CASE AUTH/2245/6/09

PRIMARY CARE TRUST PRESCRIBING SUPPORT UNIT v LUNDBECK

Cipralex letter

A primary care trust (PCT) prescribing support unit alleged that a Cipralex (escitalopram) letter sent to a hospital physician by Lundbeck selectively quoted the advice issued in the PCT's prescribing and dispensing newsletter and presented a more positive view of escitalopram than the newsletter conveyed.

The PCT newsletter stated: 'Escitalopram has not been accepted as a formulary drug. However it is recognised that there may be infrequent occasions when it will be initiated by specialists for use in major depressive disorder (eg patients referred for specialist treatment and who have previously tried 3 other antidepressants) or in generalised anxiety disorder.'

The letter from Lundbeck stated: 'As you may be aware Cipralex (escitalopram) was recently reviewed for the [named] Formulary. It was recognised that there will be occasions when Cipralex will be initiated by specialists for use in the treatment of Major Depressive Disorder or Generalised Anxiety Disorder.'

The detailed response from Lundbeck is given below.

The Panel noted that although the letter in question stated that Cipralex had recently been reviewed for the local formulary it did not state that it had not been accepted as a formulary medicine. In the Panel's view, failure to state the formulary status might imply that the medicine had been approved for use. The letter further stated that it had been recognised that there would be occasions when Cipralex would be initiated by specialists for use in the treatment of major depressive disorder or generalised anxiety disorder. According to the PCT newsletter the local formulary committee, however, had considered that use of Cipralex would be infrequent ie when it was initiated by specialists for use in major depressive disorder (eg in patients referred for specialist treatment and who had previously tried three other antidepressants) or in generalised anxiety disorder.

The Panel considered that the brief statement in the letter omitted important details about the outcome of the local formulary review as reported in the PCT newsletter. In that regard the statement was not a complete or accurate reflection of the review and was thus misleading and could not be substantiated. High standards had not been maintained. Breaches were ruled.

A primary care trust (PCT) prescribing support unit complained about a Cipralex (escitalopram) letter (ref 0409/ESC/342/905) sent to a hospital physician by Lundbeck Ltd.

COMPLAINT

The complainant stated that the local PCT prescribing and dispensing newsletter, distributed in April 2009, published the advice given by the PCT's prescribing committee.

The wording for the use of escitalopram should be compared with the letter sent by Lundbeck in June. This had been distributed locally, though the complainant did not know to whom.

The complainant strongly argued that there had been selective quotation of the advice issued in the PCT's newsletter and that the Lundbeck wording presented a more positive view of escitalopram than the newsletter conveyed.

The PCT newsletter stated: 'Escitalopram has not been accepted as a formulary drug. However it is recognised that there may be infrequent occasions when it will be initiated by specialists for use in major depressive disorder (eg patients referred for specialist treatment and who have previously tried 3 other antidepressants) or in generalised anxiety disorder.'

The letter from Lundbeck stated: 'As you may be aware Cipralex (escitalopram) was recently reviewed for the [named] formulary. It was recognised that there will be occasions when Cipralex will be initiated by specialists for use in the treatment of Major Depressive Disorder or Generalised Anxiety Disorder.'

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 (sent by one of its representatives) was intended to make clinicians aware of the current licensed indications for Cipralex, according to its marketing authorization, and the existing national guidance relating to Cipralex.

The opening sentence referred to the current position of Cipralex in the PCT. Here the letter acknowledged that there would be occasions where Cipralex might be prescribed by clinicians.

Lundbeck did not specify that these occasions 'may be infrequent', since it believed that the term 'may be infrequent' was imprecise and vague and did not specify exact pre-conditions where Cipralex should and should not be prescribed, and was only accompanied by an example ie in major depressive disorder (eg patients referred for specialist treatment and who had previously tried three other antidepressants) or in generalised anxiety disorder. Lundbeck therefore did not agree that a more positive view of Cipralex was conveyed in its letter, as alleged, since the original wording was itself non-specific. Lundbeck considered that to quote this imprecise advice would be to risk inappropriate prescribing, and it was better only to mention the advice with the expectation that the clinician would have easy access to the PCT advice.

Before sending the letter to local clinicians, Lundbeck worked with a senior clinician in the PCT who agreed that the wording of the letter was appropriate. Based on that clinician's insight, Lundbeck's view was that all practising clinicians would know about the advice on the prescribing of Cipralex from their own prescribing committee, and that it was neither Lundbeck's responsibility nor the intention of the letter to reiterate, or to misrepresent that advice. The sole intention of the letter was to state clearly how Cipralex could be appropriately prescribed, according to its summary of product characteristics and marketing authorization.

The letter did not claim that Cipralex was on the local formulary.

In summary, although Lundbeck did not intend to mislead clinicians or misrepresent the PCT, it nevertheless regretted any confusion which might have been inadvertently caused by its letter. Lundbeck's genuine aim was to draw the attention of the local clinicians to the current range of licensed indications for Cipralex, and the current national guidance to add support to the advice of the local formulary committee.

PANEL RULING

The Panel noted that although the letter in question stated that Cipralex had recently been reviewed for the local formulary it did not state that Cipralex had not been accepted as a formulary medicine. In the Panel's view, failure to state the formulary status might be seen as implying that the medicine had been approved for use. The letter further stated that it had been recognised that there would be occasions when Cipralex would be initiated by specialists for use in the treatment of major depressive disorder or generalised anxiety disorder. According to the PCT newsletter the formulary committee, however, had considered that use of Cipralex would be infrequent ie when it was initiated by specialists for use in major depressive disorder (eg in patients referred for specialist treatment and who had previously tried three other antidepressants) or in generalised anxiety disorder.

The Panel noted that it was extremely important that if pharmaceutical companies reported the views of third parties such views were reported with complete accuracy, regardless of any opinions the company might have as to the wording used by the third party. The Panel further noted that a senior clinician in the PCT had agreed that the wording of the letter was appropriate. Pharmaceutical companies, however, were wholly responsible for ensuring that their materials complied with the Code. Responsibility in that regard could not be delegated to a third party.

The Panel considered that the brief statement in the letter omitted important details about the outcome of the local formulary review of Cipralex as reported in the PCT newsletter. In that regard the statement was not a complete or accurate reflection of the review and was thus misleading. A breach of Clause 7.2 was ruled. The statement regarding the outcome of the review could not be substantiated. A breach of Clause 7.4 was ruled. High standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted its rulings above but did not consider that the matter was such that it had brought discredit upon, or reduced confidence in, the industry. A ruling of a breach of Clause 2 was a sign of particular censure and reserved for such. No breach of that clause was ruled.

Complaint received **26 June 20009**

Case completed **3 August 2009**