CASE AUTH/1858/6/06 *NO BREACH OF THE CODE*

PHARMACIST v PFIZER

Newspaper article about the use of statins

A pharmacist complained about an article in The Times entitled 'Savings on heart drugs attacked as 'bad medicine''. The complainant noted that the article was about the increasing use of generic, cheaper statins which would mean less effective care for some patients. Clearly the journalist was unaware of the Heart Protection Study 2002, a double-blind, randomized, controlled trial involving over 20,000 patients in the UK. This trial used simvastatin 40mg and showed significant reductions in primary end points with numbers needed to treat of 19. The complainant thus questioned whether a doctor who prescribed simvastatin 40mg could be described as practising 'bad medicine'?

The complainant noted Pfizer's statement 'Not only does this represent bad medicine and a further assault on clinicians' freedom to prescribe the most appropriate medicine for their patients…'. The complainant asked where atorvastatin had an evidence base of a similar quality to that of simvastatin? The pharmaceutical industry would do well to promote evidence based clinical practice rather than the chasing of surrogate markers.

With regard to surrogate markers, Pfizer also stated 'On 40mg of simvastatin, a normal dose, only 33 per cent of people would reach this target (4mmol/litre). Lipitor (atorvastatin) is more potent'. The complainant agreed that thanks to the practice of evidence based medicine simvastatin 40mg was a 'normal dose'. The tone of the article was that tougher cholesterol lowering targets should be aimed at. The complainant noted the CURVES study compared the cholesterol lowering benefits of various statins. The percentage LDL-C reduction for atorvastatin 10mg 'normal dose' was 38% but those physicians who used simvastatin 40mg would only see a reduction of 41% in LDL-C!

The complainant submitted that if he wished to achieve these new tougher targets then he should prescribe simvastatin 40mg rather than atorvastatin 10mg. This contradicted Pfizer's comments. Yes, atorvastatin was more potent per milligram but not when comparing simvastatin (normal dose) with atorvastatin (normal dose).

The Panel noted that complaints about articles in the press were considered with regard to the information supplied by the pharmaceutical company to the journalist etc and not on the content of the article itself.

The Panel noted that the article in The Times reported on new guidelines which urged prescribers to write at least 60% of their statin prescriptions for simvastatin or pravastatin (excluding combination products). The article stated that Pfizer had referred to this change as 'bad medicine'; immediately before this quotation The Times article stated 'Pfizer, the drug company that makes Lipitor, the statin likely to lose market share as a result of any enforced change says that the policy risks reversing recent advances in the management of heart disease'.

Material supplied by Pfizer to the journalist stated 'The new targets will rank [PCTs] compliance on a league table based on a target of 60% use of older less effective generic statins. To reach this [60%] target clinicians may be forced to switch patients currently well controlled on newer, more effective stains to less effective generics, purely on the grounds of cost. In fact they may even be forced to attain levels of generic usage above 60% in order to avoid their PCT appearing 'bottom of the table'. Not only does this represent bad medicine and a further assault on clinicians' freedom to prescribe the most appropriate medicine for their patients, but it could also slow progress towards the government's own goal of significantly reducing deaths caused by coronary heart disease by 2010'. The Panel considered that in the briefing material it was clear that Pfizer considered that prescribing a medicine including switching well controlled patients in order to reach or exceed prescription cost targets rather than meeting the clinical needs of a patient, was 'bad medicine'; not that prescribing simvastatin or pravastatin *per se* was bad medicine compared with atorvastatin. The Panel did not consider that Pfizer's statement was misleading. No breach of the Code was ruled.

The Panel noted the complainant's submission that the normal doses of simvastatin and atorvastatin were 40mg and 10mg respectively. The summary of product characteristics (SPC) for Zocor (simvastatin) stated that in cardiovascular prevention the usual dose of Zocor was 20-40mg/day; for treatment of hypercholesterolaemia the usual starting dose was

10-20mg/day. The Lipitor (atorvastatin) SPC stated a dose of 10mg/day for prevention of cardiovascular disease; this was also the dose which controlled the majority of patients with hypercholesterolaemia.

The Panel noted the complainant's comments about the CURVES study in that the percentage LDL-C reduction for atorvastatin 10mg was 38% compared with 41% with simvastatin 40mg. Pfizer, however, had referred to the percentage of patients likely to reach the new target of total cholesterol of 4mmol/litre when it had referred to only 33% of patients hitting target with 40mg simvastatin. (Although not discussed, the comparative data for atorvastatin showed that with milligram equivalent doses more patients would be likely to achieve a target total cholesterol of <4mmol/litre with atorvastatin thus justifying the use of 'only' when referring to simvastatin). The Panel considered that the complainant had compared the doses of atorvastatin and simvastatin used to prevent cardiovascular disease (10mg and 40mg respectively) whereas Pfizer had referred to the lipid lowering ability of the two medicines whereby, milligram for milligram, more patients were likely to achieve the target of <4mmol/litre with atorvastatin than simvastatin. In that regard the information given to The Times by Pfizer was not misleading. No breaches of the Code were ruled.

A pharmacist complained about an article entitled 'Savings on heart drugs attacked as 'bad medicine'', The Times, 22 June. The article contained quotations from, *inter alia*, Pfizer.

COMPLAINT

The complainant noted that the article was about the increasing use of generic, cheaper statins which would mean less effective care for some patients. Clearly the journalist was unaware of the Heart Protection Study 2002 which was described as one of the most significant studies in recent years. This was a double-blind, randomized, controlled trial involving over 20,000 patients in the UK. This trial used simvastatin 40mg and showed significant reductions in primary end points with numbers needed to treat of 19. So was a doctor who prescribed simvastatin 40mg practising 'bad medicine'? No, just gold standard evidence based medicine.

The complainant noted that Pfizer had stated 'Not only does this represent bad medicine and a further assault on clinicians' freedom to prescribe the most appropriate medicine for their patients…'. Could Pfizer show the complainant where atorvastatin had an evidence base of a similar quality to that of simvastatin? The pharmaceutical industry would do well to promote evidence based clinical practice rather than the chasing of surrogate markers.

With regard to surrogate markers, Pfizer had also stated 'On 40mg of simvastatin, a normal dose, only 33 per cent of people would reach this target (4mmol/litre). Lipitor (atorvastatin) is more potent'.

The complainant agreed with Pfizer that thanks to the practice of evidence based medicine simvastatin 40mg was a 'normal dose'. The tone of the article was that tougher cholesterol lowering targets should be aimed at. The complainant noted the CURVES study compared the cholesterol lowering benefits of various statins. The percentage LDL-C reduction for atorvastatin 10mg 'normal dose' was 38% but those physicians who used simvastatin 40mg would only see a reduction of 41% in LDL-C!

The complainant alleged that if he wished to achieve these new tougher targets from the Joint British Societies then he should prescribe simvastatin 40mg rather than atorvastatin 10mg. This contradicted Pfizer comments. Yes, atorvastatin was more potent per milligram but not when comparing simvastatin (normal dose) with atorvastatin (normal dose).

The complainant noted that many primary care trusts had encouraged the use of simvastatin while it was on patent and more expensive than Lipitor.

The complainant found the use of articles like the one at issue annoying, and he noted that only that morning a fellow health professional had had to deal with a patient clutching the article believing they were receiving 'bad medicine'. The complainant considered that bad journalism was more appropriate.

When writing to Pfizer the Authority asked it to respond in relation to the requirements of Clauses 7.2 and 7.3.

RESPONSE

Pfizer submitted that the article related to the announcement by the Department of Health of new productivity measures with specific reference to the prescribing metric. The complainant interpreted the quote attributed to Pfizer as referring to simvastatin within the article. Pfizer submitted that the position remained that the target itself was at fault and this statement was not a reference to simvastatin.

Pfizer submitted that the quotation attributed to it paraphrased what was discussed during an interview. The point made was that simvastatin 40mg and atorvastatin 10mg per day achieved similar reductions in LDL cholesterol. With the greater dose range for atorvastatin, it was possible to treat more patients to the new lower target for cholesterol than with simvastatin. The word 'potency' was used by the journalist as synonymous with efficacy which was not how it was briefed by Pfizer.

Pfizer did not believe there were breaches of Clauses 7.2 or 7.3 of the Code as the information it provided both orally and in writing was accurate, balanced and not misleading.

Pfizer submitted that during its review it had, however, identified that material sent to the journalist was not appropriately reviewed and certified in breach of Clause 14.3 of the Code. Pfizer submitted that it had reemphasised and clarified its approval process for its employees involved with the media and undertook that this would not happen again.

In response to a request for further information, Pfizer supplied copies of the references given to The Times.

In an interview with the journalist Pfizer highlighted that not all patients would achieve the current Joint

British Society's guidelines on cholesterol reduction, to target total cholesterol of 4mmol/litre with simvastatin 40mg. This was based on two pieces of information: the average total cholesterol of UK patients, naïve to treatment, was 6.4mmol/litre and information presented in the CURVES study. The average reduction in total cholesterol seen with simvastatin 40mg would achieve target in 33% of patients. Discussion also covered that across the dose range atorvastatin could lower total cholesterol to a greater extent than simvastatin.

Modelling using the data from the CURVES study (mean percentage total cholesterol reductions at each dose with standard deviations) in a statin naïve population gave the following figures for treating to total cholesterol < 4mmol/litre atorvastatin: 10mg, 27%; 20mg, 45%; 40mg, 63% and 80mg, 70%. The figures for simvastatin were: 10mg, 13%; 20mg, 21%; 40mg, 33% and 80mg, 52%. The percentage of patients achieving target with simvastatin 40mg was discussed but no direct data regarding atorvastatin were given.

PANEL RULING

The Panel noted that complaints about articles in the press were considered with regard to the information supplied by the pharmaceutical company to the journalist etc and not on the content of the article itself.

The Panel noted that the article in The Times reported on new guidelines which urged prescribers to write at least 60% of their statin prescriptions for simvastatin or pravastatin (excluding combination products) The guidelines calculated the savings from all PCTs moving to a minimum value of 60% and the rationale in the prescribing metric was given as 'selection of drugs with low acquisition cost in line with NICE guidance'. The article in The Times stated that Pfizer referred to this change as 'bad medicine'. Immediately before the quotation from Pfizer, the article stated 'Pfizer, the drug company that makes Lipitor, the statin likely to lose market share as a result of any enforced change says that the policy risks reversing recent advances in the management of heart disease'.

Pfizer's briefing material supplied to the journalist showed that, in full, Pfizer had stated 'The new targets will rank [PCTs] compliance on a league table based on a target of 60% use of older less effective generic statins. To reach this [60%] target clinicians may be forced to switch patients currently well controlled on newer, more effective stains to less effective generics, purely on the grounds of cost. In fact they may even be forced to attain levels of generic usage above 60% in order to avoid their PCT appearing 'bottom of the table'. Not only does this represent bad medicine and a further assault on clinicians' freedom to prescribe the most appropriate medicine for their patients, but it could also slow progress towards the government's own goal of significantly reducing deaths caused by coronary heart disease by 2010'. The Panel considered that in the briefing material it was clear that Pfizer considered that prescribing a medicine including switching well controlled patients in order to reach or exceed prescription cost targets rather than meeting the clinical needs of a patient, was 'bad medicine'; not that prescribing simvastatin or pravastatin *per se* was bad medicine compared with atorvastatin. The Panel did not consider that Pfizer's statement was misleading. No breach of Clause 7.2 was ruled.

The Panel noted the complainant's submission that the normal doses of simvastatin and atorvastatin were 40mg and 10mg respectively. The summary of product characteristics (SPC) for Zocor (simvastatin) stated that in cardiovascular prevention the usual dose of Zocor was 20-40mg/day; for treatment of hypercholesterolaemia the usual starting dose was 10-20mg/day. The Lipitor (atorvastatin) SPC stated a dose of 10mg/day for prevention of cardiovascular disease; this was also the dose which controlled the majority of patients with hypercholesterolaemia.

The Panel noted the complainant's comments about the CURVES study in that the percentage LDL-C reduction for atorvastatin 10mg was 38% compared with 41% with simvastatin 40mg. Pfizer, however, had referred to the percentage of patients likely to reach the new target of total cholesterol of 4mmol/litre when it had referred to only 33% of patients hitting target with 40mg simvastatin. (Although not discussed, the comparative data for atorvastatin showed that with milligram equivalent doses more patients would be likely to achieve a target total cholesterol of <4mmol/litre with atorvastatin thus justifying the use of 'only' when referring to simvastatin). The Panel considered that the complainant had compared the doses of atorvastatin and simvastatin used to prevent cardiovascular disease (10mg and 40mg respectively) whereas Pfizer had referred to the lipid lowering ability of the two medicines whereby, milligram for milligram, more patients were likely to achieve the target of <4mmol/litre with atorvastatin than simvastatin. In that regard the information given to The Times by Pfizer was not misleading. No breach of Clauses 7.2 and 7.3 was ruled.

Complaint received **26 June 2006**

Case completed **14 September 2006**