CASE AUTH/2250/7/09

VOLUNTARY ADMISSION BY GLAXOSMITHKLINE

Travel health proposal to a local buying group

GlaxoSmithKline voluntarily admitted that it had inadvertently breached the Code in relation to a pricing proposal, written by a member of its travel health sales force, and provided to a local buying group. The Authority's Constitution and Procedure provided that the Director shall treat an admission as a complaint if, *inter alia*, it related to a potentially serious breach of the Code. Failing to certify material was a serious matter and the admission was accordingly treated as a complaint.

In March 2009 a member of a local buying group (a practice manager) asked its travel health representative for pricing information. The representative asked to present to the group but, given the timescales, this was not possible; the information was asked for in written form within two days.

The representative agreed with her regional business manager that she would compile the information. The regional business manager reviewed and approved the document. Three hard copies, together with an approved promotional item were given to the practice manager who asked for an electronic copy which was circulated to other members of the group.

In May 2009 the representative received a similar request from a different buying group and provided it with the same material, omitting only the listed names of members of the other buying group. No other practices had received this information nor had any other representatives sent similar information.

Although the material was produced as a pricing proposal, GlaxoSmithKline took the view that the claim 'Excellent Products' made this a promotional item. GlaxoSmithKline therefore believed it was in breach of the Code as the claim 'Excellent Products' was used, without qualification or substantiation; prescribing information, non-proprietary names and the statement on adverse event reporting were all omitted; neither the representative nor her manager recognised the material as a promotional item requiring submission for Code certification, they had misunderstood the Code and GlaxoSmithKline's procedures, which clearly stated that such material should be approved by head office. Therefore they had failed to maintain a high standard and despite this being contrary to their instructions, GlaxoSmithKline took full responsibility for this inappropriate conduct. The nurse audit referred to in the proposal was a medical service provided by GlaxoSmithKline. Its aim was to facilitate identification of patients for a booster injection where necessary. The non-promotional service was open to all UK practices. However, the service was referred to within this promotional material in breach of the Code.

GlaxoSmithKline took any breaches of the Code and matters of misconduct very seriously. The individuals concerned had passed their ABPI examination and there was clearly no wilful intent to contravene the Code. This was the only incident of this nature that had occurred with these two individuals. GlaxoSmithKline had maintained high standards in relation to format, suitability and taste of the material and its processes and standard operating procedures were adequate and clear and this incident did not reflect a failure in these processes. Due to the isolated nature of this incident and the corrective actions, which were outlined below, GlaxoSmithKline firmly believed that it had not brought discredit upon or reduced confidence in the industry.

GlaxoSmithKline stated that all recipients of the proposal had been told that the material was inappropriate. GlaxoSmithKline had requested that the material be destroyed or electronic copies deleted. The representative and her manager were retrained on all processes and would receive specific Code retraining. The travel health team would receive additional Code training to that regularly provided within the company.

GlaxoSmithKline deeply regretted this situation had occurred based on one piece of material with limited distribution by one person.

The detailed response from GlaxoSmithKline is given below.

The Panel noted that the travel health proposal included three sections outlining how GlaxoSmithKline Travel Health could help practices by providing 'Excellent Products', practice support services and competitive prices. The document had been provided in response to a request for pricing information. The document described GlaxoSmithKline's products as, *inter alia*, 'Excellent'. As the document contained a claim for the products it had to be considered to be promotional and could not take the benefit of the exemptions to the definition of promotion. The representative had provided another buying group with similar material.

With regard to the proposal provided to the buying group in March 2009 the Panel considered that, in the context in which it appeared, 'Excellent' implied some special merit for GlaxoSmithKline's products which was misleading. Breaches of the Code were ruled as acknowledged by GlaxoSmithKline.

The Panel noted that the document did not contain prescribing information, there were no non-proprietary names next to the most prominent display of the brand names nor was there an adverse event reporting statement. Breaches of the Code were ruled as acknowledged by GlaxoSmithKline.

The Panel considered that the representative and her manager had not maintained a high standard of ethical conduct. The document had not been certified. Breaches of the Code were ruled.

The promotional document referred to a non-promotional nurse audit which was offered as a medical service by GlaxoSmithKline. A breach of the Code was ruled as acknowledged by GlaxoSmithKline.

The Panel noted that GlaxoSmithKline had admitted a breach in that the Code required companies to be responsible for the activities of their representatives if these were within the scope of their employment even if they were acting contrary to the instructions which they had been given. The Panel considered that GlaxoSmithKline had demonstrated that it had taken responsibility for the representative and her manager.

In the Panel's view, creation of unapproved promotional material by the field force was of serious concern. High standards had not been maintained and a breach of the Code was ruled. Nonetheless, the Panel considered that the material before it was not such as to bring discredit upon or reduce confidence in the pharmaceutical industry. Clause 2 of the Code was used as a sign of particular censure and reserved for such use. No breach of Clause 2 was ruled.

GlaxoSmithKline UK Ltd voluntarily admitted that it had inadvertently breached the Code; the matter was brought to GlaxoSmithKline's attention on 10 June 2009 by a competitor company and related to a pricing proposal, written by a member of its travel health sales force, and provided to a local buying group. As soon as GlaxoSmithKline knew about the material it conducted a full and comprehensive investigation to establish how such a breach occurred and what corrective actions needed to be taken.

The action to be taken by the Authority in relation to a voluntary admission by a company was set out in Paragraph 5.4 of the Constitution and Procedure which stated, *inter alia*, that the Director shall treat the matter as a complaint if it related to a potentially serious breach of the Code. Failing to certify material was a serious matter and the Director decided that the admission should be treated as a complaint.

COMPLAINT

GlaxoSmithKline stated that in March 2009 a member of a local buying group (a practice manager) asked its travel health representative for pricing information. The representative asked for the opportunity to present the information to the group but, given the timescales to which the buying group was committed, this was not possible; the information was asked for in written form within two days.

The representative agreed with her regional business manager that she would compile the information and submit it to him for review. The regional business manager duly reviewed and approved the use of the document. Three hard copies were given in a folder, together with an approved promotional item, to the practice manager representing the buying group. The practice manager asked for an electronic copy of the pricing proposal and it appeared that this was then circulated to other members of the group.

In May 2009 the representative received a similar request from a separate buying group and provided it with the same material, omitting only the listed names of members of the other buying group.

No other practices had received this information nor had any other representatives sent similar information.

Although the material was produced as a pricing proposal, GlaxoSmithKline took the strict view that the claim 'Excellent Products' made this a promotional item in breach of the Code as follows:

- The claim 'Excellent Products' was used, without qualification or substantiation, in breach of Clauses 7.2 and 7.10.
- Prescribing information, non-proprietary names and the statement on adverse event reporting were all omitted, in breach of Clauses 4.1, 4.3 and 4.10 respectively.
- Neither the representative nor her manager recognised the material as a promotional item requiring submission for Code certification so Clause 14.1 was also breached.
- The representative and her manager had misunderstood the Code and GlaxoSmithKline's procedures, which clearly stated that such material should be approved by head office. Therefore they had failed to maintain a high standard in the discharge of their duties, and despite this being contrary to their instructions, GlaxoSmithKline took full responsibility for this inappropriate conduct. Clauses 15.2 and 15.10 had therefore been breached.
- The ITHENA Nurse Audit was a medical service provided by GlaxoSmithKline, under Clause 18. The aim of this service was to facilitate identification of patients for a booster injection where necessary. The non-promotional service was open to all UK practices. However, the service was referred to within this promotional material in breach of Clause 18.4.

GlaxoSmithKline took any breaches of the Code and matters of misconduct very seriously and this

incident was of particular concern given the extensive Code, procedural and general training its representatives received. Both the individuals concerned had passed their ABPI examination. Following a comprehensive review of the circumstances that had led to this breach, there was clearly no wilful intent to contravene the Code, in letter or in spirit, by either of the individuals involved. This was the only incident of this nature that had occurred with these two individuals. The investigation revealed that this was an isolated case, and there was no suggestion that other members of the field force similarly misunderstood the requirements. GlaxoSmithKline's intention had always been to comply with the Code. GlaxoSmithKline had maintained high standards in relation to format, suitability and taste of the material and its processes and standard operating procedures were adequate and clear and this incident did not reflect a failure in these processes. Due to the isolated nature of this incident and the corrective actions, which were outlined below, GlaxoSmithKline firmly believed that it had not brought discredit upon or reduced confidence in the industry, therefore it had not breached Clause 2.

GlaxoSmithKline stated that those involved with this case had expressed deep remorse that their failure to understand the Code's requirements had led to this breach of the Code.

GlaxoSmithKline had undertaken that:

- All recipients of the proposal had been contacted and told that the material was inappropriate. GlaxoSmithKline had requested that the material be destroyed or electronic copies deleted.
- The representative and her manager were retrained on all processes and would receive specific Code retraining. Both had received short term objectives, as part of the GlaxoSmithKline disciplinary process, to ensure that they fully understood the Code.
- The travel health team including both sales and marketing departments, would receive additional Code training this year to that regularly provided within the company.

GlaxoSmithKline deeply regretted this situation had occurred based on one piece of material with limited distribution by one person. GlaxoSmithKline stressed its commitment to maintaining high standards in all its activities.

When writing to GlaxoSmithKline to inform it that the matter would be taken up under the Code, the Authority asked the company to consider the requirements of Clause 9.1 in addition to those it had already cited.

RESPONSE

GlaxoSmithKline reiterated that it had voluntarily notified the Authority of breaches of the Code in respect of Clauses 4.1, 4.3, 4.10, 7.2, 7.10, 14.1, 15.2, 15.10 and 18.4.

The proposal at issue was produced by one of the travel health representatives in response to a request for information from a member of the local buying group.

GlaxoSmithKline took any breaches of the Code and matters of misconduct very seriously and this incident was of particular concern given the extensive Code, procedural and general training its representatives and account managers received. GlaxoSmithKline also acknowledged that the use of uncertified material was a potentially serious issue. Therefore the company had written to the two local buying groups concerned to request that all copies of the proposal were destroyed or deleted. At no time had patient safety been impacted.

As soon as GlaxoSmithKline knew about the material it conducted a full and comprehensive investigation, to establish how such a breach occurred, and what appropriate corrective actions needed to be taken. The sequence of events was outlined above. Although they did not breach the Code intentionally, the two employees involved were going through a formal disciplinary procedure.

GlaxoSmithKline had supported the ITHENA audit nurse team in order to facilitate best practice regarding completion of travel vaccination schedules. The service was available to all practices so that they might ensure that patients who had not completed their course of vaccination against hepatitis A, hepatitis B and/or typhoid, might be recalled to complete the course as appropriate. Provision of the service was not dependent on the prescribing of GlaxoSmithKline's vaccines and the briefing document enclosed made this clear.

GlaxoSmithKline noted that it had been specifically asked to comment on Clause 9.1. While it acknowledged that the document in question technically became promotional material by virtue of the inclusion of the claim 'Excellent Products', the proposal otherwise explained the discounts and services available to the local buying group in accordance with Clause 18.1. The group received the information it was seeking within the short timelines set. GlaxoSmithKline was committed to maintaining high standards through training of its employees and establishing a culture of ethical conduct. GlaxoSmithKline had taken this isolated incident seriously by putting those involved through a disciplinary procedure. GlaxoSmithKline therefore believed that Clause 9.1 was not breached, as the information requested by the buying group was provided in a timely and appropriate manner and it had acted to maintain the high standards expected of it. Both the representative and the regional business manager had passed their ABPI Medical Representative's Examination.

GlaxoSmithKline was committed to and took pride in maintaining high standards. Appropriate action had been taken and the company trusted that it had demonstrated that it had recognised that this was a very serious matter which it would ensure would not happen again.

PANEL RULING

The Panel noted that the Travel Health Proposal included three sections outlining how GlaxoSmithKline Travel Health could help practices by providing 'Excellent Products', practice support services and competitive prices. The document had been provided in response to a request for pricing information. The document described GlaxoSmithKline's products as, *inter alia*, 'Excellent'. As the document contained a claim for the products it had to be considered to be promotional and could not take the benefit of the exemptions to the definition of promotion in Clause 1.2. The representative had provided another buying group with similar material.

With regard to the proposal provided to the buying group in March 2009 the Panel considered that, in the context in which it appeared, that 'Excellent' implied some special merit for GlaxoSmithKline's products which was misleading. Breaches of Clauses 7.2 and 7.10 were ruled as acknowledged by GlaxoSmithKline.

The Panel noted that the document did not contain prescribing information for those products referred to, there were no non-proprietary names next to the most prominent display of the brand names nor was there an adverse event reporting statement. Breaches of Clauses 4.1, 4.3 and 4.10 respectively were ruled as acknowledged by GlaxoSmithKline.

The document had not been certified. A breach of Clause 14.1 was ruled.

The Panel considered that the representative and her manager had not maintained a high standard of ethical conduct. A breach of Clause 15.2 was ruled.

The promotional document referred to a non-promotional nurse audit which was offered as a medical service by GlaxoSmithKline. The supplementary information to Clause 18.4, Provision of Medical and Educational Goods and Services, stated that printed material designed for use in relation to the provision of such goods and services must be non-promotional. A breach of Clause 18.4 was ruled as acknowledged by GlaxoSmithKline.

The Panel noted that GlaxoSmithKline had admitted a breach of Clause 15.10. Clause 15.10 required companies to be responsible for the activities of their representatives if these were within the scope of their employment even if they were acting contrary to the instructions which they had been given. The Panel considered that GlaxoSmithKline had demonstrated that it had taken responsibility for the representative and her manager. No breach of Clause 15.10 was ruled. [Post meeting note: Clause 15.10 is an explanatory Clause and is not capable of infringement].

In the Panel's view, creation of unapproved promotional material by the field force was of serious concern. High standards had not been maintained and a breach of Clause 9.1 was ruled. Nonetheless, the Panel considered that the material before it was not such as to bring discredit upon or reduce confidence in the pharmaceutical industry. Clause 2 of the Code was used as a sign of particular censure and reserved for such use. No breach of Clause 2 was ruled.

Complaint received **14 July 2009**

Case completed **24 August 2009**