CASE AUTH/1844/6/06

PRIMARY CARE TRUST HEAD OF PRESCRIBING v SANOFI-AVENTIS

Rimonabant email

The head of prescribing at a primary care trust (PCT) alleged that an email which he had received from Sanofi-Aventis which discussed the licensing status of rimonabant and how the recipient could receive information about it, was in breach of the Code because it was unsolicited and referred to an unlicensed medicine. Further, despite the email referring to a medicine no prescribing information was included.

The supplementary information to Clause 3.1, Advance Notification of New Products or Product Changes, noted that PCTs and the like needed to receive advance information about the introduction of new medicines, which might significantly affect their future expenditure. When this information was required, the medicines concerned would not be the subject of marketing authorizations (though applications would often have been made) and it would thus be contary to the Code for them to be promoted. Information might, however, be provided as long as, *inter alia*, it was directed to those responsible for making policy decisions on budgets, rather than those expected to prescribe, and the likely cost and budgetary implications were indicated and such that they would make significant differences to likely expenditure. Only factual information could be provided which should be limited to that sufficient to provide an adequate and succinct account of the product's properties.

The Panel noted that the subject of the email was stated as 'new Product Horizon Scanning Information' and asked the recipient if they wished to receive information regarding the projected introduction of a new product. The email gave brief details of rimonabant, describing it as the first of a new class of medicines. It was stated that the licensing process was considering data for possible use in the treatment of obesity and associated cardiovascular/cardiometabolic risk factors. The recipient was told that information on the cost of the medicine, patient types suitable for treatment, a summary of the numbers of such patients in the local PCT and an estimate of the uptake rate could be provided on request.

The Panel considered that the primary purpose of the email was to elicit interest in rimonabant and prompt the recipient to seek further information; the information provided in the email was not sufficient to provide an adequate but succinct account of the product's properties as required and nor did the email indicate the likely cost and significant budgetary implications of rimonabant. The email thus failed to meet the requirements of the supplementary information. A breach of the Code was ruled.

The Panel noted the complainant's concern that the email had not contained prescribing information. The supplementary information to the Code, however, stated that advance notification of new products should not include mock up drafts of summaries of product characteristics or patient information leaflets. In that regard the Panel considered that mock up prescribing information should also not be provided. No breach of the Code was ruled.

The Panel noted that the email in question had been sent without the prior permission of the recipient. A breach of the Code was ruled.

The head of prescribing at a primary care trust (PCT) complained about an email which he had received from Sanofi-Aventis at the end of May 2006. The email discussed the licensing status of rimonabant and how the recipient could receive information about it.

COMPLAINT

The complainant alleged that the email was in breach of the Code, firstly because it was unsolicited and secondly, because it gave the generic name, rimonabant, of a medicine that was, to the complainant's knowledge, unlicensed. Finally, despite the email referring to a medicine produced by Sanofi-Aventis, the prescribing information was not included.

When writing to Sanofi-Aventis, the Authority asked it to respond in relation to Clauses 3.1 and 9.9 of the Code. If rimonabant had a marketing authorization then Clause 4.1 should also be borne in mind.

RESPONSE

Sanofi-Aventis stated that it expected the rimonabant marketing authorization to be granted in June 2006. The complainant had not given prior permission to receive promotional material electronically.

The email was a personal letter, albeit in email format, which provided information on a new product expected to have significant budgetary impact to the PCT. Sanofi-Aventis considered that the email complied with Clause 3.1 of the Code (advance notification of new products).

The author, a Sanofi-Aventis employee, considered that the complainant would, as a pharmaceutical advisor to a PCT, have significant influence on policy decisions on the prescribing budgetary, as required by Clause 3.1. This consideration was stated within the email; also included was a request to forward the email to a more appropriate person should the complainant not fulfil this role (although there was no reason to believe that this would not be the case). The email continued in a factual manner to outline the essential information required by the Code with respect to advance notification of new medicines. In particular, it contained details that this concerned a new medicine that was subject to review by the European Medicines Evaluation Agency, a brief factual account of the product sufficient to enable the recipient to understand where the new medicine would be likely to be used in practice, and an indication that a price band and an estimate of the impact on the local budget was available upon which further discussions could be based if desired. The letter did not provide any information beyond that

required by Clause 3.1 and was not constructed nor supplemented by any material that might give the impression that this was a promotional item.

Sanofi-Aventis was confident that the email represented a *bona fide* non-promotional personal communication, and that it complied with Clause 3.1 of the Code.

With respect to the complainant's allegations, Sanofi-Aventis submitted that no breach of the Code had occurred and that high standards had been maintained for the following reasons.

- Firstly, although the email was sent unsolicited, it was factual rather than promotional in nature, and was a personal communication as opposed to any form of direct electronic promotion. Whilst agreeing that an unsolicited promotional email would be a breach of Clause 9.9, in view of the non-promotional nature of this letter, Sanofi-Aventis considered that no breach of Clause 9.9 had occurred and that high standards had been maintained.
- Secondly, the complainant was correct in stating that rimonabant did not yet have a marketing authorization. For this reason, the contact was made in full compliance with Clause 3.1 as outlined above. In complying with these requirements in full, Sanofi-Aventis again considered that no breach had occurred and that high standards had been maintained.
- Finally, with respect to the allegation that no prescribing information was included, this was clearly in line with the requirements of the Code not to provide mock-ups of such material prior to marketing authorization and Sanofi-Aventis again considered that it had complied with Clause 3.1 and thus maintained high standards.

In response to a request for further information Sanofi-Aventis stated that the cost of rimonabant was assumed to be between £30 to £50 for 28 days' treatment. In comparison to other marketed anti-obesity products, the most frequently used was orlistat which had an NHS cost of £41.60 for the same duration. The anticipation was that rimonabant would be prescribed for a wider population than orlistat given its anticipated indication and expected utility. Sanofi-Aventis thus considered that rimonabant would present a major budgetary impact to the NHS, over and above that of orlistat. Sanofi-Aventis later confirmed the price of £55.20 for rimonabant.

PANEL RULING

The Panel noted that the supplementary information to Clause 3.1, Advance Notification of New Products or Product Changes, noted that various healthcare organizations, including PCTs, needed to estimate their likely budgets two to three years in advance in order to meet Treasury requirements and so they needed to receive advance information about the introduction of new medicines, or changes to existing medicines, which might significantly affect their level of expenditure during future years. At the time this information was required, the medicines concerned (or the changes to them) would not be the subject of marketing authorizations (though applications would often have been made) and it would thus be contrary to the Code for them to be promoted. Information might, however, be provided as long as, *inter alia*, it was directed to those responsible for making policy decisions on budgets, rather than those expected to prescribe, and the likely cost and budgetary implications were indicated and such that they would make significant differences to the organizations likely expenditure. Only factual information could be provided which should be limited to that sufficient to provide an adequate and succinct account of the products' properties.

The subject of the email was stated as 'new Product Horizon Scanning Information' and asked the recipient if they wished to receive information regarding the projected introduction of a new product. The email then went on to give brief details of rimonabant describing it as the first of a new class of medicines. It was stated that the licensing process was considering data for possible use in the treatment of obesity and associated cardiovascular/cardiometabolic risk factors. The recipient was told that Sanofi-Aventis could provide, on request, information on the cost of the medicine, patient types suitable for treatment, a summary of the numbers of such patients in the local PCT and an estimate of the uptake rate.

The Panel considered that the primary purpose of the email was to elicit interest in rimonabant and prompt the recipient to seek further information; the information provided in the email was not sufficient to provide an adequate but succinct account of the product's properties as required and nor did the email indicate the likely cost and significant budgetary implications of rimonabant. The email thus failed to meet the requirements of the supplementary information. A breach of Clause 3.1 was ruled.

The Panel noted the complainant's concern that the email had not contained prescribing information for rimonabant. The supplementary information to Clause 3.1, however, stated that advance notification of new products should not include mock up drafts of either summaries of product characteristics or patient information leaflets. In that regard the Panel considered that mock up prescribing information should also not be provided. No breach of Clause 3.1 was ruled in that regard.

Clause 9.9 of the Code stated, *inter alia*, that emails must not be used for promotional purposes except with the prior permission of the recipient. The Panel noted its ruling of a breach of Clause 3.1 of the Code. The email in question had been sent without the prior permission of the recipient. A breach of Clause 9.9 was ruled.

Complaint received **6 June 2006**

Case completed **15 August 2006**