CASE AUTH/2258/8/09

# ANONYMOUS v SANOFI-AVENTIS

## Conduct of representatives

**An anonymous uncontactable complainant alleged that Sanofi-Aventis oncology representatives in one UK region had demanded regional data on patient numbers being treated on docetaxel (Sanofi-Aventis' product Taxotere) and its competitor medicines for all local hospitals. Printouts of this data comparing 2008 and 2009 had been supplied; the complainant asked that this practice be stopped immediately. Separately, this had led to adverse event patient information for named patients being emailed to representatives in breach of patient confidentiality and adverse event reporting procedures. The complainant questioned whether Sanofi-Aventis had followed the appropriate adverse event reporting procedures.**

**The detailed response from Sanofi-Aventis is given below.**

**The Panel noted that the parties' accounts differed. The complainant had not submitted any evidence in support of their allegation. The complainant had to establish his/her case on the balance of probabilities.**

**The Panel noted Sanofi-Aventis' submission regarding arrangements for the promotion of docetaxel by its sales force and the purchase of sales data. Representatives were expected to identify customer usage of Taxotere in specific tumour types. They had not been instructed to demand such data and no briefings had been issued. The Panel considered that there was no evidence to support the allegation that representatives had demanded data on patient numbers as alleged. No breach of the Code was ruled.**

**In relation to the alleged receipt of named patient data the Panel noted that an email from a hospital pharmacist to a representative about adverse reactions to Taxotere named the patients involved; the representative subsequently forwarded the email to her line manager and two colleagues. Patient details had not been requested by the representative or by the company on the Drug Experience Report Form. There was no evidence that the representative had requested patient details as inferred by the complainant. However the Panel was very concerned that the representative had subsequently forwarded the email to two other representatives. Once the representative knew that she ought not to have named patient data and that the onward transmission of such data was unacceptable she immediately notified the other representatives not to open the email. The Panel considered that the representative's original decision to circulate the email containing named patient data to anyone other than the pharmacovigilance department was unacceptable such that she had failed to maintain a high standard of ethical conduct in the discharge of her duties. A breach of the Code was ruled. This ruling was accepted. High standards had not been maintained; a breach of the Code was ruled. Upon appeal by Sanofi-Aventis, the Appeal Board noted that the company had accepted the ruling of a breach of the Code with regard to the representative's onward transmission of confidential patient data. The representative's manager, however, quickly spotted the mistake and the representative took immediate steps to rectify her error. In that regard the Appeal Board did not consider that high standards had not been maintained and no breach of the Code was ruled. The appeal on this point was successful.**

**The Panel noted that a presentation for new starters 'The Handling of Adverse Drug Reactions' explained the importance of pharmacovigilance and reporting procedures. Refresher training gave more details. Representatives were instructed to provide details of *inter alia* 'Patient details (initials, age, age range, gender). A slide headed 'Good Reporting Practice' referred to patient's demography (mostly age); medical history/concomitant diseases and additional information. Neither presentation referred to the importance of maintaining patient confidentiality which the Panel considered was a significant omission such that the material in effect advocated a course of action which was likely to lead to a breach of the Code, a breach of the Code was ruled. Upon appeal by Sanofi-Aventis, the Appeal Board noted that neither presentation referred to the importance of maintaining patient confidentiality. This was an important omission; there should have been some reference to anonymised data. Nonetheless, the Appeal Board did not consider that such an omission positively advocated a course of action which was likely to lead to a breach of the Code. No breach of the Code was ruled. The appeal on this point was successful.**

**The representative had reported information on side effects to the company's scientific service; no breach of the Code was ruled.**

**The Panel was concerned about the conduct of the representative but noted its rulings above. Overall the Panel did not consider that the representative's conduct warranted a ruling of a breach of Clause 2 which was reserved to indicate particular censure.**

An anonymous uncontactable complainant complained about the conduct of Sanofi-Aventis oncology representatives.

**COMPLAINT**

The complainant alleged that Sanofi-Aventis oncology representatives in one UK region had demanded data on patient numbers being treated on docetaxel (Sanofi-Aventis' product Taxotere) and its competitor medicines for all local hospitals. Printouts of this data comparing 2008 and 2009 had been given to them; the complainant asked that this practice be stopped immediately. Separately, this had led to adverse event patient information for named patients being emailed to representatives in breach of patient confidentiality and adverse event reporting procedures. The complainant questioned whether Sanofi-Aventis had followed the appropriate adverse event reporting procedures.

When writing to Sanofi-Aventis the Authority asked it to respond in relation to Clauses 2, 9.1, 15.2, 15.6, 15.9 and 18.4 of the Code.

**RESPONSE**

Sanofi-Aventis submitted that it had conducted an extensive investigation into the activities of all oncology representatives in question. The investigation had included reviews of all representatives' emails and documents saved on company systems and interviews with those representatives who were most relevant to the findings. The complainant referred to data comparing 2008 and 2009 usage figures being provided to representatives; there was otherwise no clear time frame for the activities subject to complaint and, on this basis, Sanofi-Aventis had therefore concentrated its investigation on the 6 months period prior to the complaint.

Sanofi-Aventis noted that the complainant alleged that Sanofi-Aventis representatives had demanded data on patient numbers being treated on docetaxel and its competitor medicines for all hospitals within one region. Printouts of this data comparing 2008 and 2009 had been given to them and the complainant had asked that this practice be stopped immediately. Docetaxel (Taxotere) was licensed in several different tumour types but it was only actively promoted for use in breast and prostate tumours, by representatives dedicated to one or the other type. Thus, each hospital would have two Taxotere representatives, one promoting its use in breast and one in prostate. However sales data did not detail Taxotere usage according to tumour type; it simply reported total sales for any given hospital. Such data were inadequate for detailed planning and reporting purposes for individual tumour-specific representatives. In order to redress this:

- The company purchased data from the NHS which showed the breakdown by tumour type of Taxotere and its competitors, for the local area. The NHS sold this data to a wide range of companies and there was considerable uptake of the report by the pharmaceutical industry. These were the only data received by the company from the NHS which included any information on competitors. A copy of the most recent data was provided.

- Representatives were expected, in the normal course of their duties, to identify customer usage of Taxotere in specific tumour types. This was a standard part of their duties and consistent with maintaining good relations with NHS customers and appropriate planning of current and future representative activity. However, representatives were neither incentivised for obtaining such data, nor penalised for not. On this basis, there had been no formal written or verbal briefings issued on the matter. Sanofi-Aventis had conducted a thorough review of all briefing documents, none of which directed, or could be interpreted to direct, sales representatives to 'demand' usage data. It was clear that these data belonged to the NHS, and it was the goodwill of individual health professionals which enabled Sanofi-Aventis to receive this feedback; while there had never been any instruction to 'demand' such data, to do so would, in any case, be counter-productive and severely detrimental to the relationship between health professional and representative.

Although availability of such data helped the company to evaluate whether sales objectives or specific goals had been achieved, Sanofi-Aventis confirmed that collection of such data was not a specific objective for representatives.

Sanofi-Aventis was confident that its representatives maintained professional relations with all customers and it had found no evidence of any 'demands' for any data relating to product usage, either for Taxotere or competitor products. Sanofi-Aventis therefore denied any breaches of the Code as alleged by the complainant in this context.

Sanofi-Aventis attached the utmost importance to the correct and timely reporting of all suspected adverse events relating to its medicines. On this basis, all staff, including representatives, were trained in adverse event reporting requirements and related company procedures on first joining the company, and periodically thereafter. Copies of the training materials used for new staff and for refresher training of representatives were provided, as were the company's standard operating procedures for pharmacovigilance training and reporting of suspected adverse events. The requirement to report all adverse events was also included in the training on the Code given to all representatives joining the company, a copy of which was also provided.

Sanofi-Aventis noted that the complainant had also alleged that adverse event patient information for named patients had been emailed to representatives in breach of patient confidentiality and adverse event reporting procedures. As the complainant had linked this part of the complaint to the first which related to a specific UK region, Sanofi-Aventis submitted that it had again investigated this in relation to the oncology

representatives who worked in this region, over the same time period as above, ie the 6 months prior to the complaint. Again, Sanofi-Aventis had reviewed all emails and documents for each in order to identify material relevant to the complaint. Additionally, Sanofi-Aventis had reviewed all adverse event reports made via its oncology sales team nationwide over the last 12 months for any patient names or other uniquely identifying details.

Sanofi-Aventis submitted that it had identified a single incident in which a representative received patient names as part of the follow up of an adverse event report.

The representative in question visited a hospital on 15 June 2009 and was informed of several hypersensitivity reactions to Taxotere by the chemotherapy nurses. In accordance with company procedures, the representative notified the pharmacovigilance department within one working day, ie on 16 June. The same day, the pharmacovigilance department sent adverse event reporting forms to the representative for distribution to the relevant staff at the hospital. The pharmacovigilance department subsequently submitted an initial report as required by company procedures, on 19 June. Unfortunately, no follow-up information was received from the hospital and so the pharmacovigilance department asked the representative to visit the hospital again to obtain the required information. As a result, a pharmacist at the hospital subsequently emailed the representative with details of the reactions experienced, including patient names in full. At no stage had names been requested, either directly by the representative or via the Drug Experience Report Form used for adverse event reporting (an example of which was provided). The representative forwarded this email to her manager and two colleagues in the area for information; her manager responded the next day informing her that she must not be in possession of patient names as this could compromise her position and had implications for patient confidentiality (the email trail was provided). The representative subsequently:

- contacted the pharmacist at the hospital to thank her for her cooperation, but pointed out that as a representative she should not be privy to patient names and that they had been deleted;
- attempted (twice) to recall the emails with patient details which she had forwarded to colleagues; when this failed she sent a message asking that the email from the hospital pharmacist not be read;
- reported the follow-up information (with patient names deleted) to the pharmacovigilance department.

In summary, Sanofi-Aventis submitted that its extensive investigations had identified only one incident where patient names had been provided, entirely unsolicited, to an oncology representative by a hospital pharmacist. It was regrettable that the representative did not delete the patients' names from the information she sent on to her manager and two close colleagues working in the same area. However this oversight was immediately identified by her manager and the representative then took all measures available to her to mitigate the effects of her actions. Sanofi-Aventis maintained detailed systems and training on adverse event reporting for all staff including representatives, and in relation to this case, reporting requirements were adhered to as far as was possible, with the exception of the transmission of patient names. Sanofi-Aventis therefore denied any suggestions that this was anything other than an isolated incident and refuted the alleged breaches of the Code.

Sanofi-Aventis submitted that the complainant's allegations had been addressed in detail above. Whilst Sanofi-Aventis had conducted an extensive investigation into the issues involved, it noted that the complainant had not provided any evidence to substantiate his/her assertions. Overall, Sanofi-Aventis submitted that Clause 18.4 was not relevant to the circumstances and there was no evidence to indicate any breach of Clauses 2, 9.1, 15.2, 15.6 and 15.9.

**PANEL RULING**

The Panel noted that the parties' accounts differed. Sanofi-Aventis denied the complainant's allegation that representatives had demanded data on the number of patients treated with docetaxel. The complainant who was anonymous and non contactable had not submitted any evidence in support of their allegation. The complainant had to establish his/her case on the balance of probabilities.

The Panel noted Sanofi-Aventis' submission regarding arrangements for the promotion of docetaxel by its sales force and the purchase of sales data. Representatives were expected to identify customer usage of Taxotere in specific tumour types. There had been no instruction to demand such data and thus no verbal or written briefings had been issued on this point. The Panel considered that there was no evidence to support the allegation that representatives had demanded data on patient numbers as alleged. No breach of Clauses 15.2 and 15.9 was ruled.

In relation to the alleged receipt of named patient data the Panel noted that a representative had initially been told of several hypersensitivity reactions to Taxotere by hospital nurses. This was followed up by the representative and the pharmacovigilance department at Sanofi-Aventis. The Panel noted that an email from a hospital pharmacist to the representative about these adverse events named the patients involved; the representative subsequently forwarded the email **to** her line manager and two colleagues. Patient details had not been requested by the

representative or by the company on the Drug Experience Report Form. The Panel noted that the representative had legitimately followed up the initial report of the adverse events. There was no evidence that the representative had requested patient details as inferred by the complainant. However the Panel was very concerned that the representative had subsequently forwarded the email to two other representatives. Once the representative was made aware that she ought not to be in possession of named patient data and that the onward transmission of such data was unacceptable she immediately took steps to notify the other representatives not to open the email. The Panel considered that the representative's original decision to circulate the email containing named patient data to anyone other than the pharmacovigilance department was unacceptable such that she had failed to maintain a high standard of ethical conduct in the discharge of her duties. A breach of Clause 15.2 was ruled. This ruling was accepted. High standards had not been maintained; a breach of Clause 9.1 was ruled. This ruling was appealed.

The Panel noted that the presentation for new starters 'The Handling of Adverse Drug Reactions' explained the importance of pharmacovigilance and reporting procedures. The refresher training gave more details. Representatives were instructed to provide details of *inter alia* 'Patient details (initials, age, age range, gender). A slide headed 'Good Reporting Practice' referred to patient's demography (mostly age); medical history/concomitant diseases and additional information. Neither presentation referred to the importance of maintaining patient confidentiality which the Panel considered was a significant omission such that the material in effect advocated a course of action which was likely to lead to a breach of the Code, a breach of Clause 15.9 was ruled. This ruling was appealed.

The representative had reported information on side effects to the company's scientific service as required by Clause 15.6 so no breach of that clause was ruled.

The Panel was concerned about the conduct of the representative but noted its rulings above. Overall the Panel did not consider that the representative's conduct warranted a ruling of a breach of Clause 2 which was reserved to indicate particular censure. No breach of Clause 2 was ruled.

The Panel made no ruling in relation to Clause 18.4 as on receipt of the company's response it transpired that it was not relevant to the matters at issue.

**APPEAL BY SANOFI-AVENTIS**

Sanofi-Aventis submitted that its pharmacovigilance training material for representatives incorporated the requirements outlined in guidance issued by the Medicines and Healthcare products Regulatory Agency (MHRA) with regard to patient details required to be reported where there was a suspected adverse event. The training materials did not extend beyond these requirements. In particular, neither the materials nor the company advocated or suggested the collection or dissemination of patient names or other details which would compromise patient confidentiality. This was borne out by the evidence that, apart from the one incident on which this case was based, a comprehensive review of all adverse event reports showed that patient names were never used or referred to, and all patient details were within the MHRA guidance on which Sanofi-Aventis's training was based. In the one case where patient names were transmitted within the company by a representative, the names were not requested or solicited by the representative and following her manager's intervention, she contacted the reporting pharmacist to clarify the requirements in this area (audit trail previously submitted).

For the avoidance of doubt, Sanofi-Aventis would include statements to this effect in all future training materials. However, the current training materials were appropriate; they included correct and appropriate instructions on what patient data to collect, and although further detail on patient confidentiality was not formally presented, the otherwise universal adherence of representatives to these requirements did not support the notion that the materials advocated a course of action likely to lead to a breach of the Code. Sanofi-Aventis therefore appealed against the ruling of breach of Clause 15.9, ie that on the balance of probabilities, the training advocated a course of action which would be likely to breach the Code.

Sanofi-Aventis appealed the Panel's ruling of breach of Clause 9.1 because it had appealed the ruling of breach of Clause 15.9 and because its extensive investigation into the matters raised by the complainant had revealed one isolated incident of inappropriate transmission of patient names (which were unsolicited by Sanofi-Aventis representative), and otherwise no evidence of any more widespread or systematic divergence from the MHRA requirements on patient details. Given this unique event, which was not the result of any company instruction, Sanofi-Aventis submitted that it was not possible to determine, on the balance of probabilities, that it had failed to meet high standards overall.

**APPEAL BOARD RULING**

The Appeal Board noted that Sanofi-Aventis had accepted the ruling of a breach of Clause 15.2 with regard to the representative's onward transmission of confidential patient data to her field force colleagues. The representative's manager, however, quickly spotted the mistake and the representative took immediate steps to rectify her error. In that regard the Appeal Board did not consider that high standards had not been

maintained and no breach of Clause 9.1 was ruled. The appeal on this point was successful.

The Appeal Board noted that neither the presentation for new starters, 'The Handling of Adverse Drug Reactions', nor the refresher training slides referred to the importance of maintaining patient confidentiality. The Appeal Board thought that this was an important omission; there should have been some reference to anonymised data. Nonetheless, the Appeal Board did not consider that such an omission positively advocated a course of action which was likely to lead to a breach of the Code. No breach of Clause 15.9 was ruled. The appeal on this point was successful.

**Complaint received** **24 August 2009**

**Case completed** **11 November 2009**