NO BREACH OF THE CODE

CASE AUTH/3391/9/20

COMPLAINANT v SANOFI

Promotion of Praluent

A complainant, who described him/herself as a concerned UK health professional, complained about a banner advertisement which appeared on the Praluent (alirocumab) website owned by Sanofi. Praluent was a lipid lowering agent for use in certain adults with either primary hypercholesterolaemia or mixed dyslipidaemia and in certain adults with established atherosclerotic cardiovascular disease.

The banner advertisement provided by the complainant showed a picture of some runners with a man leading the group. The headline read 'He survived a CV [cardiovascular] event, now reduce his CV risk further* with Praluent'.

The complainant referred to the licensed indication for Praluent and alleged that the headline ('He survived a CV event, now reduce his CV risk further* with Praluent') did not make it at all clear that the indication was very particular and specifically that Praluent was an adjunct to other agents or for those who were intolerant of other therapies (even if the reader noticed the smaller text below which mentioned the patient was not at LDL-C goal). The complainant alleged that the advertisement would encompass considerably more patients than the licence, and therefore was off-licence promotion.

The complainant stated that the licensed indication might be mentioned much further down the web page, but the headline as it stood was misleading and should not require other parts of the web page to be factually correct.

The detailed response from Sanofi is given below.

The Panel noted Sanofi's submission that the claim at issue 'He survived a CV [cardiovascular] event, now reduce his CV risk further* with Praluent', was clearly referring to secondary prevention. The banner advertisement referred to an individual having had an MI (myocardial infarction) 6 months ago who was not at LDL-C goal. It appeared to the Panel that Sanofi was only referring to one aspect of the Praulent indication in the SPC in relation to established artherosclerotic cardiovascular disease.

The Panel noted Sanofi's submission that it was standard clinical practice to manage patients having had any acute coronary event (including an MI) with statins initially to reduce their LDL-C levels and any patient who had had an MI six months previously and was still not at LDL-C goal would, by definition (having received standard recommended care), fall into one of the following three categories: Started on statin and titrated to maximal tolerated dose after 3 months; unable to tolerate statins, but might or might not be on other lipid lowering agents; or had a contraindication to statins but might or might not be on other lipid lowering agents - all of which Sanofi submitted were within the licensed indication.

The Panel further noted Sanofi's submission that the second part of the claim at issue, '… now reduce his CV risk further with Praluent' made it clear that steps to manage cardiovascular risk factors had already been taken following the CV event, as would be usual clinical practice.

The full wording of the relevant licensed indication in the Praluent SPC was included on the webpage in a prominent box near the banner advertisement and below the navigation buttons. The Panel noted the layout of the webpage and considered that health professionals would not be misled as to the licensed indication for Praluent in established artherosclerotic cardiovascular disease. The Panel did not consider that the claim at issue was inconsistent with the Praluent SPC nor had Sanofi failed to maintain high standards. No breaches of the Code were ruled.

A complainant, who described him/herself as a concerned UK health professional, complained about a banner advertisement which appeared on the Praluent (alirocumab) website owned by Sanofi. Praluent was a lipid lowering agent for use in certain adults with either primary hypercholesterolaemia or mixed dyslipidaemia and in certain adults with established atherosclerotic cardiovascular disease.

The banner advertisement provided by the complainant showed a picture of some runners with a man leading the group. The headline read 'He survived a CV [cardiovascular] event, now reduce his CV risk further* with Praluent'.

COMPLAINT

The complainant noted that the licensed indication for Praluent [as taken from the summary of product characteristics (SPC)] was:

> 'Primary hypercholesterolaemia and mixed dyslipidaemia
>
> Praluent is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:
>
> - in combination with a statin or statin with other lipid lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin or,
>
> - alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.
>
> Established atherosclerotic cardiovascular disease
>
> Praluent is indicated in adults with established atherosclerotic cardiovascular disease to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors:
>
> -in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies or,

- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

For study results with respect to effects on LDL-C, cardiovascular events and populations studied see section 5.1.'

The complainant alleged that the headline ('He survived a CV event, now reduce his CV risk further* with Praluent') did not make it at all clear that the indication was very particular and specifically that Praluent was an adjunct to other agents or for those who were intolerant of other therapies (even if the reader noticed the smaller text below which mentioned the patient was not at LDL-C goal). The complainant alleged that the advertisement would encompass considerably more patients than the licence, and therefore was off-licence promotion.

The complainant stated that the licensed indication might be mentioned much further down the web page, but the headline as it stood was misleading and should not require other parts of the web page to be factually correct.

When writing to Sanofi, the Authority asked it to consider the requirements of Clauses 3.2 and 9.1 of the Code.

RESPONSE

Sanofi explained that the banner in question appeared at the top of the homepage of the Praluent promotional website which was restricted to UK health professionals (screenshot provided). Anyone directed to the site must declare their health professional status before landing on the homepage. There was no deep linking to this site, so the page was seen by all eligible visitors. Praluent was initiated in secondary care by specialists and the ongoing management of post myocardial infarction (MI) patients (including long-term treatment with Praluent) took place in primary care. The content on the website had been approved as appropriate for the full range of health professionals involved in the care of patients with established cardiovascular disease.

Sanofi stated that three navigation buttons lay beneath the banner in question, and immediately below the navigation buttons the reader could see, in a large and prominent box, the full wording of the licensed indication for Praluent pertaining to CV risk reduction.

Sanofi refuted the complainant's suggestion that the claim 'He survived a CV event, now reduce his risk further with Praluent' was off-label promotion. The claim made it clear that the subject of the claim was secondary prevention. This was consistent with the licensed indication in relation to 'Established atherosclerotic cardiovascular disease'. The second part of this phrase, '… now reduce his CV risk further with Praluent' made it clear that steps to manage cardiovascular risk factors had already been taken following the CV event, as would be usual clinical practice. Use of Praluent was qualified by the addition of the word 'further' to clarify that Praluent was recommended in addition to the initial management of risk reduction following the CV event. Sanofi submitted that no part of the claim was inconsistent with the indication which stated that Praluent was indicated in adults with established atherosclerotic cardiovascular disease to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors.

Sanofi noted that the banner also contained the statement 'Had an MI 6 months ago and not at LDL-C goal'. This was to add additional clarity of the patient type for which Praluent was recommended ie patients who had been managed to reduce their LDL-C, following an MI six months ago and their LDL-C was uncontrolled on current treatment, thereby necessitating further intervention. The term 'goal' indicated that steps towards achieving a LDL-C target in the past six months had been undertaken. Such steps would involve lipid lowering therapies involving statins (a copy of guidance from the National Institute for Heath and Care Excellence (NICE) was provided). This statement was just beneath the headline, was contained within the same banner, and was clear and prominent.

Sanofi noted the complainant's allegation that the two pieces of text within the banner broadened the indication by suggesting that Praluent was licensed for a wider population than represented in the actual indication. The complainant's reasoning was that the licensed indication mentioned other treatments such as statins. This contention was not factually accurate.

Sanofi stated that it was standard clinical practice to manage patients having any acute coronary event (including an MI) with statins initially to reduce their LDL-C levels. This routine clinical practice was a requirement in all local, regional and national protocols and in accordance with national guidelines. The current NICE clinical guideline on lipid management for secondary prevention stated 'Do not delay statin treatment in secondary prevention to manage modifiable risk factors' and 'If a person has acute coronary syndrome, do not delay statin treatment. Take a lipid sample on admission and about 3 months after the start of treatment.'

Sanofi submitted that any patient who had had an MI six months previously and was still not at LDL-C goal would, by definition (having received standard recommended care), fall into one of the following three categories:

- Started on statin and titrated to maximal tolerated dose after 3 months
- Unable to tolerate statins, but might or might not be on other lipid lowering agents
- Had a contraindication to statins but might or might not be on other lipid lowering agents.

Sanofi stated that the full wording of the licensed indication (prominently displayed on the webpage), confirmed that Praluent was approved for use in all of these clinical scenarios. There were no 'uncontrolled 6-month post MI' clinical patient categories that fell outside the licensed indication. The statements were factually correct and not misleading. Sanofi refuted the allegation that the banner had broadened the indication, in breach of Clauses 3.2 and 9.1.

In summary Sanofi stated that the recommended patient profile had been made clear on the webpage by use of a banner containing a visual and two statements, alongside the full licensed indication wording in a prominent box. The patient profile depicted was entirely consistent with any scenario outlined within the licensed indication and was factually correct. There were no clinical patient profiles depicted that would be outside of the Praluent indication and it was not misleading as suggested. The information on the webpage was consistent with the SPC and sufficiently complete to understand which patients were eligible for Praluent. Sanofi refuted the allegations of breaches of Clauses 3.2 and 9.1.

PANEL RULING

The Panel noted Sanofi's submission that the claim at issue 'He survived a CV [cardiovascular] event, now reduce his CV risk further* with Praluent', was clearly referring to secondary prevention. The banner advertisement referred to an individual having had an MI 6 months ago who was not at LDL-C goal. It appeared to the Panel that Sanofi was only referring to one aspect of the Praulent indication in the SPC in relation to established artherosclerotic cardiovascular disease.

The Panel noted Sanofi's submission that it was standard clinical practice to manage patients having had any acute coronary event (including an MI) with statins initially to reduce their LDL-C levels and any patient who had had an MI six months previously and was still not at LDL-C goal would, by definition (having received standard recommended care), fall into one of the following three categories: Started on statin and titrated to maximal tolerated dose after 3 months; unable to tolerate statins, but might or might not be on other lipid lowering agents; or had a contraindication to statins but might or might not be on other lipid lowering agents - all of which Sanofi submitted were within the licensed indication.

The Panel further noted Sanofi's submission that the second part of the claim at issue, '… now reduce his CV risk further with Praluent' made it clear that steps to manage cardiovascular risk factors had already been taken following the CV event, as would be usual clinical practice.

The full wording of the relevant licensed indication in the Praluent SPC was included on the webpage in a prominent box near the banner advertisement and below the navigation buttons. The Panel noted the layout of the webpage and considered that health professionals would not be misled as to the licensed indication for Praluent in established artherosclerotic cardiovascular disease. The Panel did not consider that the claim at issue was inconsistent with the Praluent SPC. No breach of Clause 3.2 was ruled.

The Panel did not consider that there was evidence that Sanofi had failed to maintain high standards in this regard and no breach of Clause 9.1 was ruled.

Complaint received **30 September 2020**

Case completed **22 February 2021**