CASE AUTH/2275/11/09 NO BREACH OF THE CODE

DOCTOR v GLAXOSMITHKLINE

Sponsorship of a supplement

A doctor complained about a supplement entitled 'ProState of the Nation Report. A call to action: delivering more effective care for BPH [benign prostatic hyperplasia] patients in the UK' sponsored by GlaxoSmithKline which was distributed, *inter alia*, with the Health Service Journal of 22 October. One of the forewords to the supplement was from the chief executive of Prostate UK.

The complainant noted that the declaration on the supplement did not state that Prostate UK received funding from GlaxoSmithKline (in addition to any honoraria paid to the chief executive if she sat on the editorial board). The complainant believed that the funding received by the charity from GlaxoSmithKline constituted a conflict of interest to which readers of the supplement should have been made aware.

The detailed response from GlaxoSmithKline is given below.

The Panel noted that the supplementary information to the Code required that the declaration of sponsorship be sufficiently prominent to ensure that readers of sponsored material were aware of it at the outset. The declaration must accurately reflect the nature of the company's involvement. The Code required that sponsorship of material be declared, not the background relationships between the parties to a project.

The Panel noted GlaxoSmithKline's submission regarding its support of Prostate UK and its declaration of interest in that regard. The supplement at issue was not Prostate UK material that had been supported by GlaxoSmithKline.

The Panel noted that GlaxoSmithKline's corporate logo appeared on the bottom left hand corner of the front page above the statement 'GSK has sponsored the production of this supplement; for details please see the back cover page of the report'. The corporate logo also appeared on the lower left hand corner of the back outside cover alongside the statement 'GSK sponsorship has included payment for a medical writer, honoraria to the editorial board and payment to a public relations agency in respect of project management support'.

The Panel considered that GlaxoSmithKline's role in the production of the supplement had been made clear. Sufficient details appeared prominently on the front page with further explanation on the outside back cover. The Panel noted

GlaxoSmithKline's explanation of its sponsorship of certain Prostate UK activities. Prostate UK had not received any monies from GlaxoSmithKline in respect of the report. Honoraria were paid directly to individual board members including those who held positions at Prostate UK. The Panel considered that the sponsorship of the report and membership of the editorial board were transparent. That Prostate UK received sponsorship monies from GlaxoSmithKline in respect of other projects did not preclude its chief executive officer from being a member of the editorial board for the supplement at issue. GlaxoSmithKline's sponsorship of activities by Prostate UK which were unrelated to its sponsorship of the report did not have to be declared in the report at issue. No breach of the Code was ruled.

A doctor complained about a supplement (ref ADT/MAM/09/43437/1) entitled 'ProState of the Nation Report. A call to action: delivering more effective care for BPH [benign prostatic hyperplasia] patients in the UK' sponsored by GlaxoSmithKline UK Ltd which was distributed, inter alia, with the Health Service Journal of 22 October 2009. One of the forewords on page 2 of the supplement was from the chief executive of the charity Prostate UK.

COMPLAINT

The complainant alleged that the supplement at issue was in breach of Clause 9.10 of the Code. The supplementary information for Clause 9.10 stated that, 'The declaration [of sponsorship] must accurately reflect the nature of the company's involvement'. The complainant noted that the declaration on the supplement did not state that Prostate UK (whose chief executive officer endorsed the supplement on page 2), received funding from GlaxoSmithKline (in addition to any honoraria paid to her if she sat on the editorial board). The complainant referred to a Prostate UK press release as evidence of this funding.

The complainant believed that the funding received by the charity from GlaxoSmithKline constituted a conflict of interest to which readers of the supplement should have been made aware.

RESPONSE

GlaxoSmithKline stated that it had been transparent in both its sponsorship of the supplement and in its support of various activities organised by Prostate UK and therefore denied the alleged breach of Clause 9.10.

GlaxoSmithKline explained that the supplement

was developed to raise awareness of BPH as an important medical condition which affected the ageing male. GlaxoSmithKline sponsored the report and briefed the medical writer. The report was reviewed and approved by an expert editorial board which had final editorial control. It was intended that the report should be entirely non promotional and solely focus on disease awareness. The report did not include the names of any specific medicines.

GlaxoSmithKline noted that it paid honoraria to members of the editorial board and for the service of a public relations agency to include project management, engaging and liaising closely with a professional medical writer and organising artwork and printing.

The report was published as a sponsored supplement to the Health Service Journal (22/10/2009) and PULSE (21/10/2009). It was also distributed at a BPH awareness event at the House of Commons (19/10/2009), which was hosted by a member of parliament, organised by Prostate UK and sponsored by GlaxoSmithKline. The report would also be distributed to NHS health professionals and budget holders by GlaxoSmithKline representatives.

GlaxoSmithKline noted that the front cover of the report featured the company logo and the statement 'GSK has sponsored the production of this supplement; for details please see the back cover page of the report'. The back cover also featured the GlaxoSmithKline logo and a statement that 'GSK sponsorship has included payment for a medical writer, honoraria to the editorial board and payment to a public relations agency in respect of project management support'. Readers would have a clear understanding of GlaxoSmithKline's involvement in the production of the report.

GlaxoSmithKline explained that Prostate UK was a registered charity which funded medical research and the training of health professionals, provided free public information on a range of prostate diseases and campaigned to raise public awareness without any government funding. GlaxoSmithKline had worked with Prostate UK on the following activities aimed at promoting awareness of BPH over the past year:

- GlaxoSmithKline along with a number of other organisations sponsored a Prostate UK disease awareness campaign ('Pants in the Park'), consisting of six sponsored fun runs across the UK in 2009. The events were held to increase awareness of prostate disease and raise money for the charity. GlaxoSmithKline's sponsorship was £5,000. As a result of these fun runs, Prostate UK raised £50,000. GlaxoSmithKline's sponsorship was clearly disclosed in material promoting the events, an example of which was provided.
- GlaxoSmithKline sponsored and attended an event at the House of Commons (19/10/2009)

which was organised by Prostate UK and hosted by a member of parliament. The event was to generate publicity for a submission made to the National Institute for Health and Clinical Excellence (NICE) by Prostate UK for the inclusion of BPH within the Quality and Outcomes Framework. GlaxoSmithKline contributed £5,285 to cover the cost of room hire, refreshments and invitations. GlaxoSmithKline's sponsorship was clearly explained in material promoting the event, an example of which was provided.

- GlaxoSmithKline sponsored the production of a film which Prostate UK developed to support its BPH awareness activities. GlaxoSmithKline contributed £11,500 to cover the costs of producing this film. Editorial control for the film lay entirely with Prostate UK. GlaxoSmithKline's role in sponsoring the film was clearly explained on-screen at both the start and end of the film.
- Prostate UK used a public relations agency which was retained by GlaxoSmithKline to assist in drafting a number of its promotional items, including press releases, about events that had been sponsored by GlaxoSmithKline. Editorial control for these items lay with Prostate UK. However, since they covered events sponsored by GlaxoSmithKline, these items were all reviewed for factual accuracy and compliance with the Code by GlaxoSmithKline. Specifically, GlaxoSmithKline asked for changes to be made in order to clarify and increase transparency in respect of its role in sponsoring these events.

One such item was the Prostate UK press release cited by the complainant, which was designed to raise awareness of the launch of its BPH disease awareness campaign and was reviewed by GlaxoSmithKline for factual accuracy and Code compliance. GlaxoSmithKline asked for the wording 'with funding from GlaxoSmithKline UK Limited (GSK)' in paragraph 1 and 'which was produced by GSK in conjunction with Prostate UK' in paragraph 6 to be added following its review of a draft sent to it by Prostate UK.

GlaxoSmithKline submitted that it developed the report and paid honoraria to an expert editorial board which had final editorial control. The editorial board comprised:

- Chairman of the editorial board, consultant urologist at the Prostate Centre and medical director of Prostate UK
- Chief executive officer of Prostate UK
- General practitioner with a specialist interest in urology
- Executive director for system reform and service innovation.

Board members were required to attend one faceto-face editorial board meeting, review a number of drafts and write a foreword for inclusion in the report. Honoraria were paid directly to the two members of the board who also held positions with Prostate UK rather than to the charity itself. Further, Prostate UK had not and would not, receive any monies from GlaxoSmithKline in respect of the report.

In conclusion, GlaxoSmithKline submitted that the complaint related to the complete and accurate declaration of GlaxoSmithKline's involvement in the report. GlaxoSmithKline's involvement was clearly and fully explained within the report. This involvement included payment of honoraria to editorial board members who also held positions within Prostate UK. All members of the editorial board were remunerated in their personal capacity, therefore Prostate UK received no monies from GlaxoSmithKline in respect of this report.

For activities where Prostate UK had received support from GlaxoSmithKline, as described previously, the nature of GlaxoSmithKline's support had been described in a detailed and transparent manner.

GlaxoSmithKline was committed to and took pride in maintaining high ethical standards. The company considered that it had upheld high standards in terms of both its sponsorship of the report and its ongoing relationship with Prostate UK. GlaxoSmithKline denied a breach of Clause 9.10.

PANEL RULING

The Panel noted that the supplementary information to Clause 9.10, Declaration of Sponsorship, required that the declaration of sponsorship be sufficiently prominent to ensure that readers of sponsored material were aware of it at the outset. The declaration must accurately reflect the nature of the company's involvement. Clause 9.10 required that sponsorship of material be declared, not the background relationships between the parties to a project.

The Panel noted GlaxoSmithKline's submission regarding its support of Prostate UK and its declaration of interest in that regard. The supplement at issue was not Prostate UK material that had been supported by GlaxoSmithKline.

The Panel noted that GlaxoSmithKline's corporate logo appeared on the bottom left hand corner of the front page above the statement 'GSK has sponsored

the production of this supplement; for details please see the back cover page of the report'. The corporate logo also appeared on the lower left hand corner of the back outside cover alongside the statement 'GSK sponsorship has included payment for a medical writer, honoraria to the editorial board and payment to a public relations agency in respect of project management support'. The report discussed disease impact and treatment options, gave summaries of current UK guidance vs the reality of management for GPs, specialists and patients in the UK, and of the NHS cost burden. The report ended with a call to action which urged the NHS to recognize BPH management and treatment as a key health priority. Treatment options and classes of medicine were discussed. No specific medicines were mentioned. The four members of the editorial board were introduced on the inside front cover including the chief executive officer at Prostate UK. GlaxoSmithKline had submitted that two members of the editorial board held positions at Prostate UK, the identity of the second ie the chairman of the editorial board who was the medical director of Prostate UK, was not clear from the report.

The Panel considered that GlaxoSmithKline's role in the production of the supplement had been made clear. Sufficient details appeared prominently on the front page with further explanation on the outside back cover. The Panel noted GlaxoSmithKline's explanation of its sponsorship of certain Prostate UK activities. Prostate UK had not received any monies from GlaxoSmithKline in respect of the report. Honoraria were paid directly to individual board members including those who held positions at Prostate UK. The Panel considered that the sponsorship of the report and membership of the editorial board were transparent. That Prostate UK received sponsorship monies from GlaxoSmithKline in respect of other projects did not preclude its chief executive officer from being a member of the editorial board for the supplement at issue. GlaxoSmithKline's sponsorship of activities by Prostate UK which were unrelated to its sponsorship of the report did not have to be declared in the report at issue. No breach of Clause 9.10 was ruled.

Complaint received 2 November 2009

Case completed 18 December 2009