CASE AUTH/2021/7/07 and AUTH/2024/7/07

HEALTH BOARDS v LUNDBECK

Letter about Cipralex

Two health boards alleged separately that a letter about Cipralex (escitalopram), which they submitted was sent to GPs by Lundbeck, misleadingly suggested that they had endorsed the use of the product for generalised anxiety disorder. Cipralex was not recommended in their local formularies for the treatment of depression and its use in generalised anxiety disorder had not yet been considered by their drug and therapeutics committees. The letter suggested that the health boards had already endorsed Cipralex, not that this was only a proposal. Sending such correspondence to GPs was alleged to be in breach of the Code and did not encourage partnership working with the pharmaceutical industry.

The Panel noted that that the local representative had amended a certified letter and sent it to a number of health professionals. This was outside Lundbeck's instructions. The Panel considered that the letters were misleading about the health boards' positions regarding the use of Cipralex and were not capable of substantiation in that regard. Breaches of the Code were ruled in each case. The Panel considered that high standards had not been maintained and thus ruled a breach of the Code. On balance the Panel did not consider that the circumstances warranted a breach of Clause 2 which was reserved as a sign of particular censure.

Two health boards complained separately about a Cipralex (escitalopram) letter (ref 0407/ESC/342/411) which they submitted was sent to local GPs by Lundbeck Ltd.

COMPLAINT

Each health board alleged that the letter misleadingly suggested that they had endorsed the use of Cipralex for generalised anxiety disorder. Neither had had any discussion with Lundbeck regarding this issue.

Cipralex was not recommended in their local joint formularies for the treatment of depression, and its use in generalised anxiety disorder had not yet been considered by either drug and therapeutics committee.

The letter suggested that the health boards had already endorsed Cipralex, not that it had only been proposed that they endorse it.

The health boards alleged that sending such correspondence to GPs was in breach of the Code and did not encourage them to work in partnership with the pharmaceutical industry.

When writing to Lundbeck, the Authority asked it to respond in relation to Clauses 2, 7.2, 7.4 and 9.1 of the Code.

RESPONSE

Lundbeck stated that the letter in question was modified from the original certified version by one of its key account executives such that the critical first paragraph was removed and therefore was sent out as unapproved copy. The letter was sent to the intended audience (thirteen budgetary decision makers in the two local health boards) and prescribing information was attached. This was not a blanket mailing to GPs as suggested by the complainants.

The original certified letter suggested a proposition that would be potentially beneficial to both parties, regarding the use of Cipralex in generalised anxiety disorder. In the certified template, there was clear guidance on the need to state the health board's current position on the prescribing of Cipralex, which should be substantiated by seen evidence. In the template, this should be followed by Lundbeck's proposition thus removing the possibility of misinterpretation. In the case of the letters at issue, the key account executive in question removed this critical first statement.

To ensure correct use of these materials, as per Lundbeck's usual procedures, a clear brief was given to the key account executive team and their managers in May 2007. The training covered the correct use of, and audience for, the letter in question and emphasised that it could not be modified beyond filling in the details to populate the template; it was further made clear that it could only be sent to key decision makers involved in guideline development and budgetary decisions. In accordance with the Code all representative briefing material was certified, including the supporting training brief.

It was significant that both complaints had originated from the same unapproved copy used by the key account executive. No complaints had been received from a customer who received the original certified copy.

Lundbeck had immediately withdrawn the template letters from use and, within a week of receipt of the complaint, had re-trained key account executives and their managers on the Code and correct use of materials. First stage disciplinary proceedings had been initiated with the key account executive in question.

Lundbeck in no way condoned or justified the use of its unapproved copy, but re-iterated that this was an incident which ran contrary to its usual high standards and processes. To this end Lundbeck had acted immediately and decisively as outlined above.

PANEL RULING

The Panel noted that that the local representative had amended a certified letter and had sent it to a number of health professionals. This was outside Lundbeck's instructions.

The Panel considered that the letters were misleading about the health boards' positions regarding the use of Cipralex and were not capable of substantiation in that regard. Breaches of Clauses 7.2 and 7.4 were ruled in each case.

The Panel considered that high standards had not been maintained and thus ruled a breach of Clause 9.1.

On balance the Panel did not consider that the circumstances warranted a breach of Clause 2 which was reserved as a sign of particular censure.

During its consideration of this case the Panel was concerned that representatives could add what might be quite detailed information about their understanding of the use of Cipralex within the local health board to a template promotional letter without the need to have the letter separately certified. This did not appear to meet the requirements of Clause 14.1 that promotional material be certified in its final form. The Panel requested that Lundbeck be advised of its concerns in this regard.

Case AUTH/2021/7/07

Complaint received	**10 July 2007**
Case completed	**28 August 2007**

Case AUTH/2024/7/07

Complaint received	**20 July 2007**
Case completed	**28 August 2007**