ANONYMOUS v SANOFI-AVENTIS

Advance notification document: Pipeline Update

An anonymous, non contactable complainant alleged that a document 'Oncology Product Pipeline Update' was provided to Sanofi-Aventis representatives so that they could promote and discuss with customers upcoming new products which did not have licences. The front of the document stated that it was 'Advanced Notification' and intended for national horizon scanning organisations, NHS managers and other professionals with a responsibility for the planning and commissioning of cancer services.

The detailed response from Sanofi-Aventis is given below.

The Panel noted that the document referred to five medicines and for each included details of; anticipated marketing indication, licence status in EU/UK, administration, replacement for/addition to other treatment options, estimated cost per patient course, service implications, eligible patients, evidence base and NICE status. No actual acquisition costs were given as these were yet to be determined. The document stated that the annual cost of each medicine was expected to be in line with other products including recently launched innovative cancer therapies.

The document was to be used by the oncology healthcare specialists. Sanofi-Aventis submitted that this team did not discuss or promote licensed medicines.

The email accompanying the document when it was distributed to the oncology sales representatives stated that the document was 'for information internally only'. The Panel noted that the document had been distributed in error to the representatives and they had had to return it.

The Panel considered that on the information before it the representatives had not been instructed to promote unlicensed medicines. The Panel considered that it was not unacceptable to send the document to the representatives but queried why, in some instances more than one copy had been sent when the information was for internal use only. Multiple copies might imply that copies had been provided to give to others and given the prohibition on the promotion of unlicensed medicines, the Panel considered that it would have been helpful if the covering note had clearly stated that the representatives must not discuss the document with anyone upon whom they called. However, on the evidence before it the Panel did not consider that representatives had promoted unlicensed indications or unlicensed products. No breach including of Clause 2 was ruled.

During its consideration of this case the Panel noted that although there was no complaint about the intended use of the document, it was nonetheless extremely concerned about its content and considered that Sanofi-Aventis would be well advised to ensure that it met all of the elements of the relevant supplementary information to the Code.

An anonymous, non contactable complainant complained about a document 'Oncology Product Pipeline Update' provided to Sanofi-Aventis representatives.

The front of the document stated that it was 'Advanced Notification' and intended for national horizon scanning organisations, NHS managers and other professionals with a responsibility for the planning and commissioning of cancer services.

COMPLAINT

The complainant stated that the document was given to sales representatives in oncology to promote and discuss with customers upcoming new products which did not have licences.

When writing to Sanofi-Aventis the Authority asked it to respond in relation to Clauses 2, 3.1, 3.2 and 9.1 of the Code.

RESPONSE

Sanofi-Aventis stated that the document was prepared for exclusive use by the team of oncology healthcare specialists who had a specific role in working with the cancer networks providing advance information to those in the NHS responsible for making policy decisions on budgets, providing them with an opportunity to prepare for medicines which might significantly affect their level of expenditure during the next few years. The purpose of the document was clearly described as an item to provide advanced notification of new products. Sanofi-Aventis submitted that it met the requirements of Clauses 3.1 and 3.2.

Unfortunately, following an administrative error, the oncology sales representatives were each sent between one and three copies of the document on 23 September 2010. No formal briefing document was included but an enclosed note stated that the document was for internal use only. Although the oncology sales representatives received this item, albeit in error, they were not directed to use it, were not trained in its use, and were specifically told that it was provided only for their own information. On this basis, Sanofi-Aventis did not consider that there was any intention or direction to the sales team to

use the item for promotion; the opposite being implied from the cover note. As such, Sanofi-Aventis did not consider there to be any direction to use the material in a way that would result in a breach of Clauses 3.1 or 3.2.

Sanofi-Aventis became aware of the distribution error at a regional sales meeting on 14 October and immediately initiated a withdrawal procedure, as well as launching an internal investigation to determine how the error occurred. This process was initiated before the complaint was received. Withdrawal had been completed, with written confirmation of the return of the document from all oncology sales representatives.

Sanofi-Aventis acknowledged that there was an error in distributing the document to sales representatives, but considered that the company took very swift action to correct this error as soon as it became apparent, in keeping with the requirement to maintain high standards at all times. There was no breach of Clauses 2 and 9.1.

In response to a request for further information Sanofi-Aventis provided job descriptions for an oncology healthcare specialist and an oncology specialist representative. The oncology healthcare specialist team was formed in September 2010. A new job description that included the standard accountability for compliance with the Code which was standard for customer-facing teams was provided. There was no written briefing instruction for using the document at issue but the team was informed verbally how to use it in line with the statement in the front of the booklet. Oncology healthcare specialists did not currently discuss or promote licensed medicines.

PANEL RULING

The Panel noted that the complainant was anonymous and that, as set out in the introduction to the Constitution and Procedure, complainants had the burden of proving their complaint on the balance of probabilities. Anonymous complaints were accepted and like all complaints were judged on the evidence provided by the parties.

The Panel noted that the document referred to five medicines and for each included details of; anticipated marketing indication, licence status in EU/UK, administration, replacement for/addition to other treatment options, estimated cost per patient course, service implications, eligible patients, evidence base and the National Institute for Health and Clinical Excellence (NICE) status. No actual acquisition costs were given as these were yet to be determined. The document stated that the annual cost of each medicine was expected to be in line with other products including recently launched innovative cancer therapies.

The document was to be used by the oncology healthcare specialists. Sanofi-Aventis submitted that this team did not discuss or promote licensed medicines. The email accompanying the document when it was distributed to the oncology sales representatives stated that the document was 'for information internally only'. The Panel noted that the document had been distributed in error to the representatives and they had had to return it.

The Panel considered that on the information before it the representatives had not been instructed to promote unlicensed medicines. The Panel considered that it was not unacceptable to send the document to the representatives but queried why, in some instances more than one copy had been sent when the information was for internal use only. Multiple copies might imply that copies had been provided to give to others and given the prohibition on the promotion of unlicensed medicines, the Panel considered that it would have been helpful if the covering note had clearly stated that the representatives must not discuss the document with anyone upon whom they called. However, on the evidence before it the Panel did not consider that representatives had promoted unlicensed indications or unlicensed products. No breach of Clauses 3.1 and 3.2 were ruled. It thus followed that there was no breach of Clauses 2 and 9.1 and the Panel ruled accordingly.

During its consideration of this case the Panel was extremely concerned about the use of the document. It noted Sanofi-Aventis's submission that the document was intended to be used for advanced notification of new products which **might** significantly affect expenditure. The Panel noted the supplementary information to Clause 3.1, Advance Notification of New Products or Product Changes, stated that health authorities and health boards and their equivalents, trust hospitals and primary care trusts and groups needed to establish 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 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 contrary to the Code for them to be promoted. The supplementary information gave guidance on the basis on which such advance information could be provided including the requirement to include the likely cost and budgetary implications which **must** make significant differences to the likely expenditure of heath authorities etc.

In general the products detailed in the document were expected to have marketing authorizations in 2011 or 2012. In that regard, the Panel queried whether the information had been supplied early enough for some of the products such that budget holders etc could be reasonably expected to act upon it.

Information could only be supplied if the product

had a significant budgetary implication. For all of the medicines detailed it was stated that there would be, or there were likely to be, budgetary and resource implications. The budgetary implications, however, had not been quantified in the document in question.

The Panel was also concerned about the job description for the oncology healthcare specialists. It queried whether it was consistent with the supplementary information to Clause 3.1 of the Code and the need for such a role to be non promotional. In this regard the Panel noted that one of the key accountabilities was to ensure that the uptake of national guidance/guidelines was maximised for Sanofi-Aventis products and the need to contribute to regional sales goals.

There was no complaint about the intended use of the document. The Panel, however, considered that Sanofi-Aventis would be well advised to ensure that the document met all the elements of the relevant supplementary information to Clause 3.1. The Panel requested that its serious concerns be drawn to Sanofi-Aventis' attention.

Complaint received **19 October 2010**

Case completed **5 November 2010**