

GENERAL PRACTITIONER v LILLY

Unsolicited provision of samples

A general practitioner complained about samples of Cialis (tadalafil), a Lilly product, which he had received by post from an agency. He had not requested them and had they been sent to him by a pharmaceutical company they would have been in breach of the Code.

Correspondence provided by the complainant indicated that the agency had told him that it had signed sample requests from three of the doctors in the practice, including the complainant, but that the complainant contended that none of the signatures were those of the doctors concerned.

The Panel noted that the Lilly representative, when collecting the signed sample request forms, dated them, completed the address details and confirmed with the practice receptionist which sample request form related to which doctor. The complainant stated that the signatures on the sample request forms were not his or those of his GP colleagues. Lilly was satisfied that the signatures were made before the sample request forms were collected by the representative. Lilly stated that it had told the complainant about this and asked that the matter be investigated. The Panel noted that the completed sample request forms each bore a different signature.

The Code required sample request forms to be both signed and dated. The supplementary information referred to preprinted sample request forms that had been signed and dated by the applicant. Contrary to the requirements, the forms had been undated when received by the representative who had dated them himself. A breach of the Code was ruled. The Panel was concerned about the overall arrangements but considered in the circumstances that there had not been a failure to maintain high standards.

The Code required that no unsolicited medicine should be sent through the post. The Panel noted that it was not possible to determine precisely who had signed the sample request forms but considered that as far as Lilly was concerned the samples had been requested. Lilly had responded to the requests in good faith. The Panel ruled no breach of the Code in that regard.

A general practitioner complained about samples of Cialis (tadalafil), an Eli Lilly and Company Limited product, which he had received by post.

COMPLAINT

The complainant stated that the samples had been sent to him by an agency rather than by Lilly. He had not

requested them and had they been sent to him by a pharmaceutical company they would have been in breach of the Code.

Correspondence provided by the complainant indicated that the agency had told him that it had signed sample requests from three of the doctors in the practice, including the complainant, but that the complainant contended that none of the signatures on them were those of the doctors concerned.

When writing to Lilly, the Authority asked it to respond in relation to Clauses 2, 9.1, 15.2, 17.3 and 17.10 of the Code.

RESPONSE

Lilly explained that its agency provided Cialis samples upon request to GPs and hospital doctors qualified to prescribe it. The sampling process stated that a doctor or specialist could only receive 10 sample packs per year.

Lilly representatives did not carry samples. Samples could only be provided to a health professional if the health professional signed a sample request form, which included the requesting health professional's name, address, date and what split of sample packs was required.

The agency fulfilled all Lilly sample requests and ensured that they were delivered to the correct named person. Before despatching the samples, the agency checked that: the doctor was registered, the doctor had signed the sample request form and that all details had been completed correctly and that no more than 10 samples had been supplied to that doctor that particular year.

The relevant representative visited the complainant's practice in November and left sample request forms for the doctors in the practice to sign if they required Cialis samples. All three doctors had previously attended group-sells in respect of Cialis and were therefore familiar with the product. The representative called back later the same day to pick up the signed sample request forms from reception. The address details were not filled out so the representative completed those himself and confirmed with the receptionist which sample sheet correlated to which doctor, in order to ensure that the sample request forms were appropriately completed before, in accordance with Lilly's sampling standard operating procedure (SOP), sending them to the agency and submitting one other copy to his manager.

Lilly had, as part of this complaint, found out that the

signatures on the sample request forms at issue were not those of the doctors indicated on them. Lilly was satisfied that the signatures were made before the forms were collected by its representative. Neither Lilly nor the agency would therefore have had any reason to believe that the sample request forms were not appropriately requested and in compliance with Clause 17 of the Code. Lilly had subsequently made the doctors at the practice aware of this and requested that the matter be investigated by the practice. Lilly did not know who had made the signatures on the sample request forms but reiterated that Lilly's SOP and consequently the provisions of the Code had been complied with.

In light of the above, Lilly did not believe that Clauses 17.3 and/or 17.10 of the Code had been breached. The samples were provided in response to signed and dated sample request forms. Lilly did not know that the sample requests were not signed by doctors and that the signatures had been forged. The doctors in question had all attended group-sells on Cialis and it was therefore reasonable for Lilly (and its agency) to respond to the signed sample request forms forwarded by the representative. The representative collected the duly signed sample request forms from the practice and had the receptionist explain which request form was signed by which doctor. Lilly considered that it had complied with its SOP in respect of sampling and consequently the Code.

In respect of Clause 15.2 Lilly believed that the representative in question had at all times maintained a high ethical conduct and complied with the Code and Lilly's SOPs. He left sample request forms at the practice to be completed by doctors, if they wanted some samples; he had not insisted on seeing the doctors for this purpose as this might have amounted to undue pressure to gain an interview and knew that the doctors in question knew the product and its profile. The representative had not logged the attendance at the practice as calls on the doctors and had returned to the surgery to collect the signed sample request forms on the same day as leaving them and was informed that they were duly signed and moreover the receptionist identified to the representative which doctor signed which sample request.

In light of Lilly's position in respect of Clauses 17.3; 17.10 and 15.2 set out above, Lilly strongly believed that it had not breached the provisions of Clauses 9.1 and/or 2, ie that high standards had been maintained at all times and that its representative's/ agency's conduct did not bring the industry into disrepute. In light of what was set out above Lilly believed that there was no case for Lilly to answer in this regard and that the Director should therefore determine that there

was no *prima facie* case to answer.

The Authority subsequently asked Lilly whether the sample request forms had been dated by the representative, the receptionist or the doctor. In response, Lilly stated that the forms were dated by its representative on the day on which they were collected from the practice.

PANEL RULING

The Panel noted that the Lilly representative, when collecting signed sample request forms from a general practice, dated them, completed the address details and confirmed with the practice receptionist which sample request form related to which doctor. The complainant stated that the signatures on the sample request forms were not his or those of his GP colleagues. Lilly was satisfied that the signatures were made before the sample request forms were collected by the representative. Lilly had made the complainant and the relevant practice aware of this and had requested that the matter be investigated by the practice. The Panel noted that the completed sample request forms each bore a different signature.

The Panel noted that Clause 17.3 required sample request forms to be both signed and dated. The supplementary information to Clause 17.3 referred to preprinted sample request forms that had been signed and dated by the applicant. Contrary to the requirements of Clause 17.3 the forms had been undated when received by the representative who had dated them himself. A breach of Clause 17.3 was ruled. The Panel was concerned about the overall arrangements but considered in the circumstances that rulings of breaches of Clauses 9.1 and 15.2 were not warranted.

Clause 17.10 required that no unsolicited medicine should be sent through the post. The Panel noted that it was not possible to determine precisely who had signed the sample request forms but considered that as far as Lilly was concerned the samples had been requested. Lilly had responded to the requests in good faith. The Panel ruled no breach of Clause 17.10.

The Panel considered that overall the circumstances did not warrant a ruling of a breach of Clause 2 of the Code which was reserved to indicate particular censure.

Complaint received 6 December 2006

Case completed 14 February 2007