PRESCRIBING ADVISOR v ASTRAZENECA

Crestor journal advertisement

A prescribing advisor alleged that an advertisement for Crestor (rosuvastatin), issued by AstraZeneca, was misleading. The advertisement featured the claim 'Bill's cholesterol only dropped so far with simvastatin, but Crestor was all he needed to achieve his treatment goals…'. The phrase 'First choice second line' appeared beneath the product logo in the bottom right hand corner.

The complainant believed that the advertisement was misleading because it implied that Crestor had been directly compared with simvastatin, which was not so. The complainant noted that a meta-analysis demonstrated that when adequate doses of simvastatin were prescribed the cholesterol lowering was identical. The complainant further considered that the advertisement implied that simvastatin was an inferior medicine and that such criticism of other products was not permitted under the Code.

The Panel did not consider that the advertisement implied that Crestor had been directly compared with simvastatin. The Panel noted AstraZeneca's submission that the meta analysis to which the complainant referred did not assess the efficacy of specific statins. The Panel considered that the claim 'Bill's cholesterol only dropped so far with simvastatin, but Crestor was all he needed to achieve his treatment goals' in conjunction with the strapline 'First choice second line' referred to the second line, use of Crestor after a patient had not achieved treatment goals on simvastatin. The Panel noted data provided by AstraZeneca in this regard. The Panel ruled no breach of the Code.

Further the Panel did not consider that the advertisement inferred that simvastatin was an inferior medicine as alleged. A reference to first and second line treatment did not in itself imply inferiority of the medicine used first line. No breach of the Code was ruled.

During its consideration of this case the Panel was concerned that the phrase 'First choice second line' implied that Crestor was the first choice for second line use. Such an implication was unacceptable in relation to the requirements of the Code. The Panel requested that the company be advised of its views in this regard.

A prescribing advisor complained about a journal advertisement (ref CRES11768) for Crestor (rosuvastatin), issued by AstraZeneca UK Limited, which had appeared in the March/April edition of Pharmacy in Practice.

The advertisement featured a man reading a newspaper in front of the Sydney Opera House and was headed 'No Worries Mate'. Beneath the heading the advertisement continued: 'Bill's cholesterol only dropped so far with simvastatin, but Crestor was all he needed to achieve his treatment goals. Now he can enjoy his trip down under'. The strapline 'First choice second line' appeared beneath the product logo in the bottom right hand corner of the advertisement.

COMPLAINT

The complainant believed that this advertisement was misleading, in breach of the Code, because:

- It implied that Crestor had been directly compared with simvastatin, when this was not the case. Indeed in a large meta-analysis of trials including over 90,000 patients it was demonstrated that when adequate doses of simvastatin were prescribed the cholesterol lowering was identical.
- It implied that simvastatin was an inferior medicine. The complainant understood that such criticism of other products was not permitted under the Code.

When writing to AstraZeneca, the Authority asked it to respond in relation to Clauses 7.2, 7.3 and 7.4 of the Code.

RESPONSE

AstraZeneca stated that the claim 'Bill's cholesterol only dropped so far with simvastatin, but Crestor was all he needed to achieve his treatment goals' described the typical experience of a dyslipidaemic patient failing to reach target on a first-line statin such as simvastatin, transferring to a more efficacious, second-line statin and then reaching target. This was supported by the strapline 'First choice second line'.

UK data showed that approximately 40% of patients given simvastatin might not reach the current UK total cholesterol target of ⩽5mmol/L. The scenario described in the advertisement would be faced by many prescribers on a regular basis, therefore the message could not be considered misleading.

The complainant referred to a Lancet report of a meta-analysis that was described as providing evidence 'that when adequate doses of simvastatin are prescribed the cholesterol lowering is identical' (Cholesterol Treatment Trialists (CTT) Collaborators Study 2005).

It was difficult to comment on this statement as, not only was the comparator unspecified when the complainant stated that 'cholesterol lowering is identical', but there was no efficacy data for simvastatin reported in the Lancet meta-analysis. Two of the 14 trials (originally reported between 1994 and 2004)

included in the study featured simvastatin as a treatment option. However no assessment of the efficacy of specific statins was provided.

Furthermore, a study designed to investigate the comparative cholesterol-lowering effects of statins across the dose ranges demonstrated that it was not possible for simvastatin, at licensed doses, to lower cholesterol to the same extent as Crestor.

The complainant alleged that the advertisement 'implied that simvastatin was an inferior medicine'.

AstraZeneca did not believe that its reference to simvastatin was anything other than accurate and objective. Health professionals were familiar with the current situation in the management of dyslipidaemia where a moderately potent generic statin was recommended first line with a more potent second line alternative available when patients failed to meet target. This pathway was recommended by many local and regional formularies. An example of this clinical scenario in action was provided by a recent report that demonstrated that 68% of dyslipidaemic patients failing to reach General Medical Services (GMS) and Quality Outcome Framework (QOF) target on simvastatin 40mg achieved it on Crestor 10mg (Kassianos et al 2006).

Similar situations existed in other therapeutic areas. AstraZeneca disagreed that reference to situations where a first line generic option had failed, could be interpreted as a 'criticism' of that treatment option, but was a valid representation of how treatment protocols should work to ensure patients achieved appropriate results.

AstraZeneca did not therefore accept that there had been breaches of Clauses 7.2, 7.3 and 7.4.

PANEL RULING

The Panel did not consider that the advertisement implied that Crestor had been directly compared with simvastatin as alleged. Indeed the Panel noted AstraZeneca's submission that the meta analysis to which the complainant referred did not assess the efficacy of specific statins. The Panel considered that the claim, 'Bill's cholesterol only dropped so far with simvastatin, but Crestor was all he needed to achieve his treatment goals …' in conjunction with the strapline beneath the product logo 'First choice second line' referred to the second line use of Crestor after a patient had not achieved treatment goals on simvastatin. The Panel noted data provided by AstraZeneca in this regard. The Panel ruled no breach of Clauses 7.2, 7.3 and 7.4 on this point.

Further the Panel did not consider that the advertisement inferred that simvastatin was an inferior medicine as alleged. A reference to first and second line treatment of a dyslipidaemic patient did not in itself imply inferiority of the medicine used first line. No breach of Clauses 7.2, 7.3 and 7.4 was ruled.

During its consideration of this case the Panel was concerned that the phrase 'First choice second line' implied that Crestor was the first choice for second line use. Such an implication was unacceptable in relation to the requirements of Clause 7.10 of the Code. The Panel requested that the company be advised of its views in this regard.

Complaint received 5 April 2007

Case completed 26 June 2007