GENERAL PRACTITIONER v SANOFI-AVENTIS

Promotion of Acomplia

A general practitioner complained about the promotion of Acomplia (rimonabant) by Sanofi-Aventis.

The complainant noted, subsequent to a ruling of no breach of the Code in Case AUTH/1976/3/07 which he did not appeal, a review of Acomplia published in the Drug and Therapeutics Bulletin, June 2007, reported that additional beneficial effects on 'Cardiometabolic Risk Factors' beyond those expected from weight loss in trials of Acomplia might not be due to the medicine itself. The complainant submitted that the article supported his original concerns about the claim 'An estimated 50% of the effects of Acomplia on Cardiometabolic Risk Factors are beyond those expected from weight loss alone'. Given the credibility of the Drug and Therapeutics Bulletin, the complainant requested that the relevance of this unproven claim for Acomplia be reconsidered.

The matter was considered as a new complaint in accordance with Paragraph 5.1 of the Constitution and Procedure. The Panel noted that the Acomplia summary of product characteristics (SPC) (Section 5.1, Pharmacodynamic Properties) stated that 'It is estimated that approximately half of the observed improvement in the HDL-C and triglycerides in patients who receive rimonabant 20mg was beyond that expected from weight loss alone'.

The review in the Drug and Therapeutics Bulletin noted that although three trial reports had stated that the effects of Acomplia on HDL-C, triglycerides and HbA_{1C} were partly independent of weight loss, it was not proven that any independent effect was wholly or partially attributable to Acomplia. The Panel noted that although the authors were not convinced about the supporting data they did not present any new evidence to refute the claim 'An estimated 50% of the effects of Acomplia on Cardiometabolic Risk Factors [HbA_{1C}, HDL-C and triglycerides] are beyond those expected from weight loss alone'. Given the content of the SPC and qualification contained in the claim ('An estimated 50% of the effects of Acomplia on Cardiometabolic Risk Factors are beyond those expected from weight loss alone' (emphasis added) the Panel considered that the claim was a fair reflection of the known data and could be substantiated. No breach of the Code was ruled.

A general practitioner complained about the promotion of Acomplia (rimonabant) by Sanofi-Aventis. The complainant was particularly concerned about the claim 'An estimated 50% of the effects of Acomplia on Cardiometabolic Risk Factors are beyond those expected from weight loss alone'. The claim had been most recently considered in Case AUTH/1976/3/07 where the Panel ruled no breach of the Code.

COMPLAINT

The complainant noted, subsequent to the no breach ruling in Case AUTH/1976/3/07 which he did not appeal, a review of Acomplia had been published in the Drug and Therapeutics Bulletin, June 2007. The review reported that additional beneficial effects on 'Cardiometabolic Risk Factors' beyond those expected from weight loss in trials of Acomplia might not be due to the medicine itself. The complainant submitted that the article supported his original concerns about the claim 'An estimated 50% of the effects of Acomplia on Cardiometabolic Risk Factors are beyond those expected from weight loss alone'.

Given the credibility of the Drug and Therapeutics Bulletin, the complainant invited the Panel to reconsider its ruling with regard to the relevance of this unproven effect of Acomplia in promotional materials.

The matter was considered as a new complaint in accordance with Paragraph 5.1 of the Constitution and Procedure.

When writing to Sanofi-Aventis the Authority asked it to respond in relation to Clauses 7.2 and 7.4 of the Code.

RESPONSE

Sanofi-Aventis noted that the complainant had previously asked whether the claim that approximately 50% of Acomplia's effects on specific risk factors were beyond those expected from weight loss alone. Sanofi-Aventis had stated that the claim was based upon statements to the same effect made in the summary of product characteristics (SPC), as a result of evidence that had been demonstrated in several randomised, controlled trials that had supported the registration of Acomplia in Europe. (Copies of these were provided with the relevant sections highlighted). The complainant now questioned whether the report in the Drug and Therapeutics Bulletin negated this evidence.

Sanofi-Aventis noted that the article in the Drug and Therapeutics Bulletin was simply a review of the existing evidence qualified by the opinion of the authors. No new research had been conducted to call into question the validity of this observation, and the suggestion [in the article] that it might be based on the lifestyle advice given to participants appeared to be most unlikely given that this was applied equally to treatment and control arms. The article was simply

a review of the available evidence with this comment on the weight independent effect being only the opinion of the authors as opposed to new research or factual information to suggest that the existing knowledge of the product was incorrect. If the importance of this evidence was to be ranked, the significance of several well designed, randomised controlled trials (level 1b) would far outweigh that of expert opinion (level 4).

In summary, the Drug and Therapeutics Bulletin did not contain any new factual information to update the existing knowledge base for Acomplia, and no new data had arisen since the Panel last considered the advertisement to be consistent with the requirements of the Code. Sanofi-Aventis considered that the advertisement complied with the Code as concluded in Case AUTH/1976/3/07.

PANEL RULING

The Panel noted that the promotion of a medicine must be in accordance with the terms of its marketing authorization and must not be inconsistent with the particulars listed in its SPC. The Acomplia SPC (Section 5.1, Pharmacodynamic Properties) stated that 'It is estimated that approximately half of the observed improvement in the HDL-C and triglycerides in patients who receive rimonabant 20mg was beyond that expected from weight loss alone'.

In addition to being in accordance with the terms of its marketing authorization and not inconsistent with the particulars listed in the SPC, claims for a medicine must be, *inter alia*, based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. The review in the Drug and Therapeutics Bulletin noted that although three trial reports had stated that the effect of Acomplia on HDL-C, triglycerides and HbA_{1C} was partly independent of weight loss, it was not proven that any independent effect was wholly or partially attributable to Acomplia. The Panel noted that although the authors were not convinced about the supporting data they did not present any new evidence to refute the claim 'An estimated 50% of the effects of Acomplia on Cardiometabolic Risk Factors [HbA_{1C}, HDL-C and triglycerides] are beyond those expected from weight loss alone'. Given the content of the SPC and the qualification contained in the claim 'An *estimated* 50% of the effects of Acomplia on Cardiometabolic Risk Factors are beyond those expected from weight loss alone' (emphasis added), the Panel considered that the claim was a fair reflection of the known data and could be substantiated. No breach of Clauses 7.2 and 7.4 was ruled.

Complaint received	**11 June 2007**
Case completed	**2 August 2007**