CASE AUTH/2782/7/15

VOLUNTARY ADMISSION BY GLAXOSMITHKLINE

Patient support items distributed from exhibition stand

GlaxoSmithKline voluntarily admitted that patient support items (demonstration devices and training whistles for the Ellipta inhaler) had been handed out at a meeting for nurses organised by a third party.

In accordance with Paragraph 5.6 of the Constitution and Procedure the Director treated the matter as a complaint.

The detailed response from GlaxoSmithKline is given below.

The Panel noted that the Code stated that patient support items must not be given out from an exhibition stand. In contravention of that requirement, however, Ellipta demonstration devices and training whistles had been given out from an exhibition stand at a third party organised meeting. The Panel noted that as all of the exhibition material had been ordered for delivery to the hotel where the meeting was to be held, it was unfortunate that neither the delivery address nor the nature of the items ordered (including an exhibition tablecloth) in themselves did not trigger further enquiry before the items were dispatched. Nonetheless, the representative who had ordered the items and the account manager who was at the meeting had been trained on the provision of patient support items and both should have known that such items could not be given out from an exhibition stand. However, as such items had been so distributed, the Panel ruled a breach of the Code. High standards had not been maintained. A further breach of the Code was ruled.

The Panel noted that a ruling of a breach of Clause 2 of the Code was a sign of particular censure and reserved for such. In that regard the Panel did not consider that the matter warranted such a ruling and so no breach of Clause 2 was ruled.

GlaxoSmithKline UK Limited voluntarily admitted a breach of the Code in that that it had handed out patient support items (21 demonstration devices and 17 training whistles for the Ellipta inhaler) from an exhibition stand at a third party meeting for nurses held in April 2015.

In accordance with Paragraph 5.6 of the Constitution and Procedure the Director treated the matter as a complaint.

VOLUNTARY ADMISSION

GlaxoSmithKline stated that in June 2015, a routine internal audit identified a discrepancy between the number of demonstration devices and training whistles issued to a representative and the number of items accounted for. The operations team consequently asked the representative to complete a report outlining what had happened. When this report, including proposed corrective and preventative actions (CAPAs), was reviewed in July, a breach of the Code was identified and the company decided to make a voluntary admission to PMCPA.

Before notifying the PMCPA, further information was requested to understand the exact sequence of events. The representative's manager was asked to contact the individuals involved for further information. The following details were obtained:

On 17 March 2015, the meeting organisers asked a GlaxoSmithKline account manager if GlaxoSmithKline wished to purchase stand space. The account manager agreed that GlaxoSmithKline would exhibit at the meeting.

On 10 April, following a request from the account manager, the representative ordered 25 Ellipta demonstration devices and 25 Ellipta training whistles to be delivered directly to the meeting venue.

The account manager manned the stand at the meeting and handed out 21 demonstration devices and 17 training whistles in breach of Clause 18.2. Each item provided was signed for by the recipient; each recipient had subsequently been verified to be a health professional.

In November 2013, both the account manager and the representative were trained on the process for managing and ordering demonstration devices and training whistles. A copy of the training attendance log was provided.

GlaxoSmithKline stated that the following preventative actions were in progress:

All commercial field team staff had been reminded in writing that it was not permissible to hand out patient support items from exhibition stands.

The current training slide deck on the provision of demonstration devices, whistles and samples had been updated to make it explicit that these items could not be handed out from exhibition stands.

The documentation outlining the process for the management of samples, placebos, demonstrators, testers and other training devices was under review to provide better clarity.

A case study would be developed for sharing with the boarder organisations to ensure that lessons were learnt from this error.

GlaxoSmithKline submitted that this was a case of human error; the individuals involved and their manager had been informed and reminded of

the requirements of the Code with regard to the provision of patient support items.

GlaxoSmithKline stated that it took its obligations for compliance with the Code seriously and was committed to ensuring that all staff were appropriately trained and acted in compliance with the Code.

When writing to GlaxoSmithKline to confirm that the matter would be taken up under the Code, the Authority asked it to provide any further comments it might have in relation to Clauses 2, and 9.1 in addition to Clause 18.2 cited by GlaxoSmithKline.

RESPONSE

GlaxoSmithKline stated that it expected its employees to comply with the Code, laws and regulations, the GlaxoSmithKline Code and policies and maintain high standards at all times. It appeared that an individual had, as a result of human error, acted such as to breach Clause 18.2. GlaxoSmithKline very much regretted this matter. The problem was identified through governance procedures and the deviation brought to the attention of senior managers who took swift and appropriate action. This resulted in the voluntary admission.

Appropriate corrective action was taken in that it had been confirmed that all the individuals to whom the devices had been provided were health professionals, and databases had been updated to record provision of these devices to these individuals. The individual involved was immediately reminded of Clause 18.2.

Preventative action had been taken in the form of a communication to all the commercial field roles reiterating the provisions of Clause 18.2. The training slides about how demonstration devices and training whistles could be provided to customers had been updated with explicit instructions that patient support items could not be handed out from exhibition stands. The documentation outlining the process for the management of samples, placebos, demonstrators, testers and other training devices was under review to provide better clarity and a case study would be developed to share with the broader organisation to ensure that lessons were learnt.

GlaxoSmithKline submitted that it always strove to maintain high standards as required by Clause 9.1 and in this instance it believed that the root cause of the problem was not a lack of process but human error by the representative. GlaxoSmithKline thus submitted that a breach of Clause 9.1 was not warranted as it had taken relevant action to correct the issue as soon as it became apparent.

GlaxoSmithKline was committed to open and transparent behaviour and in that regard it strongly believed that it had acted quickly and transparently to bring this to the attention of the PMCPA. As such, GlaxoSmithKline submitted that it had not brought the industry into disrepute.

In response to a request for further information, GlaxoSmithKline stated that a number of items were ordered for the meeting from a third party provider and despatched en bloc to the venue; a list of the items and quantities ordered was provided. In addition a giant Ellipta model was delivered to the event via a separate company. The model was shipped in a black case so that it was not visible to the public. No exhibition panels were ordered for the meeting. The account manager who attended the meeting had a pull up exhibition stand.

GlaxoSmithKline explained that it classified meetings into two categories - those organised by the company (stand alone meetings) and those organised by other third parties (sponsored meetings). Exhibitions fell into the category of a sponsored meeting; the company's databases did not specifically record a category of exhibition.

GlaxoSmithKline stated that the items required for the meeting were ordered through its electronic ordering system. On receipt of the request, the third party provider responsible for despatching such items including promotional leavepieces, samples or patient support items, would have picked and despatched the items. The third party provider was not required to review all orders manually to determine to where they were to be delivered. Only the representative would have been clear that the ordered items were for an exhibition.

GlaxoSmithKline explained that the number of demonstration devices or other patient support items a representative might order was determined by the relevant brand team and varied from item to item. Up to 25 Ellipta demonstration devices and/or 40 training whistles could be hand delivered to a customer at any one time and representatives could hold up to 50 of each to fulfil customer requests.

GlaxoSmithKline stated that the representative ordered 25 Ellipta demonstration devices and 25 Ellipta training whistles. As these quantities were well within the maximum allowed for a representative to order, an order of this size would not have triggered further enquiry.

GlaxoSmithKline stated that third party sponsored meetings might occur at a variety of venues; its internal ordering system did not have automated validation checks built in for delivery addresses. As such, there was no automated control that would have triggered further enquiry just because a hotel address had been entered. Whilst a manual check of all delivery addresses could be implemented, this would be a large resource implication for a very low number of potential triggers. GlaxoSmithKline considered that a representative's knowledge of the Code should be sufficient to understand the requirements of the Code in relation to what could be provided from an exhibition stand. Unfortunately, on this occasion, the expected standards were not met.

PANEL RULING

The Panel noted that Clause 18.2 stated that items intended to be passed to patients as part of a formal

patient support programme must not be given out from an exhibition stand. In contravention of that requirement, however, 21 Ellipta demonstration devices and 17 training whistles had been given out from an exhibition stand at a third party organised meeting for nurses. The Panel noted that the material needed for the exhibition had been ordered en bloc for delivery to the hotel where the meeting was to be held. In that regard the Panel considered that it was unfortunate that neither the delivery address nor the nature of the items ordered (including an exhibition tablecloth) in themselves did not trigger further enquiry before the items were dispatched. Nonetheless, the representative who had ordered the items and the account manager who was at the meeting to man the stand, had been trained on the provision of patient support items and both should have known that such items could not be given out from exhibition stands. The Panel did not consider that the matter was a failing of one individual as submitted by GlaxoSmithKline. The Panel noted that the prohibition on the provision of patient support items from exhibition stands had been a requirement of the Code since 2011 and so in that regard there should have been a very well established company procedure such that no thought would ever be given to distributing such items from stands. However, patient support items had been distributed from an exhibition stand and so the Panel ruled a breach of Clause 18.2. High standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted that a ruling of a breach of Clause 2 of the Code was a sign of particular censure and reserved for such. In that regard the Panel did not consider that the matter warranted such a ruling and so no breach of Clause 2 was ruled.

Complaint received **21 July 2015**

Case completed **19 August 2015**
