ANONYMOUS EMPLOYEE v SANOFI-AVENTIS

Duties of a representative

An employee of Sanofi-Aventis complained that, as part of a small specialist team, he was being asked to talk about Plavix and off label indications. He had also been asked to gain information about a new competitor product that had not come to the market place. This made him very uncomfortable.

As the complainant was anonymous and non-contactable, and little evidence had been provided, the Panel was extremely cautious in deciding what weight, if any, to attach to the complaint.

The Paned noted that Sanofi-Aventis had denied promoting Plavix for unlicensed indications; scientific advisors, however, were expected to react to unsolicited requests for such information.

The Panel noted that the job description included in the scientific advisor's reference folder was headed 'Scientific Advisor Role Profile-Cardiovascular Business Unit'. It was stated that scientific advisors were critical to the functioning of the cardiovascular business unit by ensuring all scientific information was updated and communicated to health professionals within the NHS in order to maximise business operations. They were also to act as a resource to the sales force; they were to be 'proactive' and a 'self starter'. One of the key objectives and responsibilities was to provide educational information on licensed and unlicensed indications in strict accordance with, *inter alia*, the Code.

Further guidance stated that the role was reactive only when responding to a written request for information about unlicensed use and this point was stressed in the performance metrics. The scientific advisors could work proactively at any other time including contacting customers to introduce themselves and their roles and arranging meetings.

The role was described as predominately customer facing with leads generated by the sales team. Examples given of how the scientific advisors in another business unit supported the business unit included 'Difficult to access customers – Different approach, new and unlicensed data, Investigator initiated trials, audits, advisory boards'.

A separate job description (not included in the folder) described one of the objectives and responsibilities of scientific advisors as management of contact and development of regional key opinion leaders in conjunction with the marketing department.

The Panel was concerned about the arrangements for the scientific advisors and the potential for them to undertake a promotional role. The definition of promotion in the Code included any activity undertaken by a pharmaceutical company which promoted the prescription, supply, sale or administration of its medicines. Examples drawn from other parts of the company appeared to encourage the cardiovascular scientific advisors to use unlicensed data proactively with difficult to access customers.

Although the Panel was very concerned about the documentation, it nonetheless considered there was no evidence on the balance of probabilities that Sanofi-Aventis had promoted Plavix outside its licensed indication as alleged and thus no breach of the Code was ruled.

It was normal commercial practice to seek information about competitor products and this was not in itself a breach of the Code. Sanofi-Aventis had denied activity in this regard other than in accordance with the requirements of the Code.

There being no evidence that Sanofi-Aventis had acted improperly, and no recourse to the complainant for further information the Panel ruled that on the balance of probabilities there had been no breach of the Code.

An employee of Sanofi-Aventis complained about the duties he was being asked to perform.

COMPLAINT

The complainant stated that, as part of a small specialist team he was being asked to talk about Plavix (clopidogrel) and unlicensed indications. He had also been asked to gain information about a competitor product that was not yet marketed. This made him very uncomfortable.

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 and stated it was unclear whether the allegation about gaining information about a competitor product was covered by the Code. This should become clear on receipt of Sanofi-Aventis' response.

RESPONSE

Sanofi-Aventis was disappointed that an employee had directed their concerns to the Authority without having first used the established company policies on whistleblowing, or discussed the matter with any member of Sanofi-Aventis staff.

Sanofi-Aventis emphasised that members of its Plavix promotional teams were not involved in off licence

discussions and knowledge of any contravention of this policy would result in investigation and disciplinary sanctions. Only employees with a non-promotional role namely, medical information officers and medical affairs (including scientific advisors) were permitted to respond to such requests from health professionals on a reactive basis only. The company did not permit the proactive provision of information on unlicensed use of its products outside specialist circumstances eg clinical triallists' meetings, in compliance with the supplementary information to Clause 3.

Sanofi-Aventis explained that it had field-based medical representatives who promoted Plavix in primary and secondary care. However, the company believed that the complainant's reference to a small specialist team referred to either the professional relations executive (PRE) or the scientific advisor (SA) teams. The role and responsibilities of these teams were described below;

The PREs were a field-based promotional team of five who reported to a group product manager based in head office. The PRE team's main role was to interact with local and national opinion leading health professionals supporting their needs through centrally funded programmes and small local projects. They developed local advocacy for company products as well as identified the areas of interest for customers with respect to medical education programmes. The roles and responsibilities were described in the PRE job description which was provided.

The cardiovascular SAs were a non-promotional team of four who reported directly to the cardiovascular medical manager within the medical affairs department. Their roles were cross functional, working with medical information, promotional affairs, clinical operations and commercial on non-promotional scientific activities. Due to the nature of their role, scientific advisors did not use promotional materials. The interaction between scientific advisors and health professionals was reactive to unsolicited requests for scientific or medical information. A full description of their role and responsibilities was included in the job description and the scientific advisors' folder, both of which were provided.

Sanofi-Aventis explained that all of its employees, including members of the PRE and SA teams, had been instructed not to proactively raise any off-licence discussions with health professionals.

Guidance on what to do when a representative received an unsolicited request for off-licence information was given in Code of Practice training during the induction period of a new entrant. If during a discussion with a health professional an employee received an unsolicited request for off-licence information he/she should refer the health professional to a non-promotional member of the company (ie medical information office or a scientific advisor).

Members of the PRE and SA teams were expected to collect information on competitors if the issue was raised by a health professional and then to relay this to the relevant member of the marketing/medical team. This activity was carried out in a manner consistent with the high standards required by the Code and did not involve subterfuge, misrepresentation or disparagement of other companies or their products.

In summary, Sanofi-Aventis stated that it was committed to complying with the Code and upholding high standards required therein; and that all the activities which involved members of the promotional teams were within the licensed indication(s) for the products which they promoted. Sanofi-Aventis therefore did not accept that there had been breaches of the Code as alleged. Specifically, Clause 3 had been adhered to, with clear expectations and briefing as to what actions were permissible in the context of discussions on unlicensed indications of Plavix. High standards had been maintained; the two teams had been briefed on the requirements of the Code and operated within these in both letter and spirit. Collection of competitor information was not prohibited under the Code provided that this did not involve any activity which otherwise contravened its requirements, and again Sanofi-Aventis' briefing did not advocate any such action. Sanofi-Aventis noted that the complainant had offered no evidence to substantiate their vague and general allegations. Taking these factors into consideration, Sanofi-Aventis believed that there had accordingly been no breach of Clause 2, either to reduce confidence in the industry or to bring discredit upon it.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable and little evidence had been provided. Thus the Panel was extremely cautious in deciding what weight, if any, to attach to the complaint.

The Panel noted that it had no way of knowing what role the complainant had in Sanofi-Aventis; he had described himself as being 'part of a small specialist team' that talked about Plavix. Sanofi-Aventis had submitted that two roles fitted that description – a scientific advisor or a professional relations executive. The professional relations executive was a promotional role, reporting to a group product manager. Sanofi-Aventis had submitted that all of its employees, including the professional relations executives and the scientific advisors, had been instructed not to proactively raise any off-licence discussions with health professionals. Sanofi-Aventis had denied promoting Plavix for unlicensed indications. The scientific advisors however, were expected to react to unsolicited requests for such information.

The Panel examined the job description for a cardiovascular scientific advisor. There appeared to be two versions, each provided by Sanofi-Aventis. The separate document provided was different to that included in the scientific advisor's reference folder which was headed 'Scientific Advisor Role Profile-

Cardiovascular Business Unit'. The folder stated that scientific advisors were critical to the functioning of the cardiovascular business unit by ensuring all scientific information was updated and communicated to health professionals within the NHS in order for business operations to be maximised. They were also to act as a resource to the sales force.

The folder listed skills and behaviours as 'proactive' and 'self starter'. One of the key objectives and responsibilities was to provide educational information on licensed and unlicensed indications in strict accordance with the Code and Medicines Act. The Panel noted that in order to comply with the Code this could not be a proactive role but would have to be a reactive role. Scientific advisors were to attend the sales conference.

The folder gave some information about the role in relation to the Code. The guidance stated that the role was reactive only when responding to a written request for information about unlicensed use. The scientific advisors could work proactively at any other time including contacting customers to introduce themselves and their roles and arranging meetings.

The performance metrics included 'Exchange of out of licence scientific information - reactive basis only'.

The folder described the role as predominately customer facing with leads generated by the sales team. It also gave examples in the form of slides of how the scientific advisors in another business unit (metabolism) supported the business unit which included 'Difficult to access customers – Different approach, new and unlicensed data, Investigator initiated trials, audits, advisory boards'.

The separate job description described one of the objectives and responsibilities as 'Management of contact and development of regional KOLs [key opinion leaders] in conjunction with the Marketing Department'.

The Panel was concerned about the arrangements for the scientific advisors and the potential for them to undertake a promotional role. The definition of promotion in Clause 1.2 included any activity undertaken by a pharmaceutical company which promoted the prescription, supply, sale or administration of its medicines. The slides could be read such as to imply that the cardiovascular scientific advisors had been encouraged to use unlicensed data proactively with difficult to access customers.

Although the Panel was very concerned about the documentation, it nonetheless considered there was no evidence on the balance of probabilities that Sanofi-Aventis had promoted Plavix outside its licensed indication as alleged and thus no breach of Clauses 3.1 and 3.2 was ruled. The Panel also ruled no breach of Clauses 2 and 9.1.

It was normal commercial practice to seek information about competitor products and this was not in itself a breach of the Code. Sanofi-Aventis had denied activity in this regard other than in accordance with the requirements of the Code.

As the complaint had been submitted anonymously, there could be no recourse to the complainant for further information.

There being no evidence that Sanofi-Aventis had acted improperly, the Panel ruled that on the balance of probabilities there had been no breach of Clause 9.1.

Complaint received	**7 September 2007**
Case completed	**24 September 2007**