

ANONYMOUS v MERCK SERONO

Alleged inappropriate hospitality

An anonymous, uncontactable complainant alleged that Merck Serono had breached the Code at a recent meeting for fertility nurses.

The complainant alleged that Merck Serono had provided entertainment at the meeting in the form of an after dinner speaker at the gala dinner. The complainant considered that this was outside the spirit of the Code and even though the speaker was medically trained his remit was one of entertainment rather than being educational.

The complainant was further concerned that the vast number of delegates that were fully sponsored by Merck Serono were from centres which exclusively used its fertility portfolio and that there were only a handful of attendees that were from non-Merck Serono centres that were self-payers.

The complainant also suspected that the sales team was being asked to sell Pergoveris outside its licensed indication.

The detailed response from Merck Serono is given below.

The Panel noted that the meeting was an annual conference for nursing professionals and paramedical staff involved in fertility. The meeting was sponsored by Merck Serono and lasted two and a half days. The Panel had not been provided with a copy of the original brief but a document showed that the speaker had been asked to present a thought provoking examination of the NHS in a light-hearted manner with particular attention to the changing role of the nurse. He was asked to engage the audience on: access to NHS funding; the changing role of the nurse in fertility treatment and the role of the regulator. To finish with a question and answer session the speaker was told that his talk would come at the end of a long day of educational training. Merck Serono submitted that the speaker had spoken to delegates to understand their issues and tailor his talk accordingly.

The Panel considered that given his experience as a media doctor, the presentation would have been amusing despite the subject matter being educational and relevant. He had not been given a remit to provide entertainment. In that regard and in the context of the educational content of the entire meeting the Panel did not consider that the after dinner speech had been inappropriate as alleged. No breach of the Code was ruled.

The Panel noted that the complainant further alleged that Merck Serono had mainly sponsored delegates from centres that exclusively used its

fertility products. The Panel considered that there was no evidence to show that product usage had influenced delegate sponsorship. No breach of the Code was ruled.

The statements in the training material and the promotional material were consistent with the indication as stated in the summary of product characteristics. The Panel considered that there was no evidence to show the sales force had been asked to sell Pergoveris outwith its licensed indication as alleged. No breach of the Code was ruled.

The Panel considered that, given its rulings above, there could be no breach of Clause 2.

An anonymous, uncontactable complainant alleged that Merck Serono had breached the Code at a recent Insights meeting for fertility nurses held on 1-3 October in Brighton.

COMPLAINT

The complainant alleged that Merck Serono had provided entertainment at the meeting in the form of an after dinner speaker at the gala dinner held on 2 October. The complainant considered that this was outside the spirit of the Code and even though the speaker was medically trained his remit was one of entertainment rather than being educational.

The complainant was further concerned that the vast number of delegates that were fully sponsored by Merck Serono were from centres which exclusively used its fertility portfolio and that there were only a handful of attendees that were from non-Merck Serono centres that were self-payers.

The complainant also suspected that the sales team was being asked to sell Pergoveris outside of its licensed indication.

When writing to Merck Serono the Authority asked it to respond in relation to Clauses 2, 3.1, 15.9 and 19.1 of the Code. The matter was considered under the 2006 Code using the 2008 Constitution and Procedure.

RESPONSE

Merck Serono explained that the INSIGHTS annual conference was in its 24th year and in that time had become one of the most important and highly valued educational vehicles for nurses specialised in the treatment of infertility. Merck Serono had sponsored this conference since its inception in

1984. Insights 2008 was held from 1-3 October and was attended by 134 fertility specialist nurses (124 delegates plus 10 steering committee members). The 3 day programme was developed by the Insights steering committee which was principally made up of members of the senior infertility nurse group. A list of clinics represented on the steering committee was provided. The steering committee planned Insights 2008 using feedback from the 2007 conference as well as incorporating hot topics reflecting current nursing needs. The focus of the meeting was, as always, the nurse educational content. The aim was to provide a stimulating programme along with a forum for useful debate as well as time for networking with colleagues from around the country. Over the 3 days, more than 13 hours of education was provided by 24 expert speakers. A copy of the agenda and invitation to the meeting was provided.

On the evening of the 2 October after the final conference dinner, the speaker gave a talk to the delegates on the current state of the health service with particular reference to the changing role of the nurse. The speaker was a practicing GP with relevant experience in sexual health. Merck Serono disputed the allegation that the remit was purely one of entertainment. Whilst the talk was delivered in an entertaining manner, as was often the case with accomplished speakers, the content was educational and relevant. A copy of the brief was provided. In the absence of a full transcript Merck Serono noted some of the topics covered in the 30-40 minute talk:

- His experience, as a GP, of the struggles faced by infertile couples seeking access to NHS funding.
- The role of the regulator in medicine including the role of the Human Fertilisation and Embryo Authority within the fertility arena
- The changing role of both doctors and nurses in medical practice
- Questions and answers.

In addition, before his presentation, the speaker talked to delegates to better understand their issues and tailor his talk accordingly. Throughout his talk he encouraged the delegates to share their experiences on the topics covered.

In summary, Merck Serono submitted that an appropriate speaker was used and that the topics covered were relevant and educational to the delegates.

Following the conference, delegates were anonymously surveyed to ascertain their feedback on the quality of the education provided and to what extent the conference had been successful in fulfilling their personal educational objectives. 98% of delegates rated the quality of the education excellent or good with 2% rating it as satisfactory with nobody rating it as poor. 98% of delegates considered the conference had been very successful or mostly successful in fulfilling their personal educational objectives. 2% considered it slightly

successful and nobody rated it as not successful. A copy of this feedback report was provided. As well as rating the meeting, the delegates were also able to make additional comments on the feedback form. No negative feedback on the content or delivery of the presentation at issue was received.

The cost of the dinner on 2 October was negotiated as part of a 24 hour delegate rate of £162 per person. This included accommodation, 3 course dinner (menu provided), afternoon tea, coffee and biscuits, buffet lunch, morning tea, coffee and pastries, and breakfast. This cost also included the hire of the main conference room.

Splitting out the cost of the dinner was difficult as it was included in the 24 hour delegate rate. However the bed and breakfast rate (for those staying only one night was £109 and the day delegate rate (to include lunch, room hire, teas, coffee, biscuits in morning and afternoon) was £48 giving a total of £157. As the 24 hour delegate rate was £162 (to include all of the above plus dinner) the cost of the dinner per person was £5. Each delegate was provided with half a bottle of house wine. The cost of the food and wine at the conference dinner was £14.25 per person.

In addition to the food and wine provided on the evening of the 2 October, Merck Serono noted that the hotel provided a glass of complementary house sparkling wine prior to dinner by way of apology to the delegates for disappointment caused following an error made on the previous evening. This service was not paid for, or requested by Merck Serono. An explanatory email from the hotel was provided.

With regard to the sponsorship of delegates Merck Serono submitted that 124 delegates attended at least part of the conference. Seventy nine delegates (64%) were fully sponsored by Merck Serono to include:

- Full conference registration.
- Accommodation and breakfast at the conference hotel on the 1 and 2 October
- Lunch, tea and coffee throughout the conference
- Dinner on 1 and 2 October.

Members of the steering committee were in addition offered full sponsorship to attend the meeting. Ten members of the steering committee attended.

The remaining 45 delegates (36%) were offered a subsidised full conference package for £390. It included:

- Full conference registration.
- Accommodation and breakfast at the conference hotel on the 1 and 2 October
- Lunch, tea and coffee throughout the conference
- Dinner on the 1 and 2 October.

A subsidised daily delegate rate was also available for £60 per day that included:

- Conference registration fee for the chosen day(s)
- Lunch, tea and coffee for chosen day(s).

One hundred and twenty four delegates, 10 steering committee members, 12 members of Merck Serono staff and 3 members from the event management company attended. The cost per head was therefore £666, substantially more than the £390 per head which the self-funding delegates paid to attend.

The number of Merck Serono fully sponsored delegates was limited to 80. Due to the high value placed on Insights by fertility specialist nurses, demand for fully sponsored places always outstripped availability. In order to be as equitable as possible, in the first instance Merck Serono aimed to offer fully sponsored places to clinics that did not receive them the previous year for whatever reason. If fully sponsored places still remained, they were offered on a first come first served basis. Places were offered to clinics not to individuals. Clinics decided who they would like to attend.

Registration for subsidised self-funders was open to any fertility specialist nurse through the Insights website from July 2008. Pages of the website were provided. In 2008 the number of subsidised self-funders was limited to 50 as the conference room booked had a capacity of 150.

In response to the allegation 'that the vast number of delegates that were fully sponsored by Merck Serono were from centres exclusively using its fertility portfolio', Merck Serono noted the following points:

- The meeting was aimed at and attended by fertility specialist nurses. Fertility nurses were not able to prescribe medicines used in the treatment of infertility
- Merck Serono knew of no fertility clinic in the UK that exclusively used one company's products. It was important to ensure that clinics had access to a range of different medicines so they could offer choice to their patients.

Of course, particular clinics had a preference for particular products. It was however impossible for Merck Serono to know with any degree of certainty what this preference was at any particular time. Clinics did not make their product usage data publicly or commercially available.

In the absence of this data however, Merck Serono had estimated the current level of usage of its fertility products in the clinics of the fully sponsored delegates and in those of the subsidised self-funders. Details were provided

In summary, all delegates were either fully sponsored or substantially subsidised to attend Insights 2008, over one third falling in the latter category. Merck Serono submitted that it had made every effort to ensure that full sponsorship was offered in as equitable a manner as possible and that the estimated Merck Serono product usage profile of fully sponsored delegates did not differ significantly from that of the subsidised self-funders.

With regard to the third allegation centred on the promotion of Pergoveris. Merck Serono stated that it was very difficult to respond when the complainant has not provided any evidence for their suspicion. The company refuted the allegation.

Pergoveris received its marketing authorization in June 2007 and was launched in the UK in October 2007. The Merck Serono sales team was trained on its use in September 2007. In April 2008 the sales team had this training refreshed using the same training slides. Copies of the slides were provided. At both of these training sessions the licensed indication for the product was clearly stated.

Merck Serono provided copies of the current Pergoveris promotional literature and summary of product characteristics (SPC) and stated that these materials were available at the conference.

PANEL RULING

The Panel noted that the Insights 2008 meeting was an annual conference for nursing professionals and paramedical staff involved in fertility. The meeting was sponsored by Merck Serono and lasted two and a half days (from 10am, 1 October to 1pm, 3 October). The complainant alleged that the after dinner speaker on 2 October (the speaker) had provided entertainment rather than education. The Panel had not been provided with a copy of the original brief given to the speaker but a document from the event organising company showed that he had been asked to present a thought provoking examination of the NHS in a light-hearted manner with particular attention to the changing role of the nurse. He was asked to engage the audience on: access to NHS funding; the changing role of the nurse in fertility treatment and the role of the regulator. The speaker was asked to finish off the talk with a question and answer session and told that his talk would come at the end of a long day of educational training. The Panel noted Merck Serono's submission that the speaker had spoken to delegates to understand their issues and tailor his talk accordingly.

The Panel considered that given his experience as a media doctor, the presentation would have been amusing despite the subject matter being educational and relevant. He had not been given a remit to provide entertainment. In that regard and in the context of the educational content of the entire meeting the Panel did not consider that the after dinner speech had been inappropriate as alleged. No breach of Clause 19.1 was ruled.

The Panel noted that the complainant further alleged that Merck Serono had mainly sponsored delegates from centres that exclusively used its fertility products. The complainant had not produced any evidence in this regard. Merck Serono had stated that it was impossible for it to know exactly which products were used in particular clinics at any one time. The company had submitted

that its sponsorship of delegates did not show preference to those clinics that favoured its products although such data could only be based on estimates. The Panel considered that there was no evidence to show that product usage had influenced delegate sponsorship. No breach of Clause 19.1 was ruled.

The Panel noted the complainant also suspected that the sales team was being asked to sell Pergoveris outside its licensed indication. No further details were given. Merck Serono had provided copies of the representatives' training slides and a copy of a current piece of promotional literature. The training slides clearly stated that the licensed indication was for the stimulation of follicular development in women with severe LH (leuterising hormone) and FSH (follicle stimulating hormone) – in clinical trials these patients were

defined by an endogenous serum LH level < 1.2 IU/L. The promotional material stated that Pergoveris was indicated for women with severe LH and FSH deficiency (defined as endogenous serum LH < 1.2IU/L). The statements in the training material and the promotional material were consistent with the indication as stated in the SPC. The Panel considered that there was no evidence to show the sales force had been asked to sell Pergoveris outwith its licensed indication as alleged. No breach of Clauses 3.1 and 15.9 was ruled.

The Panel considered that, given its rulings above, there could be no breach of Clause 2 of the Code.

Complaint received	13 October 2008
Case completed	10 November 2008
