ANONYMOUS EX-EMPLOYEE v SANOFI

Activities of sales and medical teams

An anonymous complainant who stated he/she was an ex-employee of Sanofi, alleged that members of the medical oncology team were being pressurised to proactively generate contacts with key oncologists and contact rates were regularly monitored to reinforce the point. The complainant considered that the medical team was, at times, asked to act as an extra sales team. The complainant understood the role to be a reactive one to customer requests, however, he/she was pushed to promote unlicensed medicines. The complainant also alleged that sales representatives were instructed to make more calls per year than allowed under the Code and to ask health professionals for support in challenging a decision by the National Institute for Health and Clinical Excellence (NICE).

The detailed response from Sanofi is given below.

The Panel noted that the complainant was anonymous and non-contactable 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, judged on the evidence provided by the parties.

The Panel noted that one of the key results/accountabilities for the scientific advisors was to proactively 'engage with external stakeholders in the exchange of "within licence" scientific data in a balanced, non-promotional manner and not in conjunction with any promotional-related person or activity'. The Panel considered that, given the definition of promotion in the Code, the proactive element of the role was promotional and so the scientific advisors had a mixed role – non-promotional and promotional. When carrying out their promotional role, the scientific advisors were thus covered by the specific requirements in the Code for representatives (as defined in the Code).

The Panel noted that the complainant had provided no evidence in relation to the allegations on contact rates. Sanofi broadly expected scientific advisors to achieve a certain number of customer contacts per week to include face-to-face contacts, meetings, substantive email response or telephone calls. The Panel considered that there was no evidence to suggest that a call rate had been set that exceeded the restriction in the supplementary information to the Code and ruled no breach. The Panel was concerned that Sanofi had not provided any relevant briefing document regarding the expected contacts per week but considered that there was no evidence before it to suggest that the scientific advisors were briefed in a way that would advocate, directly or indirectly, a course of action which would be likely to lead to a breach of the Code and no breach was ruled.

The Panel considered that there was no evidence before it to suggest that the scientific advisors had proactively informed health professionals about medicines that did not have a marketing authorization and no breach of the Code was ruled.

With regard to the allegation that Sanofi representatives had asked health professionals for support in challenging a decision by NICE the Panel noted Sanofi's submission that the representative in question had contacted a health professional to request support for a Cancer Drugs Fund (CDF) application for Jevtana (cabazitaxel) funding within one region. The Panel was concerned that there was no written briefing instructions on the process but considered that there was no evidence before it to suggest that the representative in question or Sanofi had failed to maintain high standards in relation to this contact. No breaches of the Code were ruled.

The Panel noted its rulings above and consequently ruled no breach of Clause 2.

An anonymous, non-contactable complainant who stated he/she was an ex-employee of Sanofi, alleged that members of the medical oncology team were being pressurised to proactively generate contacts with key oncologists and were required to adhere to contact rates against which they were regularly monitored. In addition, the complainant alleged that sales representatives were instructed to make a number of calls per year which exceeded that stipulated in the Code and they contacted health professionals to gain support in challenging a decision by the National Institute for Health and Clinical Excellence (NICE).

When contacting Sanofi the Authority asked it to respond in relation to the requirements of Clauses 3.1, 15.2, 15.4, 15.9, 9.1 and 2.

COMPLAINT

The complainant alleged that during his/her time in the medical team he/she was constantly pressurised to proactively generate contacts with key oncologists and contact rate tables were presented against which the team was regularly monitored to reinforce the point.

The complainant stated that it was only recently that the medical team was excluded from sales team and sales strategy meetings. Previously the medical team discussed key customers and sales, and at times the complainant considered that the medical team had been asked to act as an extra sales team.

The complainant alleged that the target number of customers he/she had been given to see over a specific period of time could only be met if the team worked proactively. The complainant always

understood the role to be a reactive one to customer requests. However, he/she was pushed to carry out this promotion for a group of unlicensed medicines such as the parp inhibitor, cabazitaxel, ombrabrulin, larotaxel and alvocidib.

The complainant further alleged that the sales team was consistently instructed to plan at least 12 calls a year on key customers and it was only following the recent integration with Genzyme, whose sales team refused to carry out this mandate; they strongly stated that if they were forced to do more than what the Code stipulated they would complain. In the last few weeks communication was sent out to ignore and change the 12 contact rule.

The complainant alleged that a greater transgression occurred when cabazitaxel (Jevtana) was denied NICE approval last year. The sales team was instructed to proactively ask key customers to write to NICE to challenge the decision and show support. One of the complainant's colleagues had referred to an email from a representative who had followed the above strategy and then received an email from a consultant oncologist who stated that he believed the representative's request to be unethical and unprofessional.

The complainant stated that if a proper investigation was carried out more transgressions would be found. However, due to fear of the current regime and retaliation, currently employed individuals would not openly volunteer this information. The complainant had to leave to even have the courage to highlight certain issues around Sanofi Oncology regularly operating outside of the Code.

RESPONSE

Sanofi submitted that it had a clear, well communicated and confidential whistle-blower policy which allowed any employee to make representation if they were concerned about any activity within the company. In addition, the Sanofi Oncology scientific advisor team (of which the complainant claimed to be a former member) enjoyed a very open management style and had meetings every six to eight weeks at which any topic could be freely and openly discussed. None of the issues raised in the complaint had ever been brought to Sanofi's attention via either of these routes.

Sanofi submitted that its oncology scientific advisors were responsible for providing customers with balanced, non-promotional scientific and technical information. A copy of the scientific advisor job description was provided together with a slide set from a recent training session delivered by the head of promotional affairs and associate medical director, clarifying the role.

Sanofi stated that interviews with the oncology medical manager (to whom the scientific advisor team reported) and a member of the oncology scientific advisor team confirmed that in line with the nature of the scientific advisor role, there were no contact rate targets and contact rates formed no part of the objectives or remuneration target for scientific advisors. Similarly there was no pressure on contact rates. There was a broad expectation of a certain number of customer contacts per week (details were provided) and scientific advisors were also expected to spend one day a week on research or study to maintain their role. There was no requirement for proactive promotion.

Sanofi submitted that with regard to the products mentioned, Jevtana was a licensed product; iniparib, presumably the 'parp inhibitor' [*sic*], was an early stage development candidate; ombrabulin was in late stage development; larotaxel and alvocidib were discontinued from development in February 2010 and November 2010, respectively.

Sanofi stated that Jevtana was comprehensively briefed to the scientific advisors with regard to the mode of action, clinical data and therapeutic area (slides were provided). Iniparib and ombrabulin were mentioned in summary briefs to the scientific advisors so they were aware of the Sanofi oncology pipeline when this information became publicly available (slides were provided).

Sanofi submitted that it had found no evidence of the '12 contact rule' referred to by the complainant and that such a contact rate would be inappropriate and non-compliant.

Sanofi further submitted that it had investigated the topic of scientific advisors being at the same meetings as sales teams. The terms 'sales team and sales strategy' were not used at Sanofi and hence could not be commented upon. Sanofi stated that scientific advisors were at the same sessions as sales teams only when appropriate, eg product or therapeutic area training, general company briefing or training on adverse event reporting, the Medicines Act or the Code. Scientific advisors were not present when promotional activities were discussed or briefed.

Sanofi noted the complainant stated that the sales team was proactively asked to solicit support for the Jevtana NICE review. The sales teams were appropriately briefed on the NICE process for Jevtana with the relevant information provided to health professionals to allow them to make representations to NICE should they wish. Sanofi's investigation had identified no evidence of inappropriate approaches in this respect.

Sanofi stated that the email referred to by the complainant concerned not the NICE review but a request to support the Cancer Drugs Fund (CDF) application for Jevtana funding within one region. The representative in question provided a copy of the email in which a health professional stated, *inter alia*, that the request 'might have put his objectivity & ethical approach at risk', especially as Sanofi had supported his attendance at a European oncology congress. The representative in question had not known that the health professional had been invited to attend the congress; if he/she had, he/she would not have approached him. Subsequent discussion had resolved any misunderstanding with the health professional concerned. A copy of the email was provided.

Sanofi submitted that it had found no evidence to support the complainant's allegations and it thus denied any breach of the Code.

Following a request for further information, Sanofi confirmed that the expected number of clinician contacts per week (face-to-face, at a meeting, through substantive email response or telephone call) was in place prior to the Genzyme integration and had always been an expectation for oncology scientific advisors.

Sanofi stated that the presentation given to clarify the role of the scientific advisors was made to all scientific advisors (oncology, diabetes and cardiovascular/renal) on 20 February 2012. The presentation was not for a specific reason, it was an update/refresher to reinforce the principles that the company followed. There were several new scientific advisors in the post and it was an appropriate topic at the first cross-division medical and scientific affairs meeting of the year in order to confirm current standards and share best practice between new and experienced scientific advisors. Sanofi provided details of the number of the number of oncology scientific advisors in the UK and Ireland and stated that the team reported to the medical manager, oncology (an organogram was provided).

Sanofi submitted that the slides on pipeline products were provided to the oncology scientific advisors to update them when the information became publicly available (these slides were routinely updated on the public Sanofi.com website). No briefing was given as scientific advisors knew that before the content of these slides could be used in communications to customers they would need to be formally reviewed and approved.

Sanofi stated that scientific advisors and commercial colleagues did not meet to discuss key customers and sales or promotional activities or when promotional activities were briefed. As stated above they were only together in relevant sessions such as product or therapeutic area training etc.

Sanofi explained that the scientific advisors' objectives were as described in the job description provided and their bonus was not related to sales performance other then as a factor in overall company performance.

Sanofi confirmed that it had provided the Authority with all material used by the scientific advisors relating to the products mentioned above. There was no written instruction or brief to the sales teams about the NICE approval of Jevtana and soliciting support, nor was there any such written instruction or briefing about contacting health professionals to request support for the CDF application for Jevtana. Sanofi submitted that it concluded that there was no evidence of inappropriate approaches in relation to representatives soliciting support for the Jevtana NICE review following its interview of the sales manager and the representative in question.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable 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, judged on the evidence provided by the parties.

The Panel noted from the scientific advisor job description that one of the key results/accountabilities for the role was to proactively 'engage with external stakeholders in the exchange of "within licence" scientific data in a balanced, non-promotional manner and not in conjunction with any promotional-related person or activity'. The organogram showed that, through their manager, the scientific advisors had a solid reporting line to a business unit director in addition to a dotted reporting line to the medical director. The slide set which clarified the scientific advisors' role stated that it was non-promotional because the approach was predominantly reactive. The Panel considered, however, that, given the definition of promotion in Clause 1.2 of the Code, the proactive element of the role was promotional which meant that the scientific advisors had a mixed role – non-promotional and promotional. When carrying out their promotional role, the scientific advisors were thus covered by the specific requirements in the Code for representatives (as defined in Clause 1.6), including, *inter alia*, Clauses 15 and 16.

The Panel noted that the complainant alleged that the scientific advisors were constantly pressurised to proactively generate contacts with key oncologists and contact rate tables were regularly presented against which the team were monitored. The Panel further noted the complainant's allegation that the sales team were consistently instructed to plan at least 12 calls per year on key customers.

The supplementary information to Clause 15.4 stated that the number of calls made on a doctor or other prescriber by a representative each year should not normally exceed three on average. This did not include the attendance at group meetings, a visit requested by a doctor or other prescriber, a call made in order to respond to a specific enquiry or a visit to follow up a report of an adverse reaction.

The Panel noted that the complainant had provided no evidence in relation to the allegations on contact rates. Sanofi had submitted that it had found no evidence of the '12 contact rule' but that it had a broad expectation that scientific advisors would achieve a certain number of customer contacts per week to include face-to-face contacts, meetings, substantive email response or telephone calls. The Panel considered that there was no evidence to suggest that a call rate had been set that exceeded the restriction in the supplementary information to Clause 15.4 and ruled no breach of that clause. The Panel was concerned that despite asking it to do so, Sanofi had not provided any briefing document regarding the expected number of customer contacts that the scientific advisors would have per week. However, it considered that there was no evidence before it to suggest that the scientific advisors were briefed in a way that would advocate, either directly or indirectly, a course of action which would be likely to lead to a breach of the Code and no breach of Clause 15.9 was ruled.

The Panel noted the complainant's allegation that he/she, as a scientific advisor was pushed to promote a number unlicensed medicines. Sanofi submitted that iniparib and ombrabulin were mentioned in summary briefs to the scientific advisors so they were aware of the Sanofi oncology pipeline when this information became publicly available. This briefing took place when the information was placed on the Sanofi.com website. The Panel was concerned that there was no briefing to the scientific advisors which clearly stated that they could not proactively share the pipeline information with health professionals; there was no statement on the slides that the information was for in-house use only. However, the Panel considered that there was no evidence before it to suggest that the scientific advisors had proactively provided information to health professionals about medicines that did not have a marketing authorization and no breach of Clause 3.1 was ruled.

The Panel noted the complainant's allegation that Sanofi representatives had contacted health professionals to gain their support in challenging a decision by NICE. Sanofi submitted that the representative in question had in fact contacted a health professional to request support for the CDF application for Jevtana funding within one region. The Panel considered that it was not necessarily unacceptable for companies to ask health professionals to challenge decisions by bodies such as NICE and the CDF, but it must be done in a way that complied with the Code.

The Panel noted from the email response in question that the health professional who had been asked to support the CDF application for Jevtana funding considered that the representative's request 'might have put his objectivity & ethical approach at risk', especially as Sanofi had supported his attendance at a European oncology congress. The Panel further noted Sanofi's submission that the representative in question was unaware that the health professional had been invited by Sanofi to attend the congress and that if he/she had he/she would not have approached him. Subsequent discussion had resolved any misunderstanding with the health professional concerned. The Panel was concerned that there was no written briefing instructions on the process for contacting health professionals to request support for the CDF application. However, the Panel considered that there was no evidence before it to suggest that the representative in question or Sanofi had failed to maintain high standards in relation to this contact. No breach of Clauses 15.2 and 9.1 were ruled.

The Panel noted its rulings above and consequently ruled no breach of Clause 2.

During the consideration of this case, the Panel was concerned to note that Sanofi had provided little in the way of formal briefing documents for the scientific advisors. This was unacceptable and represented poor practice. Given the dual nature of the scientific advisors' role, Sanofi was vulnerable under the Code and had been unable to respond robustly to the allegations made. The Panel noted that the Authority had recently issued informal guidance on Clause 3 of the Code and that this discussed in detail, *inter alia*, the role of medical and scientific liaison executives and the like. The Panel considered that Sanofi would be well advised to review the role of its scientific advisors in the light of that guidance.

Complaint received **9 May 2012**

Case completed **11 July 2012**