CASE AUTH/2157/8/08

PRACTICE PHARMACIST v SANOFI-AVENTIS

Acomplia leavepiece

A practice pharmacist complained about a four page leavepiece 'Nice news for Norman' promoting Acomplia (rimonabant) left by a Sanofi-Aventis representative.

The complainant alleged that the front and back covers of the leavepiece implied that Acomplia was the treatment recommended by the National Institute for Health and Clinical Excellence (NICE) for overweight type 2 diabetics. Inside, the leavepiece stated its use for those unable to take orlistat or sibutramine but not on the outside. However NICE only recommended it for patients intolerant to, or who had inadequately responded to, orlistat or sibutramine ie third line.

The leavepiece also stated NICE 'recommends patients should continue beyond 2 years only after clinical review' whereas NICE guidance stated 'rimonabant should not be continued for longer than 2 years without a formal clinical assessment and discussion of the individual risks and benefits with the person receiving the treatment'. The leavepiece implied its virtues as an antidiabetic medicine in that it would reduce HbA1c.

The complainant alleged that the leavepiece was misleading as the bottom line appeared to be that Acomplia was first line for overweight type 2 diabetics as well as being antidiabetic.

The detailed response from Sanofi-Aventis is given below.

The Panel noted that the front and back pages stated 'NICE approves Acomplia for overweight patients (BMI>27kg/m²) with type 2 diabetes. The NICE guidance stated '[Acomplia], within its licensed indications, is recommended as an adjunct to diet and exercise for adults who are obese [BMI>30kg/m²] or overweight [BMI>27kg/m²] and who have had an inadequate response to, are intolerant of or are contraindicated to orlistat and sibutramine'. The Panel thus considered that the claim summarising the NICE guidance was misleading; it implied that NICE had approved the use of Acomplia in any type 2 diabetic who had a BMI of more than 27kg/m² which was not so. A breach of the Code was ruled.

The Panel noted that after accurately reflecting NICE guidance regarding Acomplia treatment at 6 months page 2 of the leavepiece stated 'NICE recommends that patients should continue beyond 2 years only after clinical review'. The NICE guidance stated '[Acomplia] treatment should not be continued for longer than 2 years without a formal clinical assessment and discussion of the individual risks and benefits with the person receiving treatment'. In the Panel's view, the subtle change of wording changed the meaning and emphasis of the original guidance. The Panel considered that this was not an accurate reflection of the NICE guidance. A breach of the Code was ruled.

The Panel noted that Acomplia was indicated 'As an adjunct to diet and exercise for the treatment of obese patients (BMI≥ 30kg/m²), or overweight patients (BMI≥ 27kg/m²) with associated risk factor(s), such as type 2 diabetes or dyslipidaemia'. Section 5.1 of the summary of product characteristics (SPC) referred to Acomplia's beneficial effects in lowering HbA1c stating that it was estimated that approximately half of the mean improvement in HbA1c was beyond that expected from weight loss alone.

The Panel considered that it was not necessarily unacceptable to promote the benefits of treatment as long as these were clearly expressed within the context of the product's licensed indication. The Panel noted that claims for Acomplia and its effect on HbA1c appeared on page 3 of the leavepiece beneath the heading 'Weight loss, with glycaemic control'. In that regard the Panel considered that equal emphasis had been given to weight loss, the licensed indication, and glycaemic control, the benefit of therapy. The Panel considered that glycaemic control had not been placed sufficiently within the context of weight loss and thus the leavepiece was misleading in that regard. A breach of the Code was ruled.

A practice pharmacist complained about a four page leavepiece 'Nice news for Norman' promoting Acomplia (rimonabant) left by a representative of Sanofi-Aventis.

COMPLAINT

The complainant alleged that both the front and back cover of the leavepiece implied that Acomplia was the treatment recommended by the National Institute for Health and Clinical Excellence (NICE) for overweight type 2 diabetics. Inside, the leavepiece stated its use for those unable to take orlistat or sibutramine but not on the outside. However NICE only recommended it as a treatment for those intolerant to, or who had had an inadequate response to orlistat or sibutramine ie third line.

The complainant alleged that the leavepiece also stated NICE 'recommends patients should continue beyond 2 years only after clinical review'. NICE

guidance stated 'rimonabant should not be continued for longer than 2 years without a formal clinical assessment and discussion of the individual risks and benefits with the person receiving the treatment'. The leavepiece implied its virtues as an antidiabetic medicine in that it would reduce HbA1c.

The complainant alleged that the leavepiece was misleading as the bottom line appeared to be that Acomplia was first line for overweight type 2 diabetics as well as being antidiabetic.

When writing to Sanofi-Aventis, the Authority asked it to respond in relation to Clause 7.2 of the Code. This was the same in the 2006 Code as in the 2008 Code. The case was considered under the 2008 Constitution and Procedure.

RESPONSE

Sanofi-Aventis stated that the leavepiece was designed to inform health professionals of important information following the approval of Acomplia by NICE on 25 June 2008.

Sanofi-Aventis believed that the claim on the front and back covers and the claims within the leavepiece were an accurate introductory summary of the NICE guidance for Acomplia and consistent with the Acomplia summary of product characteristic (SPC). Further clarification regarding the guidance and the reference for the full guidance were then contained within the leavepiece.

NICE guidance for Acomplia stated: 'Rimonabant, within its licensed indications, is recommended as an adjunct to diet and exercise for adults who are obese or overweight and who have had an inadequate response to, are intolerant of or are contraindicated to orlistat and sibutramine'.

The licensed indication for Acomplia was: 'As an adjunct to diet and exercise for the treatment of obese patients (BMI ≥ 30kg/m²), or overweight patients (BMI ≥ 27kg/m²) with associated risk factor(s) such as type 2 diabetes or dyslipidaemia (see Section 5.1)'. It was clear from this that NICE guidance therefore recommended the use of Acomplia in overweight (BMI ≥ 27) patients with type 2 diabetes, as it recommended the use of Acomplia within its licensed indications and the group of overweight (BMI ≥ 27) type 2 diabetics were within that licence, as above. Whilst the claim on the leavepiece did not describe every patient type covered by the licence that NICE had approved the use of Acomplia for, there was no requirement within Clause 7.2 for the entirety of a licensed indication to be promoted. Sanofi-Aventis believed that the claim on the leavepiece therefore complied with this clause.

The complainant also noted correctly that the leavepiece stated that Acomplia was approved by NICE only to be used in patients who were 'unable to take orlistat and sibutramine'. Again, NICE guidance stated: 'Rimonabant, within its licensed indications, is recommended as an adjunct to diet and exercise for adults who are obese or overweight and who have had an inadequate response to, are intolerant of or are contraindicated to orlistat and sibutramine'. This sentence clearly described that Acomplia should only be used when the patient could not take the other two weight loss products because of lack of efficacy, poor tolerability or a contraindication.

Sanofi-Aventis believed therefore that the claim in the leavepiece accurately reflected NICE guidance and clearly described what NICE had stated, that Acomplia should only be used when the other two products could not be taken by the patient.

Sanofi-Aventis believed that the phrase on the leavepiece that 'patients should continue beyond 2 years only after clinical review' adequately reflected NICE guidance, in that it would be unreasonable and outside the terms of good medical practice for a clinician to carry out a 'clinical review' of a chronic therapy that did not include a discussion of the risks and benefits with the patient, as recommended by NICE in its guidance. The leavepiece also clearly invited the reader to review the full guidance on the NICE website under this statement.

The final assertion in the complaint was that the leavepiece implied the virtues of Acomplia as an antidiabetic drug in that it would reduce HbA1c. The emphasis of the leavepiece however was on the overweight patient (BMI ≥ 27) and the phrases 'weight loss' and 'significantly reduce weight' were used first, ahead of any additional mention of beneficial change in HbA1c. The leavepiece did not describe Acomplia as an antidiabetic medicine.

It was however justifiable and not misleading to describe the additional beneficial effects of Acomplia on HbA1c as well as on weight loss. Acomplia had been shown to reduce weight and in addition HbA1c and improvements in HbA1c were also recognised in the SPC. The licence statement (see above) further recognised the beneficial changes in HbA1c in addition to weight loss, as it referred the reader to Section 5.1 of the SPC, which described this effect:

> 'In the trial in type 2 diabetic patients (RIO-diabetes) who were overweight or obese treated with metformin or sulfonylurea improvements in HbA1c and body weight were observed. The absolute change in HbA1c at one year was -0.6 for rimonabant 20mg (baseline 7.3%) and +0.1 on placebo (baseline 7.2%). Differences were statistically significant (Difference – 0.7%, CI95%; -0.5, p<0.001).'

Overall within the leavepiece, however, the beneficial improvements in HbA1c were presented only as an addition to the main beneficial changes of weight loss. This fact was particularly emphasised by the phrase 'Acomplia is proven to significantly reduce weight and, in addition, HbA1c

levels compared with placebo', which was consistent with the licensed indication and SPC.

Sanofi-Aventis did not consider that the leavepiece promoted Acomplia as first line, or as an antidiabetic medicine, and was not misleading as alleged and therefore not in breach of Clause 7.2.

PANEL RULING

The Panel noted that the front page of the four page leavepiece featured the claim 'NICE approves Acomplia for overweight patients (BMI>27kg/m²) with type 2 diabetes. This claim was repeated on the back page. In full, however, point 1.1 of the NICE guidance stated '[Acomplia], within its licensed indications, is recommended as an adjunct to diet and exercise for adults who are obese [BMI>30kg/m²] or overweight [BMI>27kg/m²] and who have had an inadequate response to, are intolerant of or are contraindicated to orlistat and sibutramine'. The Panel thus considered that the claim summarising the NICE guidance, printed on the front and back of the leavepiece, was misleading; it implied that NICE had approved the use of Acomplia in any type 2 diabetic who had a BMI of more than 27kg/m² which was not so. The claim was misleading in that regard and a breach of Clause 7.2 was ruled.

The Panel noted that the leavepiece, after accurately reflecting NICE guidance regarding Acomplia treatment at 6 months stated 'NICE recommends that patients should continue beyond 2 years only after clinical review'. Point 1.4 of the NICE guidance stated '[Acomplia] treatment should not be continued for longer than 2 years without a formal clinical assessment and discussion of the individual risks and benefits with the person receiving treatment'. In the Panel's view, the subtle change of wording was enough to change the meaning and emphasis of the original guidance – NICE had stated '[Acomplia] treatment should not be continued …' whereas the leavepiece stated 'NICE recommends that patients should continue …'. The Panel considered that when reporting the guidance of third parties, pharmaceutical companies must avoid any change of emphasis. The Panel considered that the claim in the leavepiece was not an accurate reflection of the NICE guidance. A breach of Clause 7.2 was ruled. During its consideration of this matter the Panel noted that the Acomplia SPC stated 'The safety and efficacy of rimonabant have not been evaluated beyond 2 years'.

The Panel noted that Acomplia was indicated 'As an adjunct to diet and exercise for the treatment of obese patients (BMI≥ 30kg/m²), or overweight patients (BMI≥ 27kg/m²) with associated risk factor(s), such as type 2 diabetes or dyslipidaemia'. Section 5.1 of the SPC (Pharmacodynamic properties) referred to Acomplia's beneficial effects in lowering HbA1c. It was stated that it was estimated that approximately half of the mean improvement in HbA1c in patients receiving Acomplia 20mg was beyond that expected from weight loss alone.

The Panel considered that it was not necessarily unacceptable to promote the benefits of treatment as long as such benefits were clearly expressed within the context of the product's licensed indication. The Panel noted that claims for Acomplia and its effect on HbA1c appeared on page 3 of the leavepiece beneath the heading 'Weight loss, with glycaemic control'. In that regard the Panel considered that equal emphasis had been given to weight loss, the licensed indication, and glycaemic control, the benefit of therapy. The Panel considered that glycaemic control had not been placed sufficiently within the context of weight loss and thus the leavepiece was misleading in that regard. A breach of Clause 7.2 was ruled.

Complaint received **6 August 2008**

Case completed **22 September 2008**