ANONYMOUS v LILLY

Provision of Byetta samples

An anonymous, non contactable complainant who described themself as a concerned member of staff at a named hospital complained about the distribution of Byetta (exenatide) samples by Eli Lilly and Company. The complainant alleged that Lilly had placed a large number of samples of Byetta in the pharmacy at the hospital to encourage doctors to prescribe it. The aim was to encourage use of Byetta at the hospital as initial prescriptions of Byetta would effectively be provided free of charge to patients with diabetes. The complainant did not consider this was correct practice as even if this reduced medicines costs for the hospital, doctors were being led to use an expensive medicine the cost of which would be picked up later in primary care.

The detailed response from Lilly is given below.

The Panel noted Lilly's submission that its sales representative received a request to provide samples from the lead pharmacist on behalf of the hospital pharmacy diabetes and metabolism departments. It was unclear whether it was a verbal or written request. Ten samples each were provided to four physicians. In this regard the requirements of the Code had been met and no breach was ruled. The Panel noted Lilly's submission that Byetta had received its marketing authorization in November 2006 and had thus been on the market for less than 10 years; a further ruling of no breach of the Code was ruled on this point.

The Panel noted that each sample request form had been signed and dated by the applicant as required by the Code and a further ruling of no breach was ruled.

The Panel noted that the lower section of Lilly's sample request form entitled 'Hospital Pharmacy Contact Details' required the hospital pharmacy to confirm that the supply of samples requested by the doctor named on the form complied with hospital requirements on samples. The section on the forms at issue had been signed and dated by the purchasing pharmacist on 2 February 2011 whereas each of the requesting clinicians had subsequently signed between 8 and 11 February. The forms were thus not countersigned by the purchasing pharmacist as submitted by Lilly. The Panel queried whether the pharmacist should have signed four forms on which the clinician's name had been printed but which did not bear the clinician's signature. According to Lilly, the number of samples was stated on the form when it was signed by the pharmacist. The hospital policy provided by Lilly stated in relation to samples that representatives must not leave samples with individual clinicians or staff. If a clinician wished to try a particular medicine this must be through prior arrangement with the pharmacy department and the relevant committees. The hospital policy was silent on the signing and completion of sample request forms. It was unclear whether the policy provided was indeed the latest version. In this regard the Panel noted that it was unfortunate that the complainant was anonymous and non contactable and thus it was not possible to ask him/her for further information. Irrespective of its concerns set out above the Panel considered that there was no evidence that the provision of samples had failed to comply with the hospital's requirements as set out in the policy document provided. No breach of the Code was ruled accordingly.

The Panel noted the complainant's comments about the cost of the product when the patient transferred to primary care. There was no evidence before the Panel that the samples were provided as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine contrary to the Code and no breach was ruled.

The Panel noted its rulings of no breaches of the Code above and consequently did not consider that the company had failed to maintain high standards or brought the industry into disrepute; no breaches of the Code were ruled.

An anonymous, non contactable complainant who described themself as a concerned member of staff at a hospital complained about the distribution of Byetta (exenatide) samples by Eli Lilly and Company Limited.

COMPLAINT

The complainant stated that Lilly had placed a large number of samples of Byetta in the pharmacy at his hospital to encourage doctors to prescribe it. The aim was to encourage use of Byetta at the hospital as initial prescriptions of Byetta would effectively be provided free of charge to patients with diabetes.

As a member of staff the complainant did not consider this was correct practice. Lilly should not have placed these samples into a hospital free of charge. Even if this reduced medicines costs for the hospital, doctors were being led to use an expensive medicine the cost of which would be picked up later in primary care.

When writing to Lilly, the Authority asked it to

respond in relation to Clauses 17.2. 17.3, 17.8, 17.12, 9.1 and 2 of the Code.

RESPONSE

Lilly stated that it had examined its records for the supply of Byetta to the hospital in question over the past year and believed its activities were in compliance with Clause 17 (other than Clause 17.6 which was not applicable), Clauses 2 and 9.1.

Lilly stated that its sales representative received the original request from the lead pharmacist on behalf of the pharmacy and diabetes and metabolism departments at the hospital in January 2011 to provide samples of Byetta for each (physician) prescriber in the diabetes department (Clause 17.1). The purpose of the request was to allow prescribers in the diabetes department 'to develop their limited clinical experience in the use of this product for each prescriber in the department' before the patient left hospital (Clause 17.12). Four physicians completed the relevant sample supply documentation to receive samples (a maximum of 10 samples each over the year, 40 samples in total – Clause 17.2) in February 2011. All forms were completed in full with signatures and General Medical Council numbers. The requests were countersigned by the purchasing pharmacist to confirm compliance with hospital's requirements for the supply of samples (Clauses 17.3 and 17.8). A copy of the policy was provided together with copies of the request forms. These requests were recorded as submitted and supplied on the Lilly supply database during February 2011 (Clause 17.9).

Byetta received a marketing authorization in November 2006 and had been on the UK market for less than 10 years (Clause 17.2). Each sample comprised a Byetta pre-filled pen 5mcg dose (the smallest presentation of the product on the market, Clause 17.4) and was marked 'sample' (Clause 17.5). Clauses 17.7, 17.10 and 17.11 were complied with in the distribution process.

Lilly submitted that the evidence outlined demonstrated that it had complied with all requirements of the Code. It therefore disputed the complainant's allegations that it had supplied a large number of samples to encourage doctors to supply this product as the samples were supplied free of charge.

In response to a request for further information Lilly explained that diabetologists from the department of diabetes had expressed their wish to gain experience with this group of medicines and specifically asked its representative for Byetta samples. The local hospital core policy guideline for provision of samples, stated that 'prior arrangements with the Pharmacy Department' must be put in place. Sample request forms stating the name of the physicians and the number of samples requested were then authorised by the purchasing pharmacist on 2 February 2011. Individual physicians already named on the request forms subsequently signed the documents between 8 and 11 of February 2011.

In response to a further request for information about the dates recorded in the database document Lilly explained that a third party company managed the delivery of its samples. The date of the sample request on the database document referred to the date of signatures either by the purchasing pharmacist or the requesting doctor presumably reflecting different handling of these documents by the company. All samples were dispatched between 17 and 21 of February 2011.

Lilly considered that the evidence outlined above demonstrated that it had complied with all requirements of the Code in terms of the supply of samples of Byetta to the hospital diabetes department in February, 2011. Lilly therefore disputed the contentions made in the anonymous complaint that it had supplied a large number of samples to encourage doctors to supply Byetta as the samples were supplied free of charge.

PANEL RULING

The Panel noted that the complainant was concerned that Lilly had placed Byetta samples at the hospital pharmacy to encourage doctors to prescribe it. The complainant noted that whilst there would be a cost saving for the hospital the cost of the medicine, which the complainant considered expensive, would subsequently be picked up in primary care. The Panel noted that the provision of samples was a legitimate activity so long as the requirements of the Code, and in particular Clause 17, were met.

The Panel noted that according to its summary of product characteristics (SPC) Byetta therapy should be initiated at a dose of 5mcg twice daily for at least one month in order to improve tolerability. The dose could then be increased to 10mcg twice daily to further improve glycaemic control. The Panel noted that each pre-filled pen contained 60 doses and thus enough for one month's supply for a new patient. The Panel noted the definition of a sample in the supplementary information to Clause 17.1 and queried whether, given the requirement to administer the product for at least one month before any dose adjustment, together with the fact that the patient would be transferred to the care of their GP before completing the first month of therapy, a hospital doctor would genuinely acquire meaningful experience in dealing with the product. The Panel noted Lilly's submission that the samples would allow each prescriber to develop their limited clinical experience in the use of the product before the patient left hospital.

The Panel noted Lilly's submission that its sales representative received a request to provide samples from the lead pharmacist on behalf of the hospital pharmacy diabetes and metabolism departments. It was unclear whether it was a verbal or written request. Ten samples each were provided

to four physicians. In this regard the requirement of Clause 17.2 had been met; no breach of Clause 17.2 was ruled. The Panel noted Lilly's submission that Byetta had received its marketing authorization in November 2006 and had thus been on the market for less than 10 years; a further ruling of no breach of Clause 17.2 was ruled.

The Panel noted that each sample request form had been signed and dated by the applicant as required by Clause 17.3. No breach of Clause 17.3 was thus ruled.

The Panel noted that the lower section of Lilly's sample request form entitled 'Hospital Pharmacy Contact Details' required the hospital pharmacy to confirm that the supply of samples requested by the doctor named on the form complied with hospital requirements on samples. The section on the forms at issue had been signed and dated by the purchasing pharmacist on 2 February 2011 whereas each of the requesting clinicians had subsequently signed between 8 and 11 February. The forms were thus not countersigned by the purchasing pharmacist as submitted by Lilly. The Panel queried whether the pharmacist should have signed four forms on which the clinician's name had been printed but which did not bear the clinician's signature. According to Lilly, the number of samples was stated on the form when it was signed by the pharmacist.

The hospital policy provided by Lilly stated in relation to samples that representatives must not leave samples with individual clinicians or staff. If a clinician wished to try a particular medicine this must be through prior arrangement with the pharmacy department and the relevant committees. The hospital policy was silent on the signing and completion of sample request forms. The front page of the hospital policy bore approval and adoption dates of November 2004 and April 2008. It also referred to a review in April 2011. A section within the policy document was dated 3 July 2008 in relation to an unrelated matter. It was unclear whether the policy provided was indeed the latest version. In this regard the Panel noted that it was unfortunate that the complainant was anonymous and non contactable and thus it was not possible to ask him/her for further information. Irrespective of its concerns set out above the Panel considered that there was no evidence that the provision of samples had failed to comply with the hospital's requirements as set out in the policy document provided. No breach of Clause 17.8 was ruled accordingly.

The Panel noted the complainant's comments about the cost of the product when the patient transferred to primary care. There was no evidence before the Panel that the samples were provided as an inducement to prescribe supply, administer, recommend, buy or sell any medicine contrary to Clause 17.12. No breach of Clause 17.12 was ruled.

The Panel noted its rulings of no breaches of the Code above and consequently ruled no breach of Clauses 9.1 and 2.

Complaint received	**24 June 2011**
Case completed	**20 July 2011**