PHARMACIST PRACTITIONER v ASTRAZENECA

Crestor journal advertisement

A pharmacist practitioner complained about an advertisement for Crestor (rosuvastatin) issued by AstraZeneca in GP, 7 November. The advertisement had a picture of a smaller than normal dartboard with the caption, 'Finding cholesterol targets harder to hit?'.

The complainant stated that the National Institute for Health and Clinical Excellence (NICE) guidance relating to lipid modification (Clinical Guidance (CG) 67) was published in May. The guidance recommended no target for patients being treated for primary prevention. Those being treated for secondary prevention were recommended for treatment with simvastatin 40mg. The audit level targets remained at 5mmol/L for total cholesterol and 3mmol/L for LDL cholesterol. These targets had not changed although the guidance recommended aspirational levels of 4mmol/L and 2mmol/L respectively after consideration of risks and benefits. Additionally, the guidance recommended using simvastatin 80mg or a statin of 'similar efficacy and cost'.

The complainant alleged that the advertisement was misleading in that it implied that targets had recently been reduced when in fact they had not. The advertisement also failed to mention the first line recommendations made by NICE.

The detailed response from AstraZeneca is given below.

The Panel noted that the advertisement featured a picture of a very small dartboard in the middle of an outline of a normal sized scoreboard. The dartboard had been shown in a much smaller scale than everything else around it. The only text in the advertisement, apart from the prescribing information and other required information was the product logo in the bottom right-hand corner together with the strap-line 'Finding cholesterol targets harder to hit?'.

The Panel noted that Crestor was indicated for the management of primary hypercholesterolaemia (type IIa including heterozygous familial hypercholesterolaemia) or mixed dyslipidaemia (type IIb) as an adjunct to diet when response to diet and other non-pharmacological treatments (eg exercise, weight reduction) was inadequate. Crestor could also be used for homozygous familial hypercholesterolaemia as an adjunct to diet and other lipid-lowering treatments (eg LDL apheresis) of if such treatments were not appropriate.

The Panel noted AstraZeneca's submission about the various guidance documents issued by NICE since May 2008; *inter alia,* new cholesterol goals had been set for patients with diabetes and a new target had been set for patients with familial hypercholesterolaemia. NICE recommended high intensity statins in some patients. In the Panel's view there was a difference between overall targets which might be applicable to a patient population compared with a cholesterol target for a specific patient in a high risk group. The complainant's concerns appeared to be based only on the NICE clinical guideline 67 – Lipid Modification.

On balance, the Panel considered that the strapline 'Finding cholesterol targets harder to hit?' with the small dartboard might imply that targets had recently been reduced. However the advertisement might also be read as implying that it was more difficult to hit cholesterol targets generally. Lipid targets had now been set for a broad range of patients by a range of organisations. The strapline asked a question, it did not make a statement. If the reader's answer to the question was 'yes' then perhaps Crestor might be appropriate for some patients The Panel did not consider that the strapline was misleading as alleged. No breach of the Code was ruled.

The Panel noted that the advertisement did not mention NICE at all. Thus it did not consider that the failure to mention the first line recommendations made by NICE was misleading. No breach was ruled.

A pharmacist practitioner complained about an advertisement for Crestor (rosuvastatin) placed by AstraZeneca UK Limited in GP, 7 November.

COMPLAINT

The complainant stated that the advertisement had a picture of a smaller than normal dartboard with the caption, 'Finding cholesterol targets harder to hit?'.

The National Institute for Health and Clinical Excellence (NICE) guidance relating to lipid modification (Clinical Guidance (CG) 67) was published in May and this document must be recognised as defining the national targets for cholesterol levels in England and Wales.

The guidance recommended no target for patients being treated for primary prevention. Those being treated for secondary prevention were recommended for treatment with simvastatin 40mg. The audit level targets remained at 5mmol/L for total cholesterol and 3mmol/L for LDL cholesterol.

These targets had not changed although the guidance recommended aspirational levels of 4mmol/L and 2mmol/L respectively after consideration of risks and benefits. Additionally, the guidance recommended using simvastatin 80mg or a statin of 'similar efficacy and cost'.

The complainant considered that the advertisement was misleading in that it implied that targets had recently been reduced when in fact they had not. The advertisement also failed to mention the first line recommendations made by NICE.

When writing to AstraZeneca, the Authority asked it to respond in relation to Clause 7.2 of the Code.

RESPONSE

AstraZeneca stated that cholesterol management applied to a broad spectrum of patients; this included patients with dyslipidaemia, familial hypercholesterolaemia, diabetes and secondary prevention after a cardiovascular event. Since May 2008 there had been numerous guidelines advocating lower total cholesterol and LDL cholesterol targets in order to treat these high-risk groups (ie NICE guidance for secondary prevention (CG67), diabetes (CG66) and familial hypercholesterolaemia patients (CG71)). The recommendations in these NICE guidelines had changed from previous iterations; therefore the advertisement was simply asking whether prescribers were achieving the required cholesterol levels for their patients.

The complainant recognised the NICE lipid modification guidance (CG67, May 2008), but failed to recognise the recent NICE guidance for diabetes and familial hypercholesterolaemia and other local initiatives throughout the UK.

As stated in the NICE diabetes guidance (CG66, May 2008):

> 'Consider intensifying cholesterol-lowering therapy (with a more effective statin or ezetimibe in line with NICE guidance) if there is existing or newly diagnosed cardiovascular disease, or if there is an increased albumin excretion rate, to achieve a total cholesterol level below 4.0mmol/litre (and HDL cholesterol not exceeding 1.4mmol/litre) or an LDL cholesterol level below 2.0mmol/litre.'

Thus new cholesterol goals had been set by NICE for patients with diabetes.

In August 2008 NICE issued its first guideline for patients with familial hypercholesterolaemia (CG71) where it stated for adult patients:

> 'Healthcare professionals should consider prescribing a high-intensity statin to achieve a recommended reduction in LDL-C concentration of greater than 50% from baseline.'

Thus a new target for the management of familial hypercholesterolaemia had been advocated by NICE.

The lipid modification guidance (CG67) referred to by the complainant, stated that in secondary prevention patients:

> 'People with acute coronary syndrome should be treated with a higher intensity statin. Any decision to offer a higher intensity statin should take into account the patient's informed preference, comorbidities, multiple drug therapy, and the benefits and risks of treatment.'

The NICE lipid modification guidance, familial hypercholesterolaemia guidance and the diabetes guidance all defined a 'high intensity statin' as any statin that had higher LDL cholesterol lowering efficacy than simvastatin 40mg, eg the familial hypercholesteraemia guidance stated:

> 'High intensity statin: statins are classified as high intensity if they produce greater LDL-cholesterol reductions than simvastatin 40mg (e.g. simvastatin 80mg and appropriate doses of atorvastatin and rosuvastatin).'

The NICE lipid modification guidance also stated:

> 'In people taking statins for secondary prevention, consider increasing to simvastatin 80mg or a drug of similar efficacy and acquisition cost if a total cholesterol of less than 4mmol/litre or an LDL cholesterol of less than 2mmol/litre is not attained. Any decision to offer a higher intensity statin should take into account informed preference, comorbidities, multiple drug therapy, and the benefit and risks of treatment.'

The cholesterol lowering effect of various statins at different doses were listed in the lipid modification guidance, which showed that all doses of rosuvastatin provided greater total and LDL cholesterol lowering than simvastatin 40mg.

However, AstraZeneca recognised that the lipid guidance also stated:

'An "audit" level of total cholesterol of 5mmol/litre should be used to assess progress in populations or groups of people with CVD, in recognition that more than a half of patients will not achieve a total cholesterol of less than 4mmol/litre or an LDL cholesterol of less than 2mmol/litre.'

> This was just an audit standard and not a treatment goal for an individual patient. NICE clearly recognised that not all patients would be able to achieve a target for total cholesterol <4mmol/L and LDL cholesterol <2mmol/L and therefore a minimum audit level of total cholesterol <5mmol/L and LDL cholesterol <3mmol/L could be used when assessing cholesterol treatment at a population level.

Apart from recent NICE guidance for England and Wales there was also additional evidence of cholesterol targets changing at a national and local level. For example in Northern Ireland (from the Department of Health, Social Services and Public Safety) the national guidance was to 'aim for a total cholesterol of <4mmol/L, LDL cholesterol of <2mmol/L and an HDL cholesterol >1mmol/L'.

On a local level the Essex Cardiac Network which covered five PCTs had issued guidance since the NICE guidance was issued (September 2008) to treat to a total cholesterol of <4mmol/L, LDL cholesterol <2mmol/L, triglycerides <1.7mmol/L and HDL cholesterol > 1mmol/L for men and >1.3mmol/L for women.

The above examples demonstrated that cholesterol management in a broad range of patients was becoming more challenging due to changes in local and national targets and therefore AstraZeneca did not consider that the advertisement at issue was misleading and in breach of Clause 7.2.

AstraZeneca considered that the wording 'Finding cholesterol targets harder to hit?' gave the reader the option to decide for themselves whether this question was important to them in the management of their patients. If indeed the reader/prescriber had not found their patients' cholesterol targets harder to hit then this advertisement might not apply to them.

AstraZeneca did not therefore accept that there had been a breach of Clause 7.2.

PANEL RULING

The Panel noted that the advertisement featured a picture of a very small dartboard in the middle of an outline of a normal sized scoreboard. The diameter of the dartboard appeared to be less than the length of some darts which lay below it. The dartboard had thus been shown in a much smaller scale than everything else around it. The only text in the advertisement, apart from the prescribing information and other required information was the product logo in the bottom right-hand corner together with the strap-line 'Finding cholesterol targets harder to hit?'.

The Panel noted that Crestor was indicated for the management of primary hypercholesterolaemia (type IIa including heterozygous familial hypercholesterolaemia) or mixed dyslipidaemia (type IIb) as an adjunct to diet when response to diet and other non-pharmacological treatments (eg exercise, weight reduction) was inadequate. Crestor could also be used for homozygous familial hypercholesterolaemia as an adjunct to diet and other lipid-lowering treatments (eg LDL apheresis) if such treatments were not appropriate.

The Panel noted AstraZeneca's submission about the various guidance documents issued by NICE since May 2008; *inter alia*, new cholesterol goals had been set for patients with diabetes and a new target had been set for patients with familial hypercholesterolaemia. NICE recommended high intensity statins in some patients. In the Panel's view there was a difference between overall targets which might be applicable to a patient population compared with a cholesterol target for a specific patient in a high risk group. The complainant's concerns appeared to be based only on the NICE clinical guideline 67 – Lipid Modification.

On balance, the Panel considered that the strapline 'Finding cholesterol targets harder to hit?' with the small dartboard might imply that targets had recently been reduced. However the advertisement might also be read as implying that it was more difficult to hit cholesterol targets generally. Lipid targets had now been set for a broad range of patients by a range of organisations. The strapline asked a question, it did not make a statement. If the reader's answer to the question was 'yes' then perhaps Crestor might be appropriate for some patients The Panel did not consider that the strapline was misleading as alleged. No breach of Clause 7.2 was ruled.

The Panel noted that the advertisement did not mention NICE at all. Thus it did not consider that the failure to mention the first line recommendations made by NICE was misleading. No breach of Clause 7.2 was ruled.

Complaint received **17 November 2008**

Case completed **6 January 2009**