CASE AUTH/2264/9/09

ANONYMOUS v GLAXOSMITHKLINE

Invitation to a satellite symposium

An anonymous and uncontactable complainant, complained about an invitation from GlaxoSmithKline to a satellite symposium entitled 'Living with PAH [pulmonary arterial hypertension] – Challenges and Options' at the European Society of Cardiology (ESC) Congress in Barcelona 2009.

The complainant alleged that the symposium promoted Flolan (epoprostenol) and Volibris (ambrisentan) (both marketed by GlaxoSmithKline). In fact the third talk was simply full of Volibris data. The complainant alleged that it was disguised promotion; the invitation, from which it appeared that the symposium was about PAH as a disease, should have made clear that talks contained product information so he could decide not to attend. The complainant further noted that prescribing information was missing from the invitation, there was no date and the colours of the invitation were the same as the Volibris logo.

The detailed response from GlaxoSmithKline is given below.

The Panel noted that the invitation to the symposium, which had been freely available for delegates to pick up from GlaxoSmithKline's exhibition stand, clearly stated that the event was sponsored by GlaxoSmithKline and a brief description referred to a presentation of the latest data regarding long-term treatment with ambrisentan. The invitation included the agenda and listed the third presentation 'Long-term Treatment with Ambrisentan: FCII and CTD'. In the Panel's view, it was clear from the invitation that the symposium would include information about treatment options, including Volibris. The Panel did not consider that the symposium was disguised promotion. No breach of the Code was ruled.

The Panel considered that as the invitation referred to ambrisentan and its use in PAH it was, in effect, promotional material for Volibris and in that regard it should have included prescribing information; as it did not a breach of the Code was ruled.

The complainant had stated, *inter alia*, that there was no date on the invitation by which the Panel assumed that he meant that there was no date of preparation. The Code required all promotional material other than advertisements appearing in professional publications to include the date on which the material was drawn up or last revised. Thus, in the Panel's view, the invitation should have included a 'date of preparation'. GlaxoSmithKline had not been asked to respond in relation to the requirements of the relevant clause, Clause 4.10 and so the Panel could make no ruling in that regard. The Panel requested that the company be advised of its view.

An anonymous and uncontactable complainant, writing as an 'Unhappy Physician', complained about an invitation (ref P/03/09/190) from GlaxoSmithKline (UK) Limited to a satellite symposium.

COMPLAINT

The complainant explained that he had attended this year's European Society of Cardiology (ESC) Congress in Barcelona where he was handed an invitation to a symposium entitled 'Living with PAH [pulmonary arterial hypertension] – Challenges and Options'. The complainant was interested and so decided to learn more about the disease.

When the complainant sat down it became clear that the symposium promoted Flolan (epoprostenol) and Volibris (ambrisentan) (both marketed by GlaxoSmithKline). Had the complainant known this at the outset he would not have attended as it seemed from the invitation to be a symposium about the disease. In fact the third talk was simply full of Volibris data.

The complainant was still angry at the way this symposium was advertised; he alleged that it was disguised promotion. The complainant had discussed this issue with a fellow physician who worked for the industry and it seemed that the invitation should have made clear that talks contained product information so he could decide not to attend. The fellow physician also mentioned that other elements were missing from the invitation such as 'prescription information' which, apparently, implied its promotional nature as products were directly mentioned. The complainant noted that the colours of the invitation were the same as the Volibris logo and there was no date on the invitation.

The complainant hoped his complaint was taken seriously and future advertising was clearer as he had better things to do with an hour of his time than sit in industry symposia being sold to.

When writing to GlaxoSmithKline the Authority asked it to respond in relation to Clauses 2, 4.1, 9.1 and 12.1 of the Code and to note the requirements of Clause 1.7 and its supplementary information referring to the applicability of codes.

RESPONSE

GlaxoSmithKline regretted the disappointment felt

by the complainant and took the issues raised very seriously. GlaxoSmithKline noted that an industry physician had advised the complainant about the specific matters to raise.

GlaxoSmithKline stated that the symposium at issue was organised by its European Critical Diseases Business Unit, a pan-European group that operated at an above country level and was made up of medical and marketing staff. Invitations to the symposium were freely available on the GlaxoSmithKline conference exhibition stand for delegates to pick up and attend if they wished. GlaxoSmithKline did not take a note of the estimated 175 symposium attendees. The ESC meeting was the world's biggest international meeting in cardiology with over 30,000 delegates. The nationality of attendees at the symposium was likely to reflect the make-up of the delegates in general.

The invitation, abstract booklet, symposium banners and question cards all clearly stated that the symposium was organised by GlaxoSmithKline. The biographies and abstracts booklet were provided to each attendee in the meeting by being placed on every seat as well as being available at the entrance to the meeting room. The booklet contained declarations of GlaxoSmithKline's involvement with the symposium as well as the prescribing information. Whilst the symposium was organised and arranged by GlaxoSmithKline and therefore required full review under the relevant codes of practice, such symposia were also platforms for legitimate exchange of scientific information and clinicians valued their content.

GlaxoSmithKline submitted that all efforts were made to ensure that those reading the invitation would know that the symposium would contain information about ambrisentan. The third talk listed on the invitation was entitled 'Long-Term Treatment with Ambrisentan: FCII and CTD'. It thus should not have been a surprise that this talk contained Volibris data. All attendees would have received the abstract booklet before the symposium started which made clear that ambrisentan data was going to be discussed. Therefore the complainant had two opportunities to understand the nature of the meeting and decide then whether to attend.

GlaxoSmithKline understood why the complainant thought the invitation should include prescribing information but noted that it simply presented the titles of the meeting together with a message from the Chairman; there were no claims or any other information. However, the abstract book, which contained summaries of the symposium presentations, did provide prescribing information. The omission of the prescribing information from the invitation would not mislead a symposium attendee as to the information to be discussed at the meeting.

The meeting was held in Barcelona and was reviewed and approved by the central team and, under Spanish regulations, by GlaxoSmithKline's Spanish medical department.

The symposium slides were provided as requested. GlaxoSmithKline submitted that the presentations represented a fair and balanced view of the 'Challenges and Options' of living with PAH.

The complainant inferred that the symposium contained little other than Flolan and Volibris data. GlaxoSmithKline stated that the slide set only referred to the generic names of the medicine, not the brand names and the speakers only mentioned the generic names of all the medicines. Many medicines were mentioned in all talks.

The third talk entitled 'Long-Term Treatment with Ambrisentan' contained many references to ambrisentan as would be expected. Three out of the twenty-three slides explained the adverse event data. GlaxoSmithKline submitted that the ESC Congress in Barcelona was the first European meeting since the European launch of ambrisentan and therefore data about its place in PAH management and its risks and benefits would be relevant to the majority of attendees.

GlaxoSmithKline stated that although it regretted that a health professional was disappointed by the invitation and the meeting itself, the company had acted in a responsible manner: sponsorship of the symposium was clear; topics to be discussed were clear on the invitation; prescribing information was provided as appropriate. GlaxoSmithKline's intent was to arrange a meeting where speakers would present valuable information, and when presenting data on GlaxoSmithKline medicines, to ensure that this was presented transparently and with fair balance. GlaxoSmithKline submitted that it was in line with its intentions.

GlaxoSmithKline stated that this was a highly valuable symposium organised to benefit many congress delegates from across Europe. This included delegates who would have been interested in reviewing recent ambrisentan data. GlaxoSmithKline also believed that in organising this symposium it had adhered to the ABPI Code and other relevant national codes.

GlaxoSmithKline submitted that the meeting was not disguised promotion and thus not in breach of Clause 12.1. GlaxoSmithKline had complied with the relevant codes and standards, maintained high standards and had not brought the industry into disrepute and therefore, was not in breach of Clauses 1.7, 9.1 or 2.

GlaxoSmithKline provided confidential copies of the speaker slides the speaker agreements.

In response to a request for further information GlaxoSmithKline stated that the company's presence and activities at the Barcelona meeting were subject to, and approved under both the UK and Spanish Codes as described in the

supplementary information to Clause 1.7. The European Critical Disease Business Unit head office was based in the UK and the local operating companies were located in their respective European countries.

GlaxoSmithKline confirmed that all relevant materials were reviewed in accordance with the UK Code.

PANEL RULING

The Panel noted that GlaxoSmithKline had sponsored a satellite symposium at the ESC meeting in Barcelona which it had approved under both the UK and Spanish Codes.

The Panel first had to consider whether or not the UK Code applied. The symposium was organised from the UK and arrangements were also made to ensure compliance with the Spanish Code of Practice. It was clear from the supplementary information to Clause 1.7 that because the symposium was organised from the UK and held in Spain, both the UK and Spanish Codes applied.

The Panel noted that the invitation to the symposium had been freely available for delegates to pick up from GlaxoSmithKline's exhibition stand. The invitation clearly stated that the symposium was sponsored by GlaxoSmithKline and a brief description of the event referred to a presentation of the latest data regarding long-term treatment with ambrisentan. The invitation included the agenda and listed the third presentation 'Long-term Treatment with Ambrisentan: FCII and CTD'. In the Panel's view, it was clear from the invitation that the symposium would include information about treatment options, including Volibris. Thus the Panel did not consider that the symposium was disguised promotion. No breach of Clause 12.1 was ruled.

The Panel noted that the invitation referred to ambrisentan and its use in PAH. The Panel thus considered that the invitation was, in effect, promotional material for Volibris and in that regard it should have included prescribing information; as it did not a breach of Clause 4.1 was ruled.

The Panel noted its ruling above of a breach of Clause 4.1 but nonetheless did not consider that it meant that high standards had not been maintained. The Panel did not consider that the circumstances warranted ruling a breach of Clause 2 which was used as a sign of particular censure and reserved for such.

The Panel noted that the complainant had stated, *inter alia*, that there was no date on the invitation by which it assumed that the complainant meant that there was no date of preparation on the material given that it bore the date of the symposium. Clause 4.10 required that all promotional material other than advertisements appearing in professional publications must include the date on which the material was drawn up or last revised. Thus, in the Panel's view, the invitation should have included a 'date of preparation' or similar which it did not. The Authority, however, had not asked GlaxoSmithKline to respond in relation to the requirements of Clause 4.10 and so the Panel could make no ruling in that regard. The Panel requested that the GlaxoSmithKline be advised of its view.

Complaint received **10 September 2009**

Case completed **22 October 2009**