GENERAL PRACTITIONER v BOEHRINGER INGELHEIM

Sponsored article on linagliptin

In Case AUTH/2424/8/11 a general practitioner, complained about an article on linagliptin (marketed as Trajenta by Boehringer Ingelheim) which had appeared in Future Prescriber. As part of his appeal in that case, the complainant widened the scope of his complaint and subsequently requested that this be taken up as a new complaint (Case AUTH/2445/10/11).

The article, *inter alia*, compared linagliptin with other medicines in the same class and stated that its cost was anticipated to be similar (ie around £32/month).

The complainant alleged that as the article promoted linagliptin prelicence, the provision of an unconfirmed price to all health professionals, including those without budgetary responsibility, was inconsistent with the requirements for the provision of advanced notification. The complainant submitted that Future Prescriber was not an appropriate forum in which to provide such information and alleged that Boehringer Ingelheim had tried to use the article to circumvent the requirements of the Code and directly compare the cost of linagliptin with other medicines in the same class.

The detailed response from Boehringer Ingelheim is given below.

The Panel queried whether a company-sponsored article in a journal would ever satisfy the requirements of the Code with regard to the provision of advanced notification of new products and product changes, particularly the need to restrict the distribution of such information to those responsible for making policy decisions.

The Panel noted that Case AUTH/2424/8/11 had established that as Boehringer Ingelheim was inextricably linked to the production of the article it was responsible for its content under the Code.

The Panel noted that the anticipated cost of linagliptin quoted in the article was 'around £32 per month'. The actual cost of Trajenta, which had now received a marketing authorization, was £33.26 for a 28 day supply. The anticipated cost stated in the article was thus similar to the eventual cost.

The Panel noted that the complainant had alleged that citing an unconfirmed price of a medicine was inconsistent with the requirements for advanced notification. In that regard the Panel noted that the supplementary information to the Code stated that such information must indicate the *likely* cost and budgetary implications. It was not necessary to state the final confirmed cost although in the Panel's view the two costs should not be dissimilar. The Panel queried whether linagliptin was a medicine for which advanced notification could have been provided given its similarity in cost to other medicines in the same class.

The Panel did not consider that the article constituted the advance notification of Trajenta; Boehringer Ingelheim submitted that it had not used the article for that, or any other purpose. In that regard, and on the narrow grounds of the complaint, the Panel ruled no breach of the Code. The Panel noted that in Case AUTH/2424/8/11 it had considered, *inter alia*, that the article promoted Trajenta prior to the grant of a marketing authorization and in that wider sense it had already ruled a breach of the Code.

In Case AUTH/2424/8/11, a general practitioner complained about an article on linagliptin published in the July/August edition of Future Prescriber (Volume 12, Issue 2, 2011). Linagliptin (marketed as Trajenta by Boehringer Ingelheim) was granted a marketing authorization in August 2011, ie after the article had been published. As part of his appeal in Case AUTH/2424/8/11 the complainant widened the scope of his complaint and raised a matter which had not been previously considered by the Panel and which could thus not be the subject of an appeal. The complainant was so informed and he requested that the matter be taken up as a new complaint.

The article, *inter alia*, compared linagliptin with other medicines in the same class and stated that its cost was anticipated to be similar (ie around £32 per month).

COMPLAINT

The complainant stated that as the article at issue was deemed to promote linagliptin prelicence and Boehringer Ingelheim was responsible for its content, then the provision of an unconfirmed price to all health professionals, including those without budgetary responsibility, was inconsistent with the rules regarding the provision of advance notification information. The purpose of the latter was to allow budget holders to assess the impact of any new medicine based on both its efficacy and cost; Future Prescriber was clearly not the appropriate forum to achieve this as defined by the Code.

The complainant alleged that Boehringer Ingelheim had tried to use the article to circumvent the requirements of the process for advanced notification to invite a direct comparison of the cost of this medicine with others in the same class.

When writing to Boehringer Ingelheim, the Authority asked it to respond in relation to Clause 3.1.

RESPONSE

Boehringer Ingelheim explained that as in Case AUTH/2424/8/11, it did not commission the article at issue, determine its outline, authorize its contents or approve its use, and despite the article being published contrary to the company's direct instructions to the publisher, it actively limited its distribution once a complaint had been received.

In terms of the specific complaint, no price for linagliptin was mentioned in this article. Boehringer Ingelheim acknowledged that the authors had expressed an opinion that 'The cost of linagliptin is anticipated to be similar to the other already marketed DPP-4 inhibitors (ie around £32 per month)'. Again, this was not an opinion that Boehringer Ingelheim had influenced, nor had it authorized or approved the use of this statement or any other part of the article. Boehringer Ingelheim submitted that it had not used the article for any purpose and certainly not for the advance notification of a new product. Consequently Boehringer Ingelheim denied a breach of Clause 3.1.

PANEL RULING

The Panel noted that the supplementary information to Clause 3.1 stated that health authorities and health boards and their equivalents, trust hospitals and primary care trusts and groups needed to estimate their likely budgets two to three years in advance in order to meet Treasury requirements and there was a need for them 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. It was noted that 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 must be indicated and must be such that they would make significant differences to the likely expenditure of health authorities and trust hospitals and the like.

The Panel queried whether publication of a company-sponsored article in a journal would ever satisfy the requirements of Clause 3 and the supplementary information to Clause 3.1, Advance Notification of New Products or Product Changes, particularly with regard to the need to restrict the distribution of such information to only those responsible for making policy decisions.

The Panel noted Boehringer Ingelheim's submission with regard to its involvement in the production of the article. Nonetheless it had been established in Case AUTH/2424/8/11 that a business proposal between the publishers and Boehringer Ingelheim showed that the company had known from the outset that the article would support Trajenta. Although Boehringer Ingelheim did not pay for the article *per se*, it in effect commissioned it through an agreement to purchase 2,000 reprints. The Panel considered that Boehringer Ingelheim was inextricably linked to the production of the article and in that regard it was responsible for its content under the Code.

The Panel noted that the anticipated cost of linagliptin quoted in the article was 'around £32 per month'. The actual cost of Trajenta, which had now received a marketing authorization, was £33.26 for a 28 day supply. In that regard the Panel noted that the anticipated cost stated in the article was similar to the eventual cost.

The Panel noted that the complainant had alleged that citing an unconfirmed price of a medicine was inconsistent with the requirements for advanced notification. In that regard the Panel noted that the supplementary information to Clause 3.1, Advance Notification of New Products or Product Changes, stated that such information must indicate the *likely* cost and budgetary implications. It was not necessary to state the final confirmed cost although in the Panel's view the two costs should not be dissimilar. The Panel queried whether linagliptin was a medicine for which advanced notification could have been provided given its similarity in cost to other medicines in the same class.

The Panel did not consider that the article in question constituted in itself the advance notification of Trajenta; Boehringer Ingelheim submitted that it had not used the article for that, or any other, purpose. In that regard, and on the narrow grounds of the complaint, the Panel ruled no breach of Clause 3.1. The Panel noted that in Case AUTH/2424/8/11 it had considered, *inter alia*, that the article promoted Trajenta prior to the grant of a marketing authorization and in that wider sense it had already ruled a breach of Clause 3.1 .

Complaint received **14 October 2011**

Case completed **18 November 2011**