The Panel noted that a number of companies paid for exhibition space and considered that the amount charged did not appear unreasonable. The Panel noted that the exhibitor's fee included 3 tickets for the conference dinner. (The Panel noted that the ISU had informed some of the companies that the cost of the exhibition stand at €1,850 represented around 2% of the total cost of hosting the scientific programme. Nineteen companies had supported the meeting thus covering 38% of the costs. The ISU stated that the sponsorship from exhibitors did not assist with the expense of the social functions including golf, conference dinner, gala dinner or accommodation). The exhibitor registration form included a section headed 'social programme' which stated that tickets for the conference dinner and gala dinner were €60 and €70 respectively. There was no mention of golf on this form. The Panel did not know how much the ISU charged for the golf. The Panel noted that the meeting programme referred to the golf and the gala dinner. The Panel considered that in this regard the two events were part of the formal proceedings of the meeting albeit that they occurred after the medical/scientific sessions had finished and had to be paid for by the delegates themselves.

The Panel further noted that the declaration of pharmaceutical company sponsorship on the back page of the programme was not clear as to exactly what had been supported. It was not unreasonable to assume that the companies listed had supported everything in the programme including the golf and gala dinner.

The Panel was also mindful of the established principle that a pharmaceutical company could not support a third party activity if that activity was itself in breach of the Code.

PANEL RULING IN CASE AUTH/2546/11/12

The Panel noted Astellas UK's submission that its Irish affiliate forgot to get UK approval for this meeting. The Panel considered that the Irish affiliate should know that any meeting which it sponsored in Northern Ireland was covered by the UK Code. This was clearly set out in the supplementary information to Clause 1.8 of the ABPI Code and reflected requirements in the EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals. The Panel noted that Astellas Europe had taken action to prevent such an oversight happening again.

The Panel noted that the venue was a 5 star conference hotel and would thus be seen as luxurious. In that regard the Panel queried whether the venue met the requirements of the Code. It noted Astellas UK's submission regarding the conference facilities offered by the venue but considered that other non-luxurious venues would have had adequate

conference facilities. The Panel further noted that Astellas's External Meeting Policy clearly stated that 5 star hotels should not be used for meetings.

Taking all the circumstances into account it appeared that the pharmaceutical companies listed on the back page of the programme had supported all the arrangements for the two-day meeting held at a luxurious venue with golf and a gala dinner. There was no indication that the majority of companies listed had only paid to exhibit at the meeting. The conference programme stated that without participation from the pharmaceutical and medical equipment industries the meeting would not be possible. The Panel considered that the arrangements for the meeting as described in the programme and the impression given were unacceptable. In this regard, high standards had not been met. The Panel ruled Astellas UK in breach of Clause 9.1.

The Panel noted that Astellas's involvement went further than paying for a trade exhibition. Astellas Ireland had paid £1012.40 for what was described in the programme as a drinks reception. The itemised bill was paid at 1.15am. The receipt recorded 125 covers and 265 items. Astellas UK stated that the drinks reception was immediately before dinner. The Panel was concerned about the arrangements in that attendees were given two tickets which allowed them to obtain two drinks of their choice; Astellas had no control over what was provided. In the Panel's view this was unacceptable. The itemised bill showed that a number of spirits (gin, whiskey, vodka and rum) had been ordered and it also included 2 Irish coffees, 3 liqueurs and a number of other drinks which were more likely to be consumed after dinner than before dinner. There was no way of knowing at what time the drinks were provided.

The Panel also noted that Astellas Ireland had supported the attendance of 6 delegates from the Irish Republic. Some of these delegates had their accommodation paid for, one dinner had been paid for and some registration fees.

The Panel considered that by supporting health professionals' attendance by paying for accommodation, subsistence and registration fees and its lack of control regarding drinks on the evening of the conference dinner rendered the level of hospitality provided by Astellas inappropriate. A breach of Clause 19.1 was ruled. High standards had not been met in this regard and a further breach of Clause 9.1 was ruled.

The Panel noted that a ruling of a breach of Clause 2 was a sign of particular censure and was reserved for such circumstances. The Panel noted its rulings above and the submission that Astellas had not paid for delegates to attend the golf or gala dinner. It decided that, on balance, the circumstances did not warrant such a ruling and no breach of Clause 2 was ruled.

CASE AUTH/2547/11/12 ALLERGAN

RESPONSE

Allergan stated that it received a request in December 2011 for sponsorship from the Royal College of

Surgeons in Ireland (RCSI) to support the ISU Annual Meeting. The meeting was of an extremely high educational standard with a full programme of scientific sessions, guest lectures and a moderated poster session with top experts in the field of urology. A copy of the programme for the previous annual meeting was provided by the RCSI for reference.

Allergan was informed of the meeting venue in Northern Ireland and that there would be attendees from both the Republic of Ireland and Northern Ireland.

The request for support for the meeting was reviewed and approved as a sponsorship request. Allergan had provided €1,850. A letter sent to the RCSI detailed the terms of Allergan's support, the €1,850 was to support the venue hire and AV costs for the meeting. Allergan requested that the following statement be added to all the associated materials produced in relation to the event:

'An educational grant was provided by Allergan Ltd to the Irish Society of Urology to support this independent course. Allergan has had no involvement in the logistics, design or content of the course.'

When considering the sponsorship request Allergan was aware of the proposed location and that the format would be similar to the 2011 Annual Meeting. It did not have the proposed 2012 agenda.

Allergan considered that the venue was acceptable. It was chosen by the ISU and met the logistical requirements of the delegates. The hotel was convenient for delegates flying in from around Ireland and the costs were not dissimilar to other business/congress hotels in Ireland. The complainants' description of the hotel reflected the hotel's marketing on its website, which was designed to attract customers to the venue.

Allergan understood that lunch and an evening meal would be provided on day 1 (Friday). There was a lunch break of 55 minutes and an evening conference BBQ in 2011 (lunch and a Conference Dinner in 2012). The subsistence meals on both of the Fridays were reasonable considering there was a full day of scientific content. The arrangements for day 1 for 2011 regarding subsistence were acceptable and appropriate when considering sponsorship of the 2012 event.

On day 2 (Saturday) in 2011, lunch was provided following a half day of scientific content and the meeting closed at 1.30pm. A similar format was used in 2012. Allergan submitted that the arrangements presented for 2011 for day 2 regarding subsistence were acceptable and appropriate when considering sponsorship of the 2012 event.

Neither the golf nor the gala dinner were part of the ISU meeting which concluded at midday. The ISU had confirmed that both the golf and gala dinner occurred after the scientific meeting had ended. Delegates who wished to play golf or attend the gala dinner paid their own costs and Allergan had no involvement in any part of these post-meeting activities.

Regarding the request for copies of the invitation, agenda, programme and any other materials, Allergan did not receive any of the documentation for the 2012 meeting as explained above. It did not select or pay for any health professional to attend the meeting.

Allergan understood the initial impression given by the meeting might cause concern. However, it hoped that the above information provided assurance that Allergan provided appropriate sponsorship, in line with the Code. Allergan understood that when sponsoring a meeting it needed to take into account the suitability of all the arrangements, in line with Clause 19.1. This was outlined in its standard operating procedures (SOPs).

The venue was considered to be acceptable, it was chosen by the ISU and met the logistical requirements of the delegates. The subsistence meals provided throughout the one and a half day meeting were appropriate given the length and scientific content of the meeting.

The golf and gala dinner were not part of the meeting. Allergan did not sponsor either of these activities.

In summary, Allergan submitted that it supported a high calibre, independently organised meeting in an acceptable venue and did not fund any social or sporting events. Therefore, it did not believe it had breached Clauses 19.1, 9.1 or 2.

In response to a request for further information Allergan explained that it was fairly new to the field of urology. In 2011 Allergan did not have any products licensed in the UK in this field although it anticipated a licence extension in quarter three or four of 2012 for Botox (botulinum toxin type A) for the management of urinary incontinence in adults with neurogenic detrusor overactivity. At the end of September 2012 Allergan received a UK licence for Botox for the management of urinary incontinence in adults with neurogenic detrusor overactivity due to subcervical spinal cord injury (traumatic or non-traumatic) or multiple sclerosis, who were not adequately managed with anticholinergics; patients should be already catheterising or willing and able to catheterise if required. Therefore, when the RCSI contacted the company about the meeting it did not wish to be an exhibitor as it had no product to promote.

However, it was happy to consider supporting the ISU Annual Meeting. The meeting was of an extremely high educational standard with a full programme of scientific sessions, guest lectures and a moderated poster session with top experts in the field of urology. Therefore, the RCSI was advised to complete an Allergan Sponsorship/Donation Request form and it selected the option 'Meeting Attendance'.

The request for support for the meeting was reviewed and approved as a sponsorship request. Allergan did not want to be an exhibitor at the meeting but was happy to provide support towards venue hire and AV costs. The letter that was sent to the RCSI detailed the terms of the support. Allergan requested that the following statement be added to all the associated materials produced in relation to the event.

'An educational grant was provided by Allergan Ltd to the Irish Society of Urology to support this independent course. Allergan has had no involvement in the logistics, design or content of the course.'

Whilst the request selected 'Meeting Attendance' (in error), Allergan clarified the terms of its support ie, via an educational grant, rather than as an exhibitor. Allergan did not have an exhibition stand at the meeting.

Only a regional scientific services (RSS) manager from Allergan attended the meeting. Allergan submitted that this was a non-promotional role and the RSS manager was present in a non-promotional capacity to attend the scientific sessions and meet with top experts in the field of urology. No Allergan employees attended the conference dinner on Friday, 21 September 2012.

Allergan did not complete an exhibitor registration form.

PANEL RULING IN CASE AUTH/2547/11/12

In addition to its general comments set out above, the Panel noted that Allergan had not had an exhibition stand at the meeting and its support was for the venue hire and AV costs. The company had clearly stated its terms of support in a letter to the RCSI.

The Panel noted that the venue was a 5 star conference hotel and would thus be seen as luxurious. In that regard the Panel queried whether the venue met the requirements of the Code. It noted Allergan's submission regarding the conference facilities offered by the venue but considered that other non-luxurious venues would have had adequate conference facilities. The Panel further noted that Allergan's SOP stated that in general a 4 star rating would be the top level of hotel to be selected as a venue.

Taking all the circumstances into account it appeared that the pharmaceutical companies listed on the back page of the programme had supported all the arrangements for the two-day meeting held at a luxurious venue with golf and a gala dinner. The penultimate page of the programme referred to the educational grant provided by Allergan. It was for the same amount as that paid for an exhibition stand. There was no indication that the majority of companies listed on the back page had only paid to exhibit at the meeting. The conference programme stated that without participation from the pharmaceutical and medical equipment industries the meeting would not be possible. The Panel considered that the arrangements for the meeting as described in the programme and the impression given were unacceptable. In this regard, high standards had not been met. The Panel ruled Allergan in breach of Clause 9.1.

The Panel noted that Allergan had not sponsored any health professional to attend the meeting by paying for accommodation, subsistence or registration fees. The company had supported the venue hire and AV

costs of the meeting. The Panel considered that the venue was on the limits of acceptability given its 5 star rating but nonetheless ruled no breach of Clause 19.1.

The Panel noted that a ruling of a breach of Clause 2 was a sign of particular censure and was reserved for such circumstances. The Panel noted its ruling above and the submission that Allergan had not paid for delegates to attend the golf or gala dinner. It decided that the circumstances did not warrant such a ruling and no breach of Clause 2 was ruled.

CASE AUTH/2548/11/12 BAXTER

RESPONSE

Baxter stated that its Irish operation was conducted by an Ireland registered branch of Baxter Healthcare Limited based in Dublin, the general manager of which reported directly to the UK general manager.

Baxter was committed to ensuring all its interactions with health professionals and medical institutions were appropriate. In order to achieve this, it had an international policy to regulate all such activities and ensure that requests were reviewed and approved to the relevant local standards. It also regularly reviewed compliance at senior management team meetings.

As was common practice in the industry, Baxter was keen to support and attend scientific events where the attendees were an appropriate and a relevant audience for the company to promote its products. In this case, the ISU was a *bona fide* medical society which held an educational meeting which was CPD accredited. The policies that covered the hospitality Baxter staff could give and receive were followed in the approval of this meeting (and in the attendance and conduct of employees at this meeting). However, this complaint highlighted an important issue for all companies, which was that it had limited influence over the organisation of and advertising for meetings run by medical societies. Yet the perception resulting from additional activities and the presentation of the meeting could be damaging.

Baxter submitted that it had not breached Clauses 19.1, 9.1 or 2 as it did not offer any hospitality to the delegates and its contribution was simply to support a scientifically valid event in the provision of an exhibition stand.

This complaint had made Baxter aware of how a sponsor could be perceived as having a broader involvement in an event than was actually the case. Consequently employees involved with the approval of events were re-trained to ensure everyone was aware of this issue and that Baxter took steps to ensure the boundaries of its involvement were clear to everyone who attended the meetings it supported.

While Baxter included and referred to the letter received from the Immediate Past President of the ISU, the company neither agreed with nor endorsed the sentiments expressed about the nature of the complaint.

Baxter stated that the meeting was first discussed in November 2011, before the organiser sent details of the meeting to Baxter, as a possible opportunity to inform Irish urologists about Baxter products. In April 2012 the Baxter office in Dublin received a letter from the ISU/RCSI which offered the opportunity to hire an exhibition stand at the meeting. Both organisations had their headquarters in Dublin and were well regarded and established medical societies. The invitation requested a fee of €1,850 to cover the cost of the stand itself, access to the exhibition area and scientific sessions for company attendees, plus lunch and tea/coffee for company attendees throughout each day of the congress. In accordance with Baxter's policy the request was reviewed by the Dublin office and approved.

Further, a formal agreement between Baxter Healthcare Limited and the RCSI set out which specific event Baxter was supporting, the value of Baxter's contribution, and what Baxter would receive in return. Namely, the right to have a stand for the duration of the scientific meeting; to secure space for a satellite symposium; to present the company logo to the delegates and to be named as a sponsor of the event in any associated communications.

Baxter stated that it never offered or committed to sponsoring any of the hospitality associated with the meeting and no Baxter employee was present during any hospitality event. The company's involvement was solely to be present during the scientific meeting in order to present and promote products to relevant delegates.

The meeting agenda referred to a gala dinner and golf being available but this was after the close of the scientific meeting. As reflected in the signed agreement between the parties, Baxter had no involvement with the organisation of, sponsoring of, or attendance at the golf and gala dinner that preceded or followed the scientific event. Baxter's employees left the meeting when the scientific sessions closed at 12.30pm and this was the limit of Baxter's involvement.

Since receiving this complaint, Baxter's Dublin office had received unsolicited a letter of clarification dated 5 December from the conference organiser, the Immediate Past President of ISU about the hospitality offered at the meeting, particularly the social activities. The intention of the letter was to clarify the role of the companies involved in the conduct of the meeting. In the clarification, the Immediate Past President emphasised the Society's independence in selecting the venue and also noted that no company had ever influenced the choice of venue for this annual meeting. According to the Immediate Past President the gala dinner took place at Stormont, the venue was made available to the society by [a politician] and all attendees paid for their own meals, and any other associated costs.

Baxter submitted that it did not offer any hospitality to the delegates; the agreement between the two organisations referred solely to Baxter's financial contribution to sponsor the exhibition stand and the lunch and refreshments provided during the scientific

meeting. None of Baxter's contributions were made for hospitality and no Baxter employee was present or involved in the hospitality provided, specifically the golf and gala dinner. Therefore, there had been no breach of Clause 19.1.

As there was no evidence to support a breach of Clause 19.1 there was likewise no evidence to support a breach of Clauses 9.1 or 2.

Baxter concluded that it had not identified any breach of internal policy or process. The clearly stated limitation on its involvement in the signed agreement showed no involvement in the hospitality beyond that associated with the scientific sessions. It had found no evidence of failure on the part of its processes. Baxter provided copies of its relevant policies.

Despite Baxter acting within its processes and the Code, the final agenda for the event, as supplied by the organisers, presented additional activities outside of the meeting in a way that could have implied inappropriate sponsorship. To ensure Baxter was alert to this risk and to avoid this situation in the future, all Baxter employees involved in the approval of events would be retrained to ensure they were made aware of, and took action to avoid, this issue in future. In addition, Baxter would review its contract template to strengthen how its involvement in an event was made clear to everyone who attended the meetings it supported and it would not sponsor any meetings or congress where there could be the perception of excessive hospitality, even if Baxter had nothing to do with the provision or sponsorship of such activities.

In response to a request for further information, Baxter confirmed that it did not hold a satellite symposium at this meeting. A standard agreement template was used by the Ireland team and they omitted to remove this section from the template. Training for the Ireland sales and marketing team was organized for January 2013 and this would include a refresher on using templates.

The first Baxter UK heard of the meeting was when it received notification from the Authority.

Baxter stated that it received an initial email from the organizing secretary around March 2012 announcing this meeting. Baxter's email policy resulted in the automatic deletion of emails after a fixed period of time and the relevant employee no longer had the email.

A copy of the exhibitor registration form was provided. Baxter submitted that this showed that it did not intend to be involved in the dinner or any social event. The costs of accommodation at the venue were within the normal range and did not raise any concern. No Baxter representative attended the conference dinner.

PANEL RULING IN CASE AUTH/2548/11/12

In addition to its general comments set out above, the Panel noted that the venue was a 5 star conference hotel and would thus be seen as luxurious. In that regard the Panel queried whether the venue met the

requirements of the Code. It considered that other non-luxurious venues would have had adequate conference facilities. The Panel further noted that Baxter's SOP stated that hotels must be modest and suited for business purposes. Generally this included 4 star business or similarly situated hotels. Higher class hotels might be selected only when there were legitimate and documented reasons. Examples were given.

Taking all the circumstances into account it appeared that the pharmaceutical companies listed on the back page of the programme had supported all the arrangements for the two-day meeting held at a luxurious venue with golf and a gala dinner. There was no indication that the majority of companies listed had only paid to exhibit at the meeting. The conference programme stated that without participation from the pharmaceutical and medical equipment industries the meeting would not be possible. The Panel considered that the arrangements for the meeting as described in the programme and the impression given were unacceptable. In this regard, high standards had not been met. The Panel ruled Baxter UK in breach of Clause 9.1.

The Panel noted that Baxter had not sponsored any health professional to attend the meeting by paying accommodation, subsistence or registration fees. The company had only paid for an exhibition stand. The Panel considered that the venue was on the limits of acceptability given its 5 star rating but nonetheless ruled no breach of Clause 19.1.

The Panel noted that a ruling of a breach of Clause 2 was a sign of particular censure and was reserved for such circumstances. The Panel noted its rulings above and the submission that Baxter had not paid for delegates to attend the golf or gala dinner. It decided that the circumstances did not warrant such a ruling and no breach of Clause 2 was ruled.

CASE AUTH/2552/11/12 FERRING

RESPONSE

Ferring Pharmaceuticals (UK) Ltd contacted colleagues in Ferring Ireland for confirmation of the details. Ferring Pharmaceuticals (Ireland) Ltd was a wholly owned subsidiary of Ferring BV in the Netherlands. Ferring Ireland did not report into Ferring Pharmaceuticals (UK) Ltd, although both companies were part of the Ferring Group.

Ferring submitted that the ISU was a 32 county, all Ireland medical body that represented medical professionals involved in urology in Ireland. The ISU, part of the Royal College of Surgeons in Ireland (RCSI) and based in Dublin, was a renowned professional society that arranged high calibre annual scientific meetings.

The President of the ISU confirmed to Ferring that the ISU independently chose the venue for the meeting. Neither Ferring Ireland, nor any other pharmaceutical company, had any control or influence over the choice of location or venue. The venue had excellent conference facilities. Ferring UK did not believe that a

5 star rating, or the presence of a spa, represented an incentive for delegates to attend the conference, as many hotels that had previously been to be shown acceptable had similar facilities. In addition, delegates paid their own expenses to attend the meeting.

The ISU independently developed the meeting programme and decided on all arrangements for the meeting with no influence from Ferring Ireland, or any other pharmaceutical company. The scientific programme clearly showed that the educational content was of the highest quality.

Ferring Ireland telephoned a manager in Ferring UK to let him/her know that the ISU meeting would take place in Belfast in September 2012. The UK manager decided that this was specifically an ISU meeting, that it was therefore outside of the remit of the UK company and that Ferring UK would not provide any sponsorship, nor be involved in the meeting in any way.

Ferring Ireland's sponsorship of this meeting was limited solely to paying to be an exhibitor. Ferring Ireland participated in the trade exhibition to allow the ISU members from the Republic of Ireland to discuss the latest information on Ferring products with Irish health professionals. No hospitality, gifts or promotional aids such as pens were available at the Ferring Ireland stand, or at the meeting.

The President of the ISU chose to hold the gala dinner at Stormont, which was made available by a politician.

No member of Ferring Ireland played golf or used the spa at the meeting. Ferring Ireland had no influence on any of the ISU arrangements, including transport for golf on the Saturday afternoon or the gala dinner. The Ferring Ireland exhibition stand closed as the scientific programme ended at lunch time on the Saturday.

Ferring Ireland did not pay for, or select, any medical professional to attend the meeting, made no additional arrangements with delegates before the meeting or provide any additional hospitality.

The Immediate Past President of the ISU confirmed in writing that no pharmaceutical company had any hand, act or part in any of the issues raised by the anonymous complainants, and that Ferring Ireland, and other pharmaceutical companies, had merely exhibited at this scientific meeting. As Ferring Ireland did not provide or facilitate any hospitality at this meeting, the question of the level of subsistence was not relevant. The Immediate Past President of the ISU also confirmed that all delegates were responsible for all their own expenses during the meeting, including registration fees, meals, accommodation and golf, for which the ISU made arrangements for those delegates who wished to play at their own expense at the conclusion of the scientific programme, at a course that was located several miles from the meeting venue.

A copy of the scientific programme for the meeting was provided. No invitations were sent out by Ferring

Ireland, nor was any information sent out to delegates.

In light of the information provided, Ferring UK did not believe that breaches of Clauses 19.1, 9.1, or 2 could be ruled. Ferring UK was not involved in any way in this meeting, and Ferring Ireland did not provide, or facilitate any hospitality. All delegates who attended this independently organised, well regarded, professional scientific meeting were responsible for all own expenses. Ferring Ireland attended the meeting solely in the capacity of a trade exhibitor and acted in a professional manner, maintaining high standards of conduct.

In response to a request for further information, Ferring confirmed that there was no correspondence between Ferring Ireland and the ISU and/or the RCSI in relation to the meeting in question other than the exhibitor registration form. This was an important scientific meeting that Ferring Ireland was well aware of and since no other support was to be offered, there was no need for any additional correspondence.

Ferring Ireland purchased two tickets for the conference dinner that was held on Friday, 21 September, but these were subsequently not used by any Ferring employee and nor were not passed on to anyone else. Ferring Ireland also purchased a ticket for the gala dinner held on Saturday, 22 September. A Ferring Ireland employee attended the dinner as a mark of respect for the ISU and its President. He had confirmed that he did not buy any drinks at the dinner. Ferring Ireland did not sponsor any guests to attend the gala dinner or sponsor any part of the function.

PANEL RULING IN CASE AUTH/2552/11/12

In addition to its general comments set out above, the Panel noted Ferring UK's submission and considered that Ferring Ireland should know that any meeting which it sponsored in Northern Ireland was covered by the UK Code. This was clearly set out in the supplementary information to Clause 1.8 of the ABPI Code and reflected requirements in the EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals.

The Panel noted that the venue was a 5 star conference hotel and would thus be seen as luxurious. In that regard the Panel queried whether the venue met the requirements of the Code. It noted Ferring UK's submission regarding the conference facilities offered by the venue but considered that other non-luxurious venues would have had adequate conference facilities.

Taking all the circumstances into account it appeared that the pharmaceutical companies listed on the back page of the programme had supported all the arrangements for the two-day meeting held at a luxurious venue with golf and a gala dinner. There was no indication that the majority of companies listed had only paid to exhibit at the meeting. The conference programme stated that without participation from the pharmaceutical and medical equipment industries the meeting would not be possible. The Panel considered that the arrangements

for the meeting as described in the programme and the impression given were unacceptable. In this regard, high standards had not been met. The Panel ruled Ferring UK in breach of Clause 9.1.

The Panel noted that Ferring had not sponsored any health professional to attend the meeting by paying accommodation, subsistence or registration fees. The Panel considered that the venue was on the limit of acceptability given its 5 star rating but nonetheless ruled no breach of Clause 19.1.

The Panel noted that Ferring's involvement went further than paying for a trade exhibition. One employee had attended the gala dinner.

The Panel considered that purchasing a ticket for the gala dinner was inappropriate. Although health professionals paid for their own tickets it was not acceptable for a company to be involved in such an event. The educational content of that day (3 hours 40 minutes in the morning) did not justify the gala dinner in the evening which appeared to be a social event. A breach of Clause 19.1 was ruled. High standards had not been met in this regard and a further breach of Clause 9.1 was ruled.

The Panel noted that a ruling of a breach of Clause 2 was a sign of particular censure and was reserved for such circumstances. The Panel noted its rulings above and the submissions that Ferring had not paid for delegates to attend the golf or gala dinner. It decided that, on balance, the circumstances did not warrant such a ruling and no breach of Clause 2 was ruled.

CASE AUTH/2554/11/12 IPSEN

RESPONSE

Ipsen Limited stated that it was extremely dismayed to receive the complaint about the ISU meeting. Ipsen Pharmaceuticals, named as one of the sponsors of the meeting, was the Irish operating company; Ipsen Limited was the UK operating company. Ipsen Limited took responsibility for this meeting as it was held in the UK.

The meeting was an annual academic event which attracted urological surgeons primarily from the Republic of Ireland, with smaller delegations from Northern Ireland and the UK mainland. The statistics for participants were provided.

On 18 May 2012 Ipsen was invited to complete the exhibitor booking form in order to have a stand at the meeting. In June 2012 an email exchange between the Irish and UK operating companies confirmed that, since the meeting was in Belfast, ABPI compliant stands and materials would be required, and also that the stand would be managed by one representative from the UK and two from the Irish company. It was agreed that the cost of the stand would be split 1:2 with the UK reimbursing the Irish company for one third of the total cost of €1,850.

On 3 July 2012 a senior product manager reviewed the preliminary details of the meeting as per the current local SOP. At that time, the only details from

ISU were the dates, venue and the fact that the meeting was organised by the ISU which Ipsen knew was a well-respected, academic association based in the Irish Republic but which described itself as an all island society.

Ipsen stated that this situation was very common when conference organisers initially approached companies about stand space and sponsorship. The venue had already been selected by the ISU and, while possibly at the limits of acceptability for ABPI Code compliance, it was a very well-known conference venue with the capacity to cope with a moderately sized meeting both in conference rooms and overnight accommodation, and was extremely well situated to suit the delegates travelling from the Republic, Northern Ireland and the UK as it was close to major road networks, Belfast City airport and the docks. This meeting was known to be an important event for the Irish urological community and it would have been the scientific programme and not the venue which was the main attraction. The meeting was therefore 'approved' with the proviso that there were no major sporting/leisure activities occurring at the same time and that the programme was of a scientific nature.

On 29 August 2012 the UK office received the final agenda for the meeting which confirmed the scientific nature of the meeting.

Ipsen did not advertise the meeting or produce any materials specific to the meeting and it did not sponsor any delegates to attend. Ipsen did not provide any sponsorship beyond the cost of the stand: its sponsorship in this regard was acknowledged on the last page of the programme. Both the stand and materials on it were already certified for use under the ABPI Code. Ipsen representatives did not attend the conference dinner on Friday night [see below]. All Ipsen representatives (and, in fact, the representatives from the other companies present) left at the end of the scientific meeting, defined clearly in the programme as 12.10pm on Saturday ('Lunch & Close of Meeting' in the 'programme at a glance' and 'Close of Meeting – Lunch and Exhibition' on the detailed agenda). The stand was dismantled late morning and was collected between 1–1.15pm. The impression to the delegates attending the meeting would have supported the scientific meeting ending at lunchtime as the company stands were packed up, collected and company staff left. Ipsen had no part in the organisation or sponsorship of either the golf or the gala dinner which were paid for separately from the meeting by the delegates themselves. Ipsen received an unsolicited letter from the ISU in December 2012 confirming this and the fact that the golf was arranged for a time after the scientific meeting had ended.

In response to the specific points raised by the Authority, Ipsen submitted that it had demonstrated that it had sponsored a stand at the meeting (jointly shared by the Irish and UK affiliates and with UK-appropriate materials) with no other sponsorship provided to either the ISU or any individual delegates; the venue was acceptable based on the geography of the delegates attending and was a known conference venue; the ISU was a well-respected academic

institution and the final programme for the meeting reflected the high quality of the clinical programme and posters presented; the scientific meeting clearly ended at lunchtime on Saturday and this was obvious from the programme provided to delegates by ISU; no pharmaceutical company had any part in the after-meeting arrangements. Thus Ipsen did not believe that it was in breach of Clauses 19.1 or Clause 2.

Ipsen followed its own SOPs and believed that the scientific meeting arrangements, venue and hospitality were appropriate to the nature of the meeting and the delegates attending. With hindsight, the wording of the programme was perhaps not ideal as the sponsors were listed after the end of Saturday's events (including the after-meeting events) and not after the end of the scientific meeting which would have more accurately reflected Ipsen's involvement. It was possible that it could have written to the ISU after it received the final programme at the end of August to ask it to clarify this and amend the programme accordingly, but Ipsen did not, which was regrettable but not, it submitted, a failure to maintain high standards and it was not, therefore, in breach of Clause 9.1.

In response to a request for further information, Ipsen provided a copy of the exhibitor registration form. It confirmed that two Ipsen representatives from the Irish affiliate attended both the meeting and the dinner. Ipsen apologised that this was not known when it first responded. The managing director of the Irish affiliate had only been told on 7 January that the two Irish affiliate representatives had attended. Ipsen did not consider that this materially changed any of the points in its original response as the conference dinner was an integral part of the scientific congress.

PANEL RULING IN CASE AUTH/2554/11/12

In addition to its general comments set out above, the Panel noted that the venue was a 5 star conference hotel and would thus be seen as luxurious. In that regard the Panel queried whether the venue met the requirements of the Code. It noted Ipsen UK's submission regarding the conference facilities offered by the venue but considered that other non-luxurious venues would have had adequate conference facilities. The Panel further noted that Ipsen's SOP on regional, national and international sponsored meetings clearly stated that it was not acceptable to use 5 star hotels.

Taking all the circumstances into account it appeared that the pharmaceutical companies listed on the back page of the programme had supported all the arrangements for the two-day meeting held at a luxurious venue with golf and a gala dinner. There was no indication that the majority of companies listed had only paid to exhibit at the meeting. The conference programme stated that without participation from the pharmaceutical and medical equipment industries the meeting would not be possible. The Panel considered that the arrangements for the meeting as described in the programme and the impression given were unacceptable. In this regard, high standards had not been met. The Panel ruled Ipsen UK in breach of Clause 9.1.

The Panel noted that Ipsen had not sponsored any health professional to attend the meeting by paying accommodation, subsistence or registration fees. The Panel considered that the venue was on the limit of acceptability given its 5 star rating but nonetheless ruled no breach of Clause 19.1.

The Panel noted that a ruling of a breach of Clause 2 was a sign of particular censure and was reserved for such circumstances. The Panel noted its rulings above and the submissions that Ipsen had not paid for delegates to attend the golf or gala dinner. It decided that the circumstances did not warrant such a ruling and no breach of Clause 2 was ruled.

The Panel noted that two Ipsen representatives had attended the conference dinner. The Panel was concerned that Ipsen's initial response stated that its representatives had not attended the conference dinner. This was unacceptable; self regulation relied upon a full and frank disclosure of the facts at the outset. Noting all the circumstances, the Panel decided to take no further action.

CASE AUTH/2556/11/12 JANSSEN

RESPONSE

Janssen stated that it had conducted a review of the circumstances surrounding the provision of support to this meeting. The one and a half day meeting had a rigorous scientific content, with over 9 hours of lectures and other presentations on relevant medical and scientific issues.

Janssen's office in Ireland agreed to sponsor the 2012 meeting following an email exchange with the RCSI, which organised the ISU meeting. Copies of the emails were provided. When Janssen internally approved the meeting for sponsorship, it knew the timing and venue of the meeting and a 'save the date' flyer was available but there was no agenda or 'welcome message' from the ISU President for that year's meeting available, although a copy of the agenda for the 2011 ISU meeting was provided to Janssen to assist in its decision-making.

The ISU had confirmed that payment of €1,850 for an exhibition stand represented approximately 2% of the total cost of the meeting and therefore, with 19 sponsoring companies, the industry sponsorship for the meeting accounted for less than 50% of the total cost. On the basis of the above information, Janssen Ireland approved the meeting, which it considered complied with its own SOP and Clauses 16.1, 16.3, 16.4 and 16.6 of the IPHA Code of Practice.

No Janssen materials for health professionals were produced for this meeting and the exhibition stand displayed a previously approved, non-promotional, Janssen corporate banner. Two Janssen staff attended the scientific meeting, largely for their own personal education in the field of prostate cancer, but left at the close of the scientific programme and before the optional golf and gala dinner on 22 September 2012.

Although the meeting was held in Northern Ireland and attended by UK health professionals, the relevant staff in the Republic of Ireland approved the event in the same way as if it were to be held in the Republic of Ireland and did not refer the meeting to the UK office for consideration under the ABPI Code.

No health professionals, either based in the Republic of Ireland or the UK, were sponsored by Janssen to attend the meeting.

Janssen stated that although the hotel chosen by the ISU for the meeting was described as a 5 star venue, it also had dedicated conference facilities and was conveniently situated with regards to road and air links. The features of the hotel were not portrayed as an attraction to potential delegates in the information provided to Janssen at the time of approval or in the subsequent 2012 scientific programme brochure provided to health professionals who expressed an interest in attending. The room and breakfast rates offered to delegates, £120 to £150 per night, fell within Janssen's internal travel policy limits and were not excessive. The hotel amenities did not include a golf course.

Janssen noted that on the basis of the known 2011 meeting and confirmed in the 2012 scientific programme, the planned meeting had a rigorous scientific content. The ISU (founded in 1956) was a well established and respected learned society. Attendance at the 2012 meeting would have earned eligible health professionals 9 CPD points from the RCSI. In the opinion of the approving Janssen staff in Ireland, the educational value of the meeting, rather than its venue or associated social activities, would have been the overriding attraction for delegates.

Janssen submitted that although it appeared on the agenda, golf took place after the scientific meeting had closed. A letter from the then President of the ISU stated that the golf was arranged for a time after the scientific meeting had finished and when the trade exhibitors and indeed some attendees had already left. The ISU confirmed that the pharmaceutical companies' sponsorship was not used to pay for golf, and Janssen had been informed by the ISU that delegates were expected to pay for this activity themselves. No Janssen staff attended the golf, which was played on a golf course close to, but not part of, the hotel complex, and no support was provided by Janssen for any individual health professionals to play golf.

Janssen stated that as specified in the scientific programme, the gala dinner at the Northern Ireland Parliament Building at Stormont was sponsored by a politician in the Northern Ireland government. The ISU had informed Janssen that pharmaceutical sponsorship money was not used to fund the gala dinner. The current President confirmed in a letter to Janssen's Acting Head of Medical Affairs in Ireland that it had always been procedure at the ISU meetings that any social activities available to delegates, accommodation and travel expenses were funded by themselves. No Janssen employee attended the dinner, and no support was provided by Janssen for any individual health professionals to attend the event.

In considering the complaint, Janssen addressed the three clauses of the Code. The meeting had a clear and robust educational content and the non-educational content, such as optional golf and the gala dinner, was secondary to this and was not, in Janssen's opinion, the major attraction of this meeting to delegates. As mentioned above, Janssen did not sponsor any individual health professional to attend the meeting. Although the reference to a gala dinner and golf in the scientific programme brochure was unfortunate in the context of appropriateness under the Code, the organisers confirmed that financial support received from Janssen and other sponsors did not fund or subsidise these activities. Given the size of the meeting (132 delegates) and considerations of convenience and actual cost of rooms, the ISU's choice of venue could be seen to be justifiable and not inappropriate in the circumstances. In light of the information provided above, Janssen submitted that no breach of Clause 19.1 had occurred.

The review and approval of sponsorship was done according to the relevant Janssen SOP and appropriate permissions were sought. In this regard, Janssen submitted that high standards were maintained from a company perspective. The failure to review the meeting using the ABPI Code as well as the IPHA Code to a meeting organised by an all Ireland learned society held in Northern Ireland was a regrettable oversight by the Janssen staff in Ireland. As high standards were maintained, albeit without the ABPI Code being used as the standard by which the meeting was judged, Janssen submitted that no breach of Clause 9.1 had occurred.

Given the above, Janssen submitted that its support of this scientific meeting it had not brought the pharmaceutical industry into disrepute, so no breach of Clause 2 had occurred.

In response to a request for further information Janssen stated that its stand consisted of two Janssen corporate banners. Available on the stand were a reprint of a journal article, a corporate-branded blank notebook and a corporate-branded ballpoint pen. (Copies of the banners, a copy of the reprint and photographs of the notebook and pen were provided). The items were provided under the provisions of Clause 14.1 of the IPHA Code.

The stand was manned by a manager from Janssen's Irish office, who also attended some of the scientific sessions. The other Janssen staff member who attended from the Irish office, did not man the stand but attended the scientific sessions. The majority of the combined time of the two Janssen employees at the conference was spent attending the scientific sessions. Both attended the conference dinner.

Janssen noted that the ticket which it purchased for the gala dinner was not used. To confirm the information in its initial response, no Janssen employee attended the gala dinner and no health professional was given this unused ticket, nor sponsored to attend.

The draft agenda was available on 27 July 2012 and a final agenda available on 27 August 2012. Janssen received these documents on or near these dates.

PANEL RULING IN CASE AUTH/2556/11/12

In addition to its general comments set out above, the Panel noted Janssen UK's submission and considered that the Irish affiliate should know that any meeting which it sponsored in Northern Ireland was covered by the UK Code. This was clearly set out in the supplementary information to Clause 1.8 of the ABPI Code and reflected requirements in the EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals.

The Panel noted that the venue was a 5 star conference hotel and would thus be seen as luxurious. In that regard the Panel queried whether the venue met the requirements of the Code. It noted Janssen UK's submission regarding the conference facilities offered by the venue but considered that other non-luxurious venues would have had adequate conference facilities. The Panel noted that Janssen's SOP stated that venues should be modest and appropriate.

Taking all the circumstances into account it appeared that the pharmaceutical companies listed on the back page of the programme had supported all the arrangements for the two-day meeting held at a luxurious venue with golf and a gala dinner. There was no indication that the majority of companies listed had only paid to exhibit at the meeting. The conference programme stated that without participation from the pharmaceutical and medical equipment industries the meeting would not be possible. The Panel considered that the arrangements for the meeting as described in the programme and the impression given were unacceptable. In this regard, high standards had not been met. The Panel ruled Janssen UK in breach of Clause 9.1.

The Panel noted that Janssen had not sponsored any health professional to attend the meeting by paying accommodation, subsistence or registration fees. The Panel considered that the venue was on the limit of acceptability given its 5 star rating but nonetheless ruled no breach of Clause 19.1.

The Panel noted that Janssen's involvement went further than paying for a trade exhibition. A ticket had been purchased for the gala dinner which the Panel considered was inappropriate. Although health professionals paid for their own tickets it was not acceptable for a company to be involved in such an event. The educational content of that day (3 hours 40 minutes in the morning) did not justify the gala dinner in the evening which appeared to be a social event. The Panel noted that no-one from Janssen used the dinner ticket but considered that its purchase showed an intent to attend. A breach of Clause 19.1 was ruled. High standards had not been met in this regard and a further breach of Clause 9.1 was ruled.

The Panel noted that a ruling of a breach of Clause 2 was a sign of particular censure and was reserved for such circumstances. The Panel noted its rulings above and the submissions that Janssen had not paid for delegates to attend the golf or gala dinner. It decided that, on balance, the circumstances did not warrant such a ruling and no breach of Clause 2 was ruled.

The Panel noted that Janssen did not attend the meeting solely in the capacity of a trade exhibitor. Janssen had purchased a ticket for the gala dinner although this ticket was not used. The Panel was very concerned that this information had not been provided with Janssen's initial response. This was unacceptable; self regulation relied upon a full and frank disclosure of the facts at the outset.

CASE AUTH/2559/11/12 ORION

RESPONSE

Orion Pharma UK contacted Orion Pharma (Ireland) Ltd for confirmation of the details. Orion Pharma (Ireland) Ltd was a wholly owned subsidiary of Orion Corporation in Finland and operated in Ireland independently of Orion Pharma (UK) Ltd.

The ISU was based in Dublin. It was an 'all Ireland' medical body that represented medical professionals involved in urology and was part of the RCSI based in Dublin. It was a renowned professional society that arranged high calibre, annual scientific meetings.

The President of the ISU confirmed that the society independently chose the venue for the meeting. Orion Pharma Ireland did not have any control or influence over the choice of venue.

Orion submitted that the venue provided high quality conference facilities, it was centrally located with excellent transport connections and was not lavish, extravagant or deluxe. The travel industry site 'Travel Weekly', which was widely respected, rated the hotel as 'Superior First Class'. Orion did not believe that a 5 star rating, or the presence of a spa, represented an incentive for delegates to attend the conference. Many hotels that had previously been considered to be acceptable under the Code had similar facilities. In addition, individual delegates were personally responsible for meeting their own costs and expenses associated with their attendance at this meeting.

The ISU developed the programme and the arrangements for the meeting independently of all pharmaceutical companies, including Orion Pharma Ireland. The scientific programme established that the educational content of the meeting was of the highest value, demonstrating a clear, high calibre educational content with presentations and posters covering aspects of urology ranging from basic science to practical surgical matters delivered by Irish, UK and international experts.

Sponsorship by Orion Pharma Ireland was limited to a payment to the ISU for the sole purpose of registering as a trade exhibitor at the meeting. Orion Pharma Ireland participated in the trade exhibition solely to engage with members of the ISU from the Republic of Ireland. All Orion Pharma Ireland personnel left the congress at lunchtime on Saturday 22 September, at the conclusion of the scientific programme. The President of the ISU chose to hold the gala dinner at Stormont, which was made available to the society by [a named politician]. No pharmaceutical companies had any input into this event. Orion Pharma Ireland did not make any financial

contribution to this portion of the event and Orion UK understood that all attendees paid for their meals and all other costs associated with the gala dinner.

No member of Orion Pharma Ireland attended the gala dinner, played golf or used the spa at the meeting. Orion Pharma Ireland had no influence on any of the ISU arrangements, including transport for golf or the gala dinner.

Orion Pharma Ireland did not pay for, or invite, any medical professionals to attend this meeting and made no additional arrangements with delegates prior to the meeting, or provide any additional hospitality during the event.

A letter sent to Orion Pharma Ireland by the President of the ISU confirmed that no pharmaceutical company had any hand, act or part in any of the issues raised in the anonymous letter of complaint, and that Orion Pharma Ireland, and the other pharmaceutical companies, were merely exhibitors at this scientific meeting.

As Orion Pharma Ireland did not provide or facilitate any hospitality at this meeting, the question of the level of subsistence was not relevant. The President of the ISU had also confirmed that all delegates were responsible for all their own expenses during the meeting, including registration fees, meals, accommodation and golf. The ISU made arrangements for those delegates who wished to play golf, at their own expense, at the conclusion of the scientific programme.

Orion UK did not provide any sponsorship and was not involved in the meeting in any way.

In view of the information provided, Orion UK did not believe that breaches of Clauses 19.1, 9.1 or 2 could be ruled. Orion Pharma UK was not involved in any way in this meeting, and Orion Pharma Ireland did not provide, or facilitate any hospitality. All delegates attending this independently organised, well regarded, professional scientific meeting were responsible for meeting all their own expenses. Orion Pharma Ireland attended the meeting solely as a trade exhibitor and acted in a professional manner, maintaining high standards of conduct.

In response to a request for further information, Orion Pharma UK confirmed that three Orion Ireland personnel attended the conference dinner on and that no employees from Orion Ireland attended the gala dinner.

A copy of the completed exhibitor registration form was provided.

Orion Pharma Ireland received an email link to the draft programme on 30 July 2012, with the final programme being requested from the organisers on 18 September 2012.

PANEL RULING IN CASE AUTH/2559/11/12

In addition to its general comments set out above, the Panel noted that the venue was a 5 star conference

hotel and would thus be seen as luxurious. In that regard the Panel queried whether the venue met the requirements of the Code. It noted Orion UK's submission regarding the conference facilities offered by the venue but considered that other non-luxurious venues would have had adequate conference facilities.

Taking all the circumstances into account it appeared that the pharmaceutical companies listed on the back page of the programme had supported all the arrangements for the two-day meeting held at a luxurious venue with golf and a gala dinner. There was no indication that the majority of companies listed had only paid to exhibit at the meeting. The conference programme stated that without participation from the pharmaceutical and medical equipment industries the meeting would not be possible. The Panel considered that the arrangements for the meeting as described in the programme and the impression given were unacceptable. In this regard, high standards had not been met. The Panel ruled Orion UK in breach of Clause 9.1.

The Panel noted that Orion UK had not sponsored any health professional to attend the meeting by paying accommodation, subsistence or registration fees. The Panel considered that the venue was on the limit of acceptability given its 5 star rating but nonetheless ruled no breach of Clause 19.1.

The Panel noted that a ruling of a breach of Clause 2 was a sign of particular censure and was reserved for such circumstances. The Panel noted its ruling above and the submission that Orion had not paid for delegates to attend the golf or gala dinner. It decided that the circumstances did not warrant such a ruling and no breach of Clause 2 was ruled.

CASE AUTH/2560/11/12 PFIZER

RESPONSE

Pfizer stated that the ISU was a society that promoted the specialty of urology and its related medical sciences in Ireland. The society was advisory to the Irish Department of Health and Joint Committee on Higher Surgical Training (JCHST) for UK & Ireland and had historically included health professionals from Northern and Southern Ireland. Pfizer Ireland was approached in February 2012 and again in May 2012 to take an exhibition stand during the scientific meeting exhibition times. Nineteen pharmaceutical and medical device companies exhibited at this meeting. There were no attendees from Pfizer UK and one representative from Pfizer Ireland at the meeting. No health professionals were sponsored to attend by Pfizer Ireland or Pfizer UK. Pfizer Ireland asked Pfizer UK to provide two exhibition stands.

Pfizer Ireland reviewed the request in line with its local procedure. The totality of the event was looked at and a number of factors including the number of exhibitors, the CPD accreditation and scientific programme were considered. Pfizer Ireland asked the meeting organisers how the Pfizer funding would be allocated and how the social elements of the meeting would be funded. A comprehensive response from

the ISU in this regard was received which confirmed that the financial contribution provided by Pfizer would be allocated to the scientific programme only and was a nominal sponsorship amount (2%) in relation to the overall cost of the meeting.

The following information was sent by the ISU by email on 30 August 2012:

'This sponsorship provides the opportunity for Pfizer Healthcare and other colleagues from the pharmaceutical and medical equipment industries to promote their products and services to delegates. The sponsorship received from exhibitors assists with the overall costs involved in hosting the meeting including, the design and printing costs associated with the scientific programme, the audio-visual equipment hired for presentations and delegate day rates @ £45 each which covers tea/coffee breaks and lunch per day. We anticipate 100 – 120 delegates will attend this year's meeting. The sponsorship received from exhibitors does not assist with the expenses of the social functions including the golf, conference dinner and gala dinner or accommodation. Guests are responsible for purchasing tickets to each social event. To do this delegates register online, when registering they are also given the option to reserve tickets for the social events, if they wish to attend. Ticket prices cover the costs associated with each event (including transport and wine). We also offer the option to companies to specifically sponsor a social function or contribute towards a speaker's travel costs. Only in this instance is sponsorship used for a social event. The income produced through delegates' registrations covers the majority of the expenditure. The sponsorship of €1,850.00 accumulates 2% of the total cost of the meeting.'

Pfizer Ireland did not receive or request any further information in this regard, and agreed to the minimum level of sponsorship which only covered the educational content of the congress.

Pfizer provided a copy of a letter received from the Immediate Past President of the ISU which clarified the respective roles of the ISU and the pharmaceutical companies in the meeting arrangements.

As per the ISU email of 30 August, payment for the exhibition stand did not contribute towards any of the social events related to the meeting. This would have only occurred if the company had specifically chosen to sponsor one of these events, which it did not.

Pfizer Ireland procedure outlined the process that should be followed in managing any corporate sponsorship activity. In circumstances where Pfizer Ireland considered sponsorship of a third party event, regardless of whether the meeting was taking place in another country, this was the process that applied. In this instance Pfizer Ireland followed the process. Approval was obtained electronically based on the information submitted. As there were no UK based individuals on the steering committee of the ISU (which received the corporate sponsorship) and no UK health professionals sponsored to attend, the Irish SOP did not require approval of the meeting arrangements from the UK. This was an oversight and

the Irish SOP was being revised with immediate effect to ensure that if an Irish meeting took place in Northern Ireland then ABPI Code approval would be sought for the arrangements of the meeting.

Pfizer did not have any involvement or engage directly with any meeting delegates; information was sent directly by the ISU. Pfizer did not produce or supply any materials about the meeting arrangements that were directly provided to delegates. Nor did Pfizer (UK or Ireland) sponsor any health professionals to attend.

Pfizer accepted that due to the nature of the venue and the potential perception of the social aspects described on the agenda, it was not appropriate to provide sponsorship by taking up the offer to have an exhibition stand at the meeting. The internal processes in place within Pfizer Ireland were followed and the request was assessed in line with the Irish SOP and approved accordingly. In light of the issues that had arisen Pfizer UK was working with colleagues in Pfizer Ireland to revise the procedure to be applied in circumstances where they were invited to exhibit at meetings to be held in Northern Ireland. Pfizer accepted that a breach of Clause 19.1 had occurred.

Pfizer accepted that high standards had not been maintained and a breach of Clause 9.1 had occurred.

Pfizer's submitted that its contribution to the overall expense of this meeting represented 2% of the overall costs involved and its presence was limited to a small exhibition area, with one Pfizer Ireland employee in attendance. Pfizer provided the minimum level of sponsorship on the basis that this supported the educational activities of the meeting only. Pfizer did not sponsor any of the social aspects of the meeting, nor did its sponsorship support excessive hospitality as alleged. It did not sponsor any UK or Irish health professionals to attend and there were no Pfizer UK staff at the meeting. Pfizer strongly believed that the industry had not been brought into disrepute by sponsorship of the educational content only for a third party meeting run by the ISU and therefore no breach of Clause 2 had occurred.

In response to a request for further information, Pfizer stated that following on from a previous request from the RCSI for participation in the meeting, Pfizer Ireland called the RCSI to request additional detail on how the exhibition stand fee of €1,850 would be allocated and also to request confirmation of the ISU council members for internal approval purposes.

Pfizer Ireland confirmed its attendance on 31 August and returned the exhibitor registration form on 3 September. When the registration form was completed the Pfizer Ireland manager had not decided who and how many would attend from Pfizer Ireland. Of the three names entered on the form Pfizer Ireland confirmed that only one attended: Pfizer Ireland received from RCSI a draft agenda on 30 July. No Pfizer Ireland employee attended the conference dinner.

PANEL RULING IN CASE AUTH/2560/11/12

In addition to its general comments set out above, the Panel noted Pfizer UK's submission that its Irish SOP did not require UK approval for this meeting. The Panel considered that the Irish affiliate should know that any meeting which it sponsored in Northern Ireland was covered by the UK Code. This was clearly set out in the supplementary information to Clause 1.8 of the ABPI Code and reflected requirements in the EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals. The Panel noted that Pfizer UK had taken action to prevent such an oversight happening again.

The Panel noted that the venue was a 5 star conference hotel and would thus be seen as luxurious. In that regard the Panel queried whether the venue met the requirements of the Code. It noted Pfizer UK's submission that it was not appropriate to provide sponsorship given the nature of the venue and what it described as the social aspects stated on the agenda. The Panel considered that other non-luxurious venues would have had adequate conference facilities.

Taking all the circumstances into account it appeared that the pharmaceutical companies listed on the back page of the programme had supported all the arrangements for the two-day meeting held at a luxurious venue with golf and a gala dinner. There was no indication that the majority of companies listed had only paid to exhibit at the meeting. The conference programme stated that without participation from the pharmaceutical and medical equipment industries the meeting would not be possible. The Panel considered that the arrangements for the meeting as described in the programme and the impression given were unacceptable. In this regard, high standards had not been met. The Panel ruled Pfizer UK in breach of Clause 9.1 as acknowledged by the company.

The Panel noted that Pfizer had not sponsored any health professional to attend the meeting by paying accommodation, subsistence or registration fees. The Panel considered that the venue was on the limit of acceptability given its 5 star rating but nonetheless ruled no breach of Clause 19.1.

The Panel noted that a ruling of a breach of Clause 2 was a sign of particular censure and was reserved for such circumstances. The Panel noted its rulings above and the submission that Pfizer had not paid for delegates to attend the golf or gala dinner. It decided that the circumstances did not warrant such a ruling and no breach of Clause 2 was ruled.

CASE AUTH/2561/11/12 RECORDATI

RESPONSE

Recordati Pharmaceuticals Ltd confirmed that the response from Recordati Ireland Ltd be used as the formal response to this complaint.

No-one attended the ISU Annual Meeting from Recordati Pharmaceuticals Ltd. Recordati Ireland Ltd

did attend this meeting. This was a completely separate business to the UK subsidiary and was not connected in any way to the UK business.

In Ireland, the pharmaceutical industry had its own code of practice, the IPHA Code of Marketing Practice. Recordati Ireland submitted that it took the IPHA Code seriously and every effort was made to ensure that it was always fully compliant. Recordati Ireland submitted that it was certainly 100% compliant at the ISU Annual Meeting.

Recordati Ireland provided a letter from the Immediate Past President of the ISU together with the breakdown of the number of attendees who attended the meeting from Northern Ireland, Republic of Ireland and overseas which addressed the clear inaccuracy of the first point of the complaint.

Recordati Ireland understood that the ISU had already sent a similar letter to the PMCPA to address several other inaccuracies in the complaint. Recordati Ireland was sure that the correspondence would also clarify fully how and by whom the meeting was organised.

Recordati Ireland noted a number of points from the letter from the ISU. These being: firstly, that it did not have any input in choosing the venue for the meeting or gala dinner. Secondly, no-one from Recordati Ireland attended the gala dinner and thirdly, Recordati Ireland did not have any input into arranging/paying for golf for any delegates. None of the Recordati Ireland employees played golf at this meeting.

Recordati Ireland was invited to exhibit at the trade exhibition during the course of the meeting and a separate room was provided by the ISU for this purpose. Recordati Ireland had no part to play in the organisation or running of this meeting.

Recordati Ireland asked the PMCPA to confirm in writing to Recordati Pharmaceuticals Ltd that as it was not at the meeting in question, Case AUTH/2561/11/12 was closed. It also asked the PMCPA to confirm that it was happy with the clarification regarding Recordati Ireland's exemplary conduct at the meeting.

In response to a request for further information, Recordati Ireland provided a copy of the exhibitor registration form which was completed and returned to the ISU on 21 May 2012. Four Recordati Ireland employees attended the conference dinner.

Recordati Ireland did not sponsor any health professional to attend any part of this meeting or to attend either of the two dinners. Recordati Ireland was provided with a link to the programme on 27 August.

PANEL RULING IN CASE AUTH/2561/11/12

In addition to its general comments set out above, the Panel noted that the venue was a 5 star conference hotel and would thus be seen as luxurious. In that regard the Panel queried whether the venue met the requirements of the Code. It noted Recordati UK's submission regarding the conference facilities offered by the venue but considered that other non-luxurious venues would have had adequate conference facilities.

Taking all the circumstances into account it appeared that the pharmaceutical companies listed on the back page of the programme had supported all the arrangements for the two-day meeting held at a luxurious venue with golf and a gala dinner. There was no indication that the majority of companies listed had only paid to exhibit at the meeting. The conference programme stated that without participation from the pharmaceutical and medical equipment industries the meeting would not be possible. The Panel considered that the arrangements for the meeting as described in the programme and the impression given were unacceptable. In this regard, high standards had not been met. The Panel ruled Recordati UK in breach of Clause 9.1.

The Panel noted that Recordati had not sponsored any health professional to attend the meeting by paying accommodation, subsistence or registration fees. The Panel considered that the venue was on the limit of acceptability given its 5 star rating but nonetheless ruled no breach of Clause 19.1.

The Panel noted that a ruling of a breach of Clause 2 was a sign of particular censure and was reserved for such circumstances. The Panel noted its ruling above and the submission that Recordati had not paid for delegates to attend the golf or gala dinner. It decided that the circumstances did not warrant such a ruling and no breach of Clause 2 was ruled.

CASE AUTH/2563/11/12 TAKEDA

RESPONSE

Takeda UK was very concerned to hear of this complaint and took the allegations very seriously.

The sponsorship was arranged by Takeda Products Ireland Ltd, the Irish operating company. Takeda UK Ltd was not previously aware of this activity but took responsibility as this meeting was held in the UK.

Takeda Products Ireland paid €1,850 to have a promotional stand within the exhibition area at the meeting. The stand was staffed by three employees from Takeda Products Ireland across the two days. Two members of staff were present on the stand and the conference dinner on Friday and were joined by a third member of staff on the stand for the morning of the second day. These three employees were present on the stand until lunchtime on the second day when the meeting ended and the stand was taken down. This was the limit of their involvement and they were not present at the golf or the gala dinner, both of which took place at other venues and after the educational meeting closed.

Takeda Products Ireland Ltd did not know about the golf arranged by the ISU to take place after the end of the meeting. Takeda Products Ireland first received a confirmation email from the ISU on 30 July 2012 in which there was a link to the draft agenda. This email was sent to an administrative member of staff within Takeda Products Ireland who had been the contact for the meeting in terms of the financial arrangements. The link no longer worked and so Takeda UK was unable to check the draft programme made available at that time. However, it had been confirmed that no-

one within Takeda Products Ireland was aware of the golf arranged to take place at a local golf course separate to the hotel after the meeting. When this email was received by the operations assistant it was seen purely as a confirmation of the booking made for the stand space at the meeting.

Takeda Products Ireland had no involvement in inviting any delegates to the meeting and as such did not have any materials or invitations relating to this meeting. Takeda Products Ireland did not select or pay for or support any health professional to attend any aspect of the meeting.

The meeting was not arranged by Takeda Products Ireland, it solely paid for commercial stand space and promotional attendance at the trade exhibition at the meeting. The involvement of Takeda Products Ireland was noted at the back of the final programme provided to delegates.

This meeting had a clear and full educational programme and hence it was this educational content which attracted the delegates to the meeting and not the venue.

The meeting was an independent meeting organised by the ISU. The ISU described itself as an all island society and as such delegates might come from both the Republic of Ireland and Northern Ireland and on this occasion the meeting was held in Belfast. The educational meeting was held in high regard and indeed the President's message of welcome in the final programme commented on the number of scientific abstracts that could not be accommodated which confirmed that the scientific profile of the meeting was of a high standard. Health professionals attending this high quality event were awarded a certificate for 9 hours of CPD. The first day of the meeting was from 9am until 5pm followed by a council meeting and then the conference dinner held in the hotel. On the second day the meeting started at 8.30am and closed at 12.10pm at which point the three employees from Takeda Products Ireland left.

The content of the meeting was wholly selected and organised by the ISU without input from Takeda. Takeda Products Ireland was invited to have a stand within the trade exhibition. When Takeda Products Ireland agreed to this it knew the meeting venue but not the planned programme or the planned golf and gala dinner. When the booking form was completed the gala dinner was noted on the form but Takeda Products Ireland did not book places to attend.

Clause 19 stated that meeting venues must be appropriate and companies must not sponsor or organize entertainment. Takeda Products Ireland played no part in the selection of the venue as this was selected by the meeting organisers. However, Takeda UK considered that the venue, although a 5 star hotel, could be acceptable because it was a well used conference venue with adequate rooms for the number of delegates (132 health professionals plus meeting organisers, speakers etc) and conveniently located for transport links. The hotel's website stated that it was located close to Belfast city centre and Belfast City Airport and so it provided very good access for the delegates from across Ireland. The

hotel had eight conference suites and 500 complimentary car parking spaces and so could cater for large events such as this meeting.

The hotel did not have a golf course. The final programme showed that neither the golf nor the gala dinner were part of the educational meeting; both events took place after the meeting had closed. The gala dinner was sponsored by a named politician as stated in the programme. Takeda Products Ireland did not sponsor either event. The meals during the meeting were taken in the hotel and were not paid for or organized by Takeda. On the basis of the points detailed above Takeda refuted the alleged breach of Clause 19.1.

The payment of space for a promotional stand at the trade exhibition area of this meeting was approved by Takeda Products Ireland according to its SOP. As such Takeda UK refuted the alleged breach of Clause 9.1. It strongly refuted any allegation that this activity constituted a breach of Clause 2 which was a sign of particular censure and reserved for such circumstances. This was an isolated incident where someone had agreed and paid a small fee to have a promotional stand at a trade exhibition at an educational meeting. When it agreed to have the stand at the meeting Takeda Products Ireland was not provided with the full agenda and so did not know that the organisers would arrange for golf and a gala dinner after the close of the meeting. The gala dinner after the second day of the meeting was known to Takeda Products Ireland when it completed the booking form, but at this time there was still no mention of golf.

The draft programme was first provided to Takeda Products Ireland on 30 July 2012. An email was provided in which it could be seen that the draft programme was available by a website link. Unfortunately the link no longer worked and Takeda UK was now unable to check what aspects of the programme could be reviewed at this time. Members of the sales and marketing department reviewed the meeting venue in line with their SOP when approving support for the meeting by way of a promotional stand. When they approved this activity they did not know about the golf.

The meeting organisers had written to Takeda unsolicited upon hearing about the complaint. Takeda assumed that one of the other companies which was also subject to a complaint regarding the meeting brought the matter to the ISU's attention. A copy of the letter received on 5 December by Takeda Products Ireland was provided. This stated the ISU's position.

PANEL RULING IN CASE AUTH/2563/11/12

In addition to its general comments set out above, the Panel noted that the venue was a 5 star conference hotel and would thus be seen as luxurious. In that regard the Panel queried whether the venue met the requirements of the Code. It noted Takeda UK's submission regarding the conference facilities offered by the venue but considered that other non-luxurious venues would have had adequate conference facilities.

Taking all the circumstances into account it appeared that the pharmaceutical companies listed on the back page of the programme had supported all the arrangements for the two-day meeting held at a luxurious venue with golf and a gala dinner. There was no indication that the majority of companies listed had only paid to exhibit at the meeting. The conference programme stated that without participation from the pharmaceutical and medical equipment industries the meeting would not be possible. The Panel considered that the arrangements for the meeting as described in the programme and the impression given were unacceptable. In this regard, high standards had not been met. The Panel ruled Takeda UK in breach of Clause 9.1.

The Panel noted that Takeda UK had not sponsored any health professional to attend the meeting by paying accommodation, subsistence or registration fees. The Panel considered that the venue was on the limit of acceptability given its 5 star rating but nonetheless ruled no breach of Clause 19.1.

The Panel noted that a ruling of a breach of Clause 2 was a sign of particular censure and was reserved for such circumstances. The Panel noted its ruling above and the submission that Takeda had not paid for delegates to attend the golf or gala dinner. It decided that the circumstances did not warrant such a ruling and no breach of Clause 2 was ruled.

Complaint received **4 December 2012**

Cases completed:

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|-----------------------------|-------------------------|
| Case AUTH/2546/11/12 | 7 February 2013 |
| Case AUTH/2547/11/12 | 12 February 2013 |
| Case AUTH/2548/11/12 | 12 February 2013 |
| Case AUTH/2552/11/12 | 14 February 2013 |
| Case AUTH/2554/11/12 | 12 February 2013 |
| Case AUTH/2556/11/12 | 7 February 2013 |
| Case AUTH/2559/11/12 | 12 February 2013 |
| Case AUTH/2560/11/12 | 12 February 2013 |
| Case AUTH/2561/11/12 | 20 February 2013 |
| Case AUTH/2563/11/12 | 12 February 2013 |