CASE AUTH/2179/10/08

PHARMACIST HEAD OF PRESCRIBING TEAM v PFIZER

Lipitor mailing

A pharmacist head of prescribing team complained about a Lipitor (atorvastatin) mailing issued by Pfizer. The single A4 sheet was headed on both sides with 'Lipitor: an evidence-based choice for lowering cholesterol to improve cardiovascular outcomes'. The front page featured a bar chart showing the decrease in LDL-C from baseline with various doses of pravastatin, simvastatin, rosuvastatin and atorvastatin followed by 'Do you prescribe a treatment which has evidence of improved cardiovascular outcomes through cholesterol lowering?'. The results from various Lipitor trials in patients with moderate to high risk and high to higher risk were then stated. Overleaf it was stated that Lipitor had a wealth of published cardiovascular outcomes trials with 12 such trials for Lipitor, 2 for rosuvastatin, 1 for ezetimibe/simvastatin and none for ezetimibe.

The complainant's main concern was that the table of data stating the number of cardiovascular outcomes trials for Lipitor, rosuvastatin, ezetimibe/simvastatin and ezetimibe should also have listed simvastatin and pravastatin as there was a wealth of published data for these two medicines. The complainant alleged that the table gave a false impression of the current state of evidence relating to statins.

The detailed response from Pfizer is given below.

The Panel noted that the bar chart compared the efficacy of Lipitor with that of pravastatin, simvastatin and rosuvastatin. The Panel noted Pfizer's submission that generic statins, simvastatin, and some pravastatin, were used first line in over 90% of patients. The question below the bar chart 'Do you prescribe a treatment which has evidence of improved cardiovascular outcomes through cholesterol lowering?' implied that some treatments might not have evidence of improved cardiovascular outcomes. On turning the page readers were presented with a table which appeared to show that only Lipitor, rosuvastatin and ezetimibe/simvastatin had published cardiovascular outcomes data which was not so. The Panel noted Pfizer's submission that the purpose of the table was to demonstrate the number of published cardiovascular outcomes trials for therapies most likely to be considered alongside Lipitor as second line. This was not clear, particularly given that the bar chart on the front page compared Lipitor with, *inter alia*, the two first line statins. The Panel considered that the mailing was misleading as alleged. A breach of the Code was ruled.

A pharmacist head of prescribing team complained about a Lipitor (atorvastatin) mailing (ref LIP3086) issued by Pfizer Limited. The single A4 sheet was headed on both sides with 'Lipitor: an evidence-based choice for lowering cholesterol to improve cardiovascular outcomes'. The front page featured a bar chart showing the decrease in LDL-C from baseline with various doses of pravastatin, simvastatin, rosuvastatin and atorvastatin. Below the chart readers were asked the question 'Do you prescribe a treatment which has evidence of improved cardiovascular outcomes through cholesterol lowering?'. The results from various Lipitor trials in patients with moderate to high risk and high to higher risk were then stated. Overleaf it was stated that Lipitor had a wealth of published cardiovascular outcomes trials. It was stated that there were 12 such trials for Lipitor, 2 for rosuvastatin, 1 for ezetimibe/simvastatin and none for ezetimibe.

COMPLAINT

The complainant's main concern was that the table of data stating the number of cardiovascular outcomes trials for Lipitor, rosuvastatin, ezetimibe/simvastatin and ezetimibe should also have listed simvastatin and pravastatin as there was a wealth of published data for these two medicines. The complainant alleged that the table gave a false impression of the current state of evidence relating to statins.

When writing to Pfizer, the Authority asked it to respond in relation to Clause 7.2 which was the same in the 2006 and 2008 Codes.

RESPONSE

Pfizer stated that the objective of the mailer was to promote the wealth of published cardiovascular outcomes evidence supporting Lipitor through effective cholesterol lowering.

In the UK generic statins (mainly simvastatin, occasionally pravastatin) were generally used first line over 90% of the time, in patients who required lipid lowering therapy. Pfizer agreed that generic statins had a large body of cardiovascular outcomes data. Branded statins such as Lipitor or Crestor (rosuvastatin), the addition of Ezetrol (ezetimibe) to a statin, or the simvastatin/ezetimibe combination therapy (Inegy) were generally used second line when greater lipid lowering efficacy was required than achieved with generic statins or when generic statins were poorly tolerated. The purpose of the table was to demonstrate the number of cardiovascular outcomes trials currently published

for these alternative lipid lowering strategies.

The table was not an exhaustive list of all lipid lowering therapies available, as it did not include generic statins, fibrates, nicotinic acid or bile acid sequestrants. It was intended to provide details of the current cardiovascular trial evidence for the therapies which were most likely to be considered alongside Lipitor.

For these reasons Pfizer did not believe it was in breach of Clause 7.2.

In response to a request for further information, Pfizer submitted that the mailing had been widely distributed in primary and secondary care including pharmacists, nurses, and doctors.

PANEL RULING

The Panel noted that on the front page of the mailing a bar chart compared the efficacy of Lipitor with that of pravastatin, simvastatin and rosuvastatin. The Panel noted Pfizer's submission that generic statins, simvastatin, with some pravastatin, were used first line in over 90% of patients. The question below the bar chart 'Do you prescribe a treatment which has evidence of improved cardiovascular outcomes through cholesterol lowering?' implied that some treatments might not have evidence of improved cardiovascular outcomes. On turning the page readers were presented with a table which appeared to show that only Lipitor, rosuvastatin and ezetimibe/simvastatin had published cardiovascular outcomes data which was not so. The Panel noted Pfizer's submission that the purpose of the table was to demonstrate the number of published cardiovascular outcomes trials for therapies most likely to be considered alongside Lipitor as second line. This was not clear, particularly given that the bar chart on the front page compared Lipitor with, *inter alia*, the two first line statins. The Panel considered that the mailing was misleading as alleged. A breach of Clause 7.2 was ruled.

Complaint received **23 October 2008**

Case completed **10 December 2008**