MEMBER OF THE PUBLIC v GLAXOSMITHKLINE

Conduct of representative

A member of the public complained about the conduct of a representative from GlaxoSmithKline. The complainant alleged that a close friend had recently ended up hospitalized because he overdosed on medicines purchased privately from one of GlaxoSmithKline's representatives.

The Panel noted that GlaxoSmithKline's policy was to post samples to health professionals. Representatives were not allowed to hold supplies of samples for distribution. Representatives were allocated one demonstration pack per product which was actual stock overlabelled 'For demonstration purposes only. NOT for clinical use or to be left with customers'. Such packs could not be replaced unless there was a very good reason.

GlaxoSmithKline provided details of a recent audit of the representative's samples which tallied the quantity of samples requested with that ordered, despatched, returned and indicated that the request form had been checked. On the evidence before it the Panel considered that GlaxoSmithKline had an adequate system of control and accountability for samples and medicines. There was no evidence that samples had been provided to a non-health professional as alleged nor without a signed dated written request. The Panel did not consider that either the representative or the company had failed to maintain high standards. Thus no breaches of the Code including Clause 2 were ruled.

A member of the public complained about the conduct of a representative from GlaxoSmithKline UK Ltd.

COMPLAINT

The complainant stated that she was extremely upset and disgusted with GlaxoSmithKline and would have thought that a company on such a grand scale would keep its representatives inline with ABPI regulations and conduct in that they were largely trained to recognize how dangerous it was to sell samples to vulnerable individuals to line their own pockets. The complainant alleged that a very close friend had recently ended up hospitalized because he overdosed on medicines which were not prescribed by his general practitioner, in fact he had been purchasing the medicines privately for some time, now from one of GlaxoSmithKline's representatives. The complainant and the hospitalized person's family knew that he was as much to blame for the overdose as the irresponsible representative with unethical conduct, but at the end of the day if the representative had not been selling these medicines to vulnerable individuals, the complainant dreaded to think how many others would not be in such a disastrous state. The complainant was strongly considering bringing this matter to the attention of the police pending the recovery of their friend's health and in the meantime brought this matter to attention of the Authority. The complainant hoped the Authority would take this matter seriously and would bring in stringent checks on ensuring representatives maintained an ethical conduct as well as working with GlaxoSmithKline to basically tighten up their accountability of where and whom its medicine samples were littered to by its sales force - hopefully not the vulnerable members of the public.

When writing to the GlaxoSmithKline the Authority asked it to respond in relation to Clauses 2, 9.1, 15.2, 17.1, 17.3 and 17.9 of the Code.

RESPONSE

GlaxoSmithKline submitted that it took the allegations extremely seriously and on receipt of this complaint instigated an urgent investigation.

The representative had worked for GlaxoSmithKline for a number of years on a number of products including Levitra (vardenifil), Avodart (dutasteride) and Seretide (salmeterol/fluticasone). Recently the representatives had worked in a respiratory team.

GlaxoSmithKline submitted that the during the last 12 months the representative had only requested Incheck devices (a tool for measuring effectiveness of patient inhaler technique) and placebo inhalers. The representative had no access to any other GlaxoSmithKline medicines samples and had not requested nor distributed any samples other than those detailed. Full details of these samples and the signed request forms were provided.

As per legal requirements and the Code, both of which were reinforced by GlaxoSmithKline's Stay Safe Sheet guidance, samples were only provided to customers on receipt of a written and signed request. The request was validated against three key criteria:

- Orders must only be made to a doctor whose name and address was on the request form, as defined on GlaxoSmithKline's Triton system.
- Doctors could not receive more than ten samples of a specific formulation and dose type in any 12 month rolling period.
- The sampling initiative must be active and have an end date after which no further requests would be accepted.

GlaxoSmithKline did not allow its representatives to hold samples. All samples were dispatched directly to the health practitioner as detailed in the standard operating procedure (SOP) provided. One

demonstration pack was allocated per representative and this was solely for the representative's use during a call and was not to be left with customers.

GlaxoSmithKline also required random weekly audits of representatives' sample logs. The representative in question underwent a previous successful audit of her samples 18 months ago.

The representative was understandably shocked by the seriousness of the allegations which were vigorously refuted. GlaxoSmithKline could find no evidence to support any of the allegations and, based on the company's own sample records, supported the denials of any wrongdoing. Furthermore GlaxoSmithKline submitted that its robust process maintained control and accountability of medicines held by representatives in accordance with Clause 17.9 and the company thus strongly refuted breaches of Clauses 2, 9.1, 15.2, 17.1, 17.3 and 17.9 as alleged.

As requested GlaxoSmithKline provided:

- Details of all samples provided and distributed by the representative in the last 12 months
- Copies of signed sample request forms over the same period
- Representative's Sample Audit form for the representative
- UKMED/SOP/0026 - GlaxoSmithKline UK process for the management of Samples, Placebos and Devices
- Stay Safe Sheet 31 GlaxoSmithKline UK samples process- guidance document for representatives
- Certificate of passing the representatives' ABPI examination

PANEL RULING

The Panel noted that GlaxoSmithKline had a policy of posting samples of medicines to health professionals. Representatives were not allowed to hold supplies of samples for distribution. The relevant SOP (dated 24 June 2005) set out the detailed arrangements.

Representatives were allocated one demonstration pack per product which was actual stock overlabelled 'For demonstration purposes only. NOT for clinical use or to be left with customers'. According to the SOP such packs could not be replaced unless there was a very good reason, for example, theft and in such a case a crime reference number was required. Representatives were provided with a guidance document on the arrangements.

The Panel considered that this was a very serious allegation. The complainant provided no evidence regarding the alleged sales of samples. GlaxoSmithKline had provided copies of its SOP, its guidance notes and details of an audit of the representative's samples for the year July 2006 – July 2007. In the last 12 months the representative had requested mainly Incheck devices and placebo inhalers although it appeared that Seretide inhalers might have been ordered for two doctors (the number of samples had not been indicated on the forms) but the requests for Seretide had been rejected. Some of the requests indicated that the sample was to be sent to the practice nurse. The audit form tallied the quantity of samples requested with that ordered, despatched, returned and indicated that the request form had been checked. On the evidence before it the Panel considered that GlaxoSmithKline had an adequate system of control and accountability for samples and medicines. Thus no breach of Clause 17.9 was ruled.

There was no evidence that samples had been provided to a non-health professional as alleged nor without a signed dated written request. No breach of Clauses 17.1 and 17.3 was ruled. The Panel did not consider that either the representative or the company had failed to maintain high standards. Thus no breach of Clauses 15.2 and 9.1 was ruled.

Given its rulings above the Panel did not consider that there had been a breach of Clause 2.

Complaint received	**24 July 2007**
Case completed	**10 September 2007**