CASE AUTH/1873/8/06

SCRUTINY/DIRECTOR v GLAXOSMITHKLINE

TORCH journal advertisement

During the course of scrutiny a journal advertisement was taken up with GlaxoSmithKline because it appeared not to comply with the requirements of the Code concerning the provision of prescribing information. The advertisement featured the TORCH (Towards a revolution in COPD health) study and had appeared in Hospital Doctor.

The Authority noted that the TORCH study was a study sponsored by GlaxoSmithKline comparing, *inter alia*, GlaxoSmithKline's product Seretide upon survival in patients with COPD. The Authority considered that the advertisement was promotional and that it was a full advertisement in which no prescribing information had been provided.

GlaxoSmithKline considered that the advertisement was not promotional for a product and did not come within the scope of the Code. The Authority did not accept this, noting that the TORCH study specifically examined the efficacy of three GlaxoSmithKline products and in particular all cause mortality in patients treated with Seretide. In the Authority's view by 'advertising' the TORCH study through paid-for space, GlaxoSmithKline had indirectly referred to, and thus advertised, Serevent (salmetrol), Flixotide (fluticasone) and Seretide (salmeterol/fluticasone combination). It was a long established principle that paid-for space in a journal constituted an advertisement.

GlaxoSmithKline maintained its position and, having considered the company's comments, the Director decided that a *prima facie* case had been established and took the matter up as a formal complaint.

The Panel noted GlaxoSmithKline's submission that the purpose of the advertisement was, *inter alia*, to promote the company's role in supporting significant research studies. In the Panel's view the purpose of the advertisement was much more specific than that. It was, as submitted, to ensure that health professionals were aware that the results from the TORCH study would be available soon. GlaxoSmithKline had stated that the advertisements were to increase awareness of the study which was of major medical significance. The TORCH study was sponsored by GlaxoSmithKline and used three of its medicines. The GlaxoSmithKline press release referred to the preliminary results as being positive for Seretide. Further that GlaxoSmithKline believed the results were clinically important and would have a positive impact on the future management of COPD.

The Panel considered it immaterial that the advertisement did not refer to any clinical results. Merely raising awareness of a specific study would draw attention to it. Readers would be prompted to find out more and in that regard the Panel noted that Vestbo *et al* which described the protocol and design had been published.

The advertisement appeared in medical journals and occupied space paid for by GlaxoSmithKline. It was a long established principle that any 'paid-for' space in a journal constituted an advertisement. In the Panel's view the advertisement was not a corporate advertisement; it referred to the TORCH study in COPD, a study which specifically examined the efficacy of three GlaxoSmithKline products and in particular all cause mortality in patients treated with Seretide. On balance the Panel considered that by 'advertising' the TORCH study, GlaxoSmithKline had indirectly referred to, and thus advertised, Serevent, Flixotide and Seretide. If this were not the case then companies could pay for space and 'advertise' their latest clinical trials, and thus their products, without being bound by the restrictions in the Code. A breach of the Code was ruled.

During the course of scrutiny in accordance with Paragraph 18 of the Authority's Constitution and Procedure, a journal advertisement was taken up with GlaxoSmithKline UK Ltd because it appeared not to comply with Clause 4.1 of the Code concerning the provision of prescribing information. The advertisement (ref SFC/AVL/06/24428/1) featured the TORCH (Towards a revolution in COPD health) study and had appeared in Hospital Doctor on 20 April.

COMPLAINT

During scrutiny the Authority had noted that the advertisement related to the TORCH study which was a study sponsored by GlaxoSmithKline comparing, *inter alia*, GlaxoSmithKline's product Seretide upon survival in patients with COPD. The Authority considered that the advertisement was promotional and that it was a full advertisement in which no prescribing information had been provided, contrary to Clause 4.1 of the Code.

GlaxoSmithKline dissented from this view as it considered that the advertisement was not promotional for a product and did not come within the scope of the Code as defined in Clause 1.1 and was covered by the exclusions in Clause 1.2. The Authority did not accept this, noting that the TORCH study specifically examined the efficacy of three GlaxoSmithKline products and in particular all cause mortality in patients treated with Seretide. In the Authority's view by 'advertising' the TORCH study through paid-for space, GlaxoSmithKline had indirectly referred to, and thus advertised, Serevent (salmetrol), Flixotide (fluticasone) and Seretide (salmeterol/fluticasone combination). It was a long established principle that paid-for space in a journal constituted an advertisement.

GlaxoSmithKline maintained its position and, having considered the company's comments, the Director decided that a *prima facie* case had been established and took the matter up as a formal complaint. This accorded with Paragraph 18.5 of the Constitution and Procedure.

RESPONSE

GlaxoSmithKline stated that COPD was a chronic disease with a significant mortality that placed a large health burden on patients, carers and the NHS. It was characterised by exacerbations and an inevitable decline in respiratory function leading to disability and death. Most studies had examined symptom relief as their primary end point and as yet, no pharmaceutical intervention had been shown to be disease modifying with a benefit on survival.

The TORCH study was the largest prospective study undertaken in COPD. It was a double blind, randomised controlled trial with four arms including three GlaxoSmithKline medicines – Serevent, Flixotide, Seretide and placebo (allowing other normal therapies in the background).

The primary outcome was to determine whether there was a significant reduction in all cause mortality in COPD patients treated with Seretide compared with placebo. The full results of this study were awaited. No study had hitherto shown whether pharmacotherapy could improve survival in this disease. A number of secondary outcomes, including changes in health status and exacerbation frequency were also examined in the study, making its outcome extremely relevant to the practice of medicine in an area that was part of the government's quality outcome framework.

The TORCH study was of major medical significance whether its outcomes demonstrated a survival benefit to patients suffering from COPD or not. A result either way would provide valuable information about the usefulness of therapies used in COPD and might be able to establish the relative value of treating exacerbations. The importance of the study was underlined by the publication of a full paper describing the study protocol and design (Vestbo *et al* 2004). In constructing the advertisement, GlaxoSmithKline was mindful of the requirements of the Code in indirectly referring to its medicines and as such did not refer prescribers to that publication, recognising that there was not a licensed indication for COPD for all of the medicines in the study.

Equally, because of the importance of this study, and its share price sensitivity, a Stock Exchange announcement was made in March 2006 confirming its completion and giving only preliminary results. Analysis of the data continued however and no publication of results (either as abstracts or in full) had yet appeared.

The purpose of the advertisement was to promote the role of GlaxoSmithKline in supporting significant research studies and to ensure that health practitioners were aware that the results of this important study with enormous public health implications would be available shortly. COPD was one of the government's key areas for intervention in primary care and thus of major importance and interest to healthcare providers. Whether the results were positive or negative, the results of such a landmark study would answer an important question about the appropriateness of these interventions in COPD patients and might have major implications for healthcare resource use. Given the potential impact of these results and their importance and interest to health professionals, prior notice was quite reasonable for a study of this importance and magnitude.

Whilst GlaxoSmithKline accepted the Authority's point that paid-for space constituted an advertisement, this did not promote a particular product. GlaxoSmithKline strongly believed that both disease awareness advertisements and advertisements such as this one, publicising forthcoming study results, did not promote any medicine directly or indirectly. They were placed to inform health professionals of important factual information and were one method of increasing awareness.

The advertisement was carefully designed not to be promotional and GlaxoSmithKline emphasised the following:

- care was taken not to mention any specific product or intervention being investigated in the study
- the results of the study were not yet in the public domain, preventing anyone reading the advertisement making any inference about the outcomes of the study and thus any implied claims for any product
- given that the analysis was ongoing it was impossible at this time to comment in a balanced way on the results of the study or interpret which of the four arms produced what data; as such it would be totally inappropriate to mention one or more products and thus include prescribing information
- the study design included therapeutic indications and patients who were not within the licensed population for the three medicines under study; to include prescribing information for one or all of the three products would thus be inappropriate and would constitute promotion of one or all of these medicines outside their licensed indications
- with this knowledge GlaxoSmithKline designed the advertisement to provide information only and be strictly non promotional.

In summary, the advertisement gave health professionals advance notice of an important scientific study, which was likely to report within the next few months; it was not an advertisement for any product. No mention either directly, or indirectly was made of any product.

Given the evidence above and the careful manner in which GlaxoSmithKline had undertaken this advertisement, it anticipated that the Authority would recognise the intent and the care taken and agree with GlaxoSmithKline's interpretation of the Code.

As such GlaxoSmithKline firmly believed that this advertisement did not fall within the scope of the Code as defined by Clause 1.1 and was covered by the exclusions in Clause 1.2. GlaxoSmithKline therefore strongly believed that it could not be in breach of Clause 4.1.

PANEL RULING

The advertisement was unlike any previously considered and there were thus no case precedents to guide the Panel.

The Panel noted the submission that the purpose of the advertisement was, *inter alia*, to promote the role of GlaxoSmithKline in supporting significant research studies. In the Panel's view the purpose of the advertisement was much more specific than that. It was, as submitted, to ensure that health professionals were aware that the results from the TORCH study would be available soon. GlaxoSmithKline had stated that the advertisements were to increase awareness of the study which was of major medical significance. The TORCH study was sponsored by GlaxoSmithKline and used three of its medicines. The GlaxoSmithKline press release referred to the preliminary results as being positive for Seretide. Further that GlaxoSmithKline believed the results were clinically important and would have a positive impact on the future management of COPD.

The Panel considered it immaterial that the advertisement did not refer to any clinical results. Merely raising awareness of a specific study would draw attention to it. Readers would be prompted to find out more and in that regard the Panel noted that Vestbo *et al* which described the protocol and design had been published.

The advertisement appeared in medical journals and occupied space paid for by GlaxoSmithKline. It was a long established principle that any paid-for space in a journal constituted an advertisement. In the Panel's view the advertisement was not a corporate advertisement; it referred to the TORCH study in COPD, a study which specifically examined the efficacy of three GlaxoSmithKline products and in particular all cause mortality in patients treated with Seretide. On balance the Panel considered that by advertising the TORCH study, GlaxoSmithKline had indirectly referred to, and thus advertised, Serevent, Flixotide and Seretide. If this were not the case then companies could pay for space and advertise their latest clinical trials, and thus their products, without being bound by the restrictions in the Code.

The advertisement did not include any prescribing information. A breach of Clause 4.1 was ruled.

Proceedings commenced 2 August 2006

Case completed 4 September 2006
