CHIEF PHARMACIST v LUNDBECK

Email promotion of Cipralex

A chief pharmacist complained about a Cipralex (escitalopram) email sent on behalf of Lundbeck.

The complainant stated that Cipralex was not on the trust formulary and Lundbeck knew that new medicines had to be introduced into the trust via the medicines committee. The complainant noted that a number of local prescribers had received the email and he/she did not find that kind of blatant advertising very helpful. The complainant had arranged for the emails to be sent to SPAM and had asked the database agency not to send any more.

The detailed response from Lundbeck is given below.

The Panel noted that the complainant appeared to be concerned that Lundbeck had used the emails to circumvent local policies which prevented representatives promoting medicines which were not on the formulary. The complainant had not alleged that the email was unsolicited.

The Panel noted that the Code did not necessarily prohibit the promotion of non-formulary medicines, but such promotion had to comply with the Code.

The Panel noted the trust's code of conduct for representatives. The policy stated that within the trust representatives might seek to inform or educate but must not promote and that they must not give educational sessions about a medicine that had not been approved by the medicines committee. The policy also set out requirements for representatives' visits, educational meetings, hospitality and meetings and samples but did not otherwise restrict or comment on any other contact a company might have with health professionals within the trust ie by direct mail or email.

With regard to the use of email, the Panel noted that the Code required a company to gain prior permission from recipients before sending them promotional emails. Where permission to use emails for promotional purposes has been given, each email should inform the recipient as to how to unsubscribe to them.

The Panel noted Lundbeck's submission that the email in question had been sent to UK health professionals registered on a database of, *inter alia*, NHS employees. When health professionals registered with the database, it was made clear that from time to time pharmaceutical promotional material might be sent. Recipients could 'opt out' of future communications which the complainant appeared to have done.

The Panel noted that the email was about the impending loss of patent on Cipralex and how that would affect future prescribing costs; it did not refer to the local formulary status of Cipralex.

The Panel noted its comments above on the relevant requirements of the Code and the local guidelines. The Panel did not consider that the company had failed to maintain high standards in this regard. No breach of the Code was ruled.

A chief pharmacist complained about the email promotion of Cipralex (escitalopram) by Lundbeck Ltd (ref UK/ESC/1305/0409a). The email had been sent on Lundbeck's behalf by a database agency.

COMPLAINT

The complainant noted that a number of prescribers in the trust had received the promotional email at issue; the complainant noted that Cipralex was not on the trust formulary.

The complainant stated that this was the first of its kind. The complainant had contacted the database agency and asked it not to send any more emails. Other chief pharmacists in the area had also received the same email. The complainant stated that the IT department had been instructed to send the emails to SPAM.

The complainant stated that Lundbeck knew that new medicines/licences had to be introduced into the trust via the medicines committee. That kind of blatant advertising was really not helpful. The complainant provided a copy of the trust's policy for pharmaceutical product representatives.

When writing to Lundbeck, the Authority asked it to respond in relation to Clause 9.1 of the Code.

RESPONSE

Lundbeck explained that it developed the email in conjunction with a digital agency. That agency worked directly with an electronic marketing agency which owned a database of health professionals employed within the NHS and private healthcare sectors in the UK.

Lundbeck noted that the Authority recently considered the database in another complaint about Lundbeck Ltd (Case AUTH/2594/4/13) where no breach was ruled. Lundbeck submitted that the Panel's comments in that case about having to 'opt out' of emails sent using the database 'company by company' had been addressed and database users were now 'opted out' of all emails by default not just by individual company.

The database agency sent the email only to health professionals that had registered to the database

and had agreed to receive promotional emails from pharmaceutical companies. The email was sent in mid September only to psychiatrists registered with the database.

Registered database users had free access to information on the site, including information about prescription only medicines and medical devices, which could only be accessed by health professionals who prescribed these products. When registering with the database, users were informed of, and agreed to, the following statement:

> '[The agency] will from time to time send information by e-mail about our associated/ affiliated companies and their clients' products and services, which may include updates on specialist services, conferences and seminars, diagnostic, medical and pharmaceutical promotional materials as well as official information.'

Registered database users were contacted annually to confirm that their contact details were up-to-date and that they wished to continue their membership, including the receipt of promotional material from pharmaceutical companies.

In response to the specific points raised by the complainant, Lundbeck noted that the email did not relate to a new medicine or licence extension but rather to important information regarding the remaining 9 months' patent for Cipralex. Such information was often not readily available to clinicians and might be relevant when prescribing decisions were made which related to potentially long-term conditions such as major depression.

Lundbeck noted that the policy document provided by the complainant related to the activities of representatives working on the trust territory. The email in question, however, was organised by Lundbeck head office and, as such, did not come within the scope of the policy document. Lundbeck submitted that its local personnel knew about the trust policy. Consequently, there had been no local activity in the area for around a year as none of Lundbeck's current products were listed on the formulary. Lundbeck last met with the trust chief pharmacist to discuss a new product which followed the above policy recommendations.

Lundbeck submitted that high standards had been maintained and consequently there had been no breach of Clause 9.1.

PANEL RULING

The Panel noted that the complainant appeared to be concerned that Lundbeck had emailed promotional material to local health professionals in a bid to circumvent local policies which prevented representatives promoting medicines which were not on the local formulary. The complainant had not alleged that the email was unsolicited. Lundbeck had been asked only to consider the requirements of Clause 9.1 of the Code. Lundbeck did not know the complainant's identity.

The Panel noted that the Code did not necessarily prohibit the promotion of non-formulary medicines, but such promotion had to comply with the Code. In this regard the Panel noted that, in relation to representatives, the Code stated, *inter alia*, that the arrangements in force at any particular establishment must be observed (Clause 15.4).

The Panel noted that the trust had a policy which provided a code of conduct for representatives within the trust. This stated that representatives might seek to inform or educate but must not promote. It also stated that representatives must not give educational sessions about a medicine that had not been approved by the medicines committee. The policy also set out requirements for representatives' visits, educational meetings, hospitality and meetings and samples. The policy did not otherwise restrict or comment on any other contact a company might have with health professionals within the trust ie by direct mail or email.

With regard to the use of email, the Panel noted that Clause 9.9 of the Code required a company to gain prior permission from recipients before sending them promotional material emails. Where permission to use emails for promotional purposes has been given, each email should inform the recipient as to how to unsubscribe to them.

The Panel noted Lundbeck's submission that the email in question had been sent to UK health professionals registered on a database of, *inter alia*, NHS employees. When health professionals registered with the database, they had to agree to a statement which made it clear that from time to time they might be sent pharmaceutical promotional material. If recipients no longer wished to receive emails they could 'opt out' of future communications which the complainant appeared to have done.

The Panel noted that the email was about the impending loss of patent on Cipralex and how that would affect future prescribing costs. The material did not refer to the formulary status of Cipralex within the local trust.

The Panel noted its comments above on the relevant requirements of the Code and the local guidelines. In the Panel's view the email at issue was not covered by Clause 15.4; it was sent by head office and not a representative. The Panel did not consider that the company had failed to maintain high standards in this regard. No breach of Clause 9.1 was ruled.

Complaint received **16 September 2013**

Case completed **28 October 2013**

CASE AUTH/2642/9/13

VOLUNTARY ADMISSION BY NOVARTIS

Three advertisements in one journal

Novartis voluntarily admitted that the September 2013 edition of Ophthalmology Times Europe bore advertising for Lucentis (ranibizumab) on three pages.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Novartis.

Novartis noted that its global team in Switzerland, placed two separate single page advertisements in the journal at issue, on page 11 and on the inside back cover. The publisher, however, did not inform the global team that it intended to attach a false cover onto the journal and reproduce the total content of the original back cover on the false cover. There were thus now three pages in the journal which bore advertising for Lucentis, in breach of the Code. Novartis noted that the publishers had accepted full responsibility for the error.

The Panel agreed with Novartis that promotional material in the journal at issue was within the scope of the Code and it noted the sequence of events which led to three Lucentis advertisements appearing in it. The Panel noted that the publisher had accepted responsibility for the error. A breach of the Code was ruled, as acknowledged by Novartis.

Novartis Pharmaceuticals UK Ltd voluntarily admitted that the September 2013 edition of Ophthalmology Times Europe bore advertising for Lucentis (ranibizumab) on three pages.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Novartis.

VOLUNTARY ADMISSION

Novartis noted that its global team, Novartis Pharma AG Switzerland, placed two separate single page advertisements in the journal at issue, on page 11 and on the inside back cover. Global had sought and received clear guidance from the UK about the requirements of Clause 6 of the Code. The journal at issue was produced in the UK and so Novartis considered that it came within the scope of the Code.

Novartis noted that the publisher did not inform its global team that it intended to attach a false cover onto the journal and reproduce the total content of the original back cover on the false cover. There were thus now three pages in the journal which bore advertising for Lucentis, in breach of Clause 6.3. Novartis submitted that as soon as it knew of the situation it contacted its global colleagues and a full investigation was initiated. Novartis noted that the publishers, had accepted full responsibility for the error which led to the breach of the Code. In light of this error, the global team had re-briefed teams on the UK requirements and sought reassurance from the publishers to ensure that the error could not happen again.

When writing to confirm that the matter would be taken up under the Code, the Authority asked Novartis to provide any further comments it might have in relation to Clause 6.3.

RESPONSE

Novartis had no further comments.

PANEL RULING

The Panel had first to consider whether promotional materials published in Ophthalmology Times Europe came within the scope of the Code. The publisher, editor and assistant editor were based in the UK and so in that regard the Panel agreed with Novartis' submission that the journal was within the scope of the Code.

The Panel noted that Novartis global had submitted two single page advertisements to the journal for publication in the September issue; one to appear on page 11 and the other to appear on the inside back cover. The publishers, however, printed another advertisement from another company as a false front cover which needed a corresponding extra back cover page. To create this, the publishers replicated the original back cover, effectively printing it twice. The two back covers thus contained two Lucentis advertisements. The third advertisement for the product was published as planned on page 11 of the journal. The Panel noted from an email provided by Novartis, that the publisher had accepted responsibility for the error and had acknowledged that the additional insertion of the advertisement was not paid for or requested by Novartis. Nonetheless, it was an accepted principle under the Code that pharmaceutical companies were responsible under the Code for the acts or omissions of those who worked with their authority. That three pages of the journal bore advertising for Lucentis was a clear breach of Clause 6.3 as acknowledged by Novartis; the Panel ruled accordingly. In that regard, Novartis had been let down by the publisher.

Complaint received	**20 September 2013**
Case completed	**11 October 2013**