ANONYMOUS HEALTH PROFESSIONAL v SANOFI

Company meeting

An anonymous, non-contactable health professional complained about a meeting held in Barcelona in July 2015 that he/she was invited to attend by Sanofi.

The complainant noted that after being invited to attend the meeting, he/she was then told that it was cancelled as it was not compliant with Sanofi UK policies and the industry code of ethics as the medicine did not have a licence. The complainant alleged that the meeting was apparently still going to be held, however only some countries could attend. The complainant discovered that another UK colleague had attended and spoken at the meeting. The complainant was told that the meeting was clearly promotional about Praluent (alirocumab) and was the reason the UK did not attend. However, as that particular doctor was an investigator Sanofi had made an exception. The complainant's concern was how often and with how many other doctors exceptions had been made.

The detailed response from Sanofi is given below.

The Panel noted Sanofi's submission that the UK affiliate had no involvement in the organisation of and arrangements for the APEX meeting held in Barcelona in July 2015 which was organised by Sanofi's European Medical Affairs group for cardiovascular disease based at Sanofi's Paris office. The audience included 60 participants from Europe and 3 from China. Sanofi UK did not invite any UK health professionals to attend nor did any Sanofi UK staff attend. The Panel did not have a delegate list but noted that according to Sanofi there were no UK delegates in the audience. The Panel noted that a single UK health professional was contracted directly by the Sanofi European office to be present for the duration of the meeting.

In this regard the Panel noted that the UK company would be responsible for any acts and omissions of its overseas affiliate in relation to the speaker. Sanofi UK reviewed and confirmed that the Sanofi contractual arrangements were satisfactory.

The Panel noted that the UK health professional's role was to oversee the delivery of the meeting which included co-chairing, acting as a moderator/ facilitator for two workshops and delivering two presentations. The health professional was selected on the basis of his expertise in the epidemiology of atherosclerosis and involvement in alirocumab studies. The health professional had attended advisory boards concerning the alirocumab clinical trial programme.

The Panel noted Sanofi's submission that the objectives of the meeting were to share knowledge and experience on the clinical management of patients at high cardiovascular risk, and to provide a forum for exchange on how to facilitate the implementation of guidelines and latest evidence into clinical practice. Contrary to Sanofi's submission two of the five presentations mentioned alirocumab including the UK health professional's presentation which was also inconsistent with Sanofi's submission that he was not speaking about any Sanofi product.

The Panel had to consider whether alirocumab had been promoted to the UK health professional, prior to receiving its marketing authorisation. The Panel noted Sanofi's submission that at the time of the meeting alirocumab was under review by the EMA and subsequently received a positive opinion from the CHMP on 23 July 2015 and a European marketing authorisation in September 2015. In these circumstances and given Sanofi's role and commercial interest, the Panel queried whether such a meeting could be considered as anything other than promotional. The Panel noted the UK health professional's role at the meeting and that the contractual responsibilities required attendance for the entire time. The Panel noted Sanofi's submission that the health professional's expertise was such that he was already very familiar with all of the material presented. In the Panel's view the UK health professional was not present at the meeting at any point as a delegate. Given the health professional's role at the meeting and his involvement with the alirocumab studies, the Panel did not consider that alirocumab had been promoted to the UK health professional and thus on the narrow grounds of the complaint it had not been promoted prior to the grant of its marketing authorization. No breach of the Code was ruled. The Panel consequently ruled no breach of the Code in relation to the allegation of disguised promotion to the UK health professional. The Panel considered that there was no evidence to show that the health professional had not been suitably qualified to provide the services contracted or that his/her engagement had been an inducement to prescribe, supply, administer, recommend, buy or sell any medicine and no breaches of the Code were ruled. The Panel noted its rulings above and did not consider that Sanofi UK had failed to maintain high standards or brought discredit upon and reduced confidence in the pharmaceutical industry and ruled no breaches of the Code were ruled including Clause 2.

An anonymous, non-contactable health professional complained about a meeting titled APEX held in Barcelona 3-4 July 2015 that he/she was invited to attend by Sanofi.

COMPLAINT

The complainant stated that he/she had been invited to attend the meeting and was then told that it

was cancelled as it was not compliant with Sanofi UK policies and the industry code of ethics as the medicine was still under development and did not have a licence. The complainant alleged that the meeting was apparently still going to be held, however only some countries could attend. The complainant found this to be very ethical from Sanofi.

The complainant stated that after bumping into a colleague at the European Society of Cardiology (ESC), he/she discovered that another UK colleague had attended and spoken at the meeting. The complainant was told that the meeting was clearly promotional about Praluent (alirocumab) even though it was meant to be educational and was the reason the UK did not attend. However, as that particular doctor was the principal investigator in Sanofi's outcomes trial the company had made an exception.

The complainant found it to be very unethical and was horrified if it were true. The complainant stated that it sounded like serious misconduct and after the recent corruption and bribery headlines in the news thought it should be investigated further. The complainant's concern was how often and with how many other doctors exceptions had been made.

The complainant stated that he/she had engaged with many companies in the past and thankfully most did not act in such a manner, however it only took one to re-inforce the negative perception that many doctors already held about the pharmaceutical industry.

The complainant suggested that it was looked into as a serious matter if it were true.

When writing to Sanofi, the Authority asked it to consider the requirements of Clauses 2, 3.1, 9.1, 12.1, 18.1 and 23.1 of the Code.

RESPONSE

Sanofi stated that the APEX meeting was a medical education event organised by Sanofi's European Medical Affairs group for Cardiovascular Disease at Sanofi's Paris office. The UK affiliate had no involvement in, nor contributed to the organisation of and the arrangements for the meeting.

The meeting was a closed event organised and delivered by a steering committee of clinical experts contracted by Sanofi to deliver this service. The objectives of the meeting were to share knowledge and experience on the clinical management of patients at high cardiovascular risk, and to provide a forum for exchange on how to facilitate the implementation of guidelines and latest evidence into clinical practice. A copy of the agenda was provided along with membership of the steering committee.

The audience was by invitation, and comprised senior physicians from across Europe and China whose clinical or epidemiological practice concerned atherosclerosis and coronary heart disease. Attendees were nominated by medical affairs personnel from Sanofi. A total of 63 participants formed the audience (60 from Europe, 3 from China). In addition, 6 members of the APEX programme steering committee were present, four of whom also delivered or moderated plenary lectures. Three additional health professionals delivered or moderated plenary lectures. There were no UK clinicians in the audience and no Sanofi UK personnel attended. The Sanofi UK affiliate had not been able to receive the meeting materials in a timeframe sufficient to allow certification at a date early enough to allow attendees to make arrangements to attend. Sanofi UK therefore did not invite UK clinicians to attend.

The overall aim of the meeting was to expose the participants to up-to-date scientific knowledge on the identification, evaluation and management of patients with dyslipidaemia and at high risk of cardiovascular disease, and through the workshops to provide them with practical experience of identifying and addressing key issues.

Over the two days of the meeting, participants experienced five lectures totalling 3.5 hours, and spent 6-7 hours in workshop sessions (both contributing to their own and receiving feedback from other work streams). A copy of the final agenda was provided.

Day one of the meeting comprised an opening plenary with three lectures on epidemiology and treatment of atherosclerosis:

1 The current landscape, advances and challenges in dyslipidaemia (40 minutes)
2 The current landscape advances and challenges in atherosclerosis and high cardiovascular risk patients (40 minutes)
3 What are the challenges of diagnosing and treating familial hypercholesterolaemia in the real world? (40 minutes).

This was followed by a series of parallel workshops for participants to address key topics. In summary, the identification, management and challenges therein of patients at high risk of cardiovascular disease. The workshop session ran for 3 hours 40 minutes.

The second day started with a three hour session to review the outputs of the five work streams from Day 1. This was followed by a closing plenary session with two lectures below, before the meeting was summarised and closed.

4 The holistic management of patients with dyslipidaemia and high cardiovascular risk: the exciting future (45 minutes)
5 Moving towards absolute risk assessment to guide clinical decision making (45 minutes).

The materials used at the meeting were prepared by the individual speakers and not by Sanofi, and were in a format chosen by the presenters (either that of their own academic institution or a standard blank template). There was no style required nor applied to any materials used by presenters.

Having reviewed the entire content of the meeting, Sanofi submitted that it was clear that presentations 1, 2, 3 and 5 focussed only on dyslipidaemia/

atherosclerosis and its management. None of these presentations discussed Sanofi products (licensed or in development) – the most frequent reference to pharmacotherapy being (as expected) statins.

Presentation 4 sought to provide an overview of the various medicines and treatments currently in development for the management of dyslipidaemia/ atherosclerosis. The content of this presentation was broad, covering four areas: therapies directed against low-density lipoprotein (LDL), high-density lipoprotein (HDL), triglycerides, and other therapies. Sanofi had a product in only one of those categories – proprotein convertase subtilisin/kexin type 9 (PCSK-9) inhibitors to reduce LDL – in the form of alirocumab (Praluent), a PCSK-9 inhibitor.

In this presentation, which totalled 88 slides, PCSK-9 inhibitors were covered in 37 slides (42% of the content), of which 17 slides (19%) presented facts concerning alirocumab. A copy of the slides were provided.

At the time of the meeting alirocumab was under review by the EMA and subsequently received a positive opinion from the CHMP on 23 July 2015 and a European marketing authorisation in September 2015.

A single UK clinician attended in the role of steering committee member for the programme and was selected on the basis of his/her professional expertise in atherosclerosis. In addition, the health professional had a role in Sanofi's studies of alirocumab in atherosclerosis and had attended global advisory boards concerning the alirocumab clinical trial programme. The health professional was contracted directly by the Sanofi European office to be present for the duration of the meeting as a steering committee member. The health professional's role as steering committee member was to oversee the delivery of the meeting (which included chairing Day 1), and to act as moderator/ facilitator for two workshop sessions. In addition, the health professional was contracted to prepare and deliver two presentations:

- 'What are the challenges of diagnosing and treating familial hypercholesterolaemia in the real world?'
- 'Moving to absolute risk assessment to guide clinical decision making'.

Sanofi submitted that it was clear from the content of both the UK health professional's presentations that non-promotional lectures on those topics, were delivered. Sanofi products were not referred to at any point. In particular, there was no discussion on alirocumab.

In advance of the meeting, the UK affiliate reviewed the contractual arrangements made with the UK health professional, in accordance with its standard operating procedure (SOP) on the engagement of UK health professionals by overseas Sanofi entities. The review confirmed that:

- The UK health professional was appropriately qualified to deliver the required service.
- The nature of the meeting and hospitality/ subsistence provided were appropriate to allow a UK health professional to be contracted to deliver the service.
- The fee for service was in accordance with Sanofi's 'fair market value' policy on the determination of service fees.
- The contract between Sanofi and the UK health professional contained the specific clauses required for UK health professionals, including those concerning anti-bribery and corruption safeguards, transparency disclosure and allowable expenses for travel and subsistence.

Consideration was given as to whether the UK health professional's presentations required review and certification. Sanofi's SOP only required review of presentations by UK health professionals to a non-UK audience outside the UK when they were speaking about Sanofi products. It was clear from the details provided that the UK health professional was not speaking about any Sanofi product; the presentations were therefore neither reviewed nor certified in the UK. Responsibility to ensure the contents met the requirements where the meeting was organised/conducted (France/Spain) fell to the meeting organiser.

Copies of the UK health professional's presentations were provided; as these were not reviewed by the UK affiliate there was no certificate associated with them. A copy of the contract with the UK health professional was also provided.

Sanofi submitted that the meeting in question was organised independently of the UK company, which played no part in any arrangements, including the choice of venue, speakers, content of the meeting or selection of attendees. The UK's only action was to decline involvement through not being able to certify materials sufficiently in advance of the meeting to allow UK physicians to arrange to attend. Sanofi submitted that in that respect it applied sound principles consistent with the letter and spirit of the Code, and that no breach with respect to those points had occurred.

The UK health professional was contracted to be present at the entire meeting in his role as steering committee member and (at times) facilitator and speaker. The content of his presentations concerned disease processes only, without reference to Sanofi products. Furthermore, there was no audience member from the UK. Sanofi submitted that it was clear from the agenda that the health professional was not contracted to deliver promotion nor disguised promotion in any way. In that respect there was no evidence of any breach of Clause 18.1. The UK health professional was contracted to deliver the services described above as required by Clause 23.1, and Sanofi contended there had been no breach of that section of the Code.

The main question however was whether alirocumab was promoted to the UK health professional whilst he/she was present at the meeting. Sanofi submitted that this did not occur. The UK health professional attended the entire meeting in the contracted role of

steering committee member responsible for delivery of the meeting, rather than as a member of the audience to receive information. In that role health professional would already be familiar with the material that all speakers were to deliver.

Beyond this, the level of information provided in the plenary that covered alirocumab would be far less than that already known by the UK health professional considering his role in the alirocumab development programme. The health professional would have already been familiar with the properties of alirocumab in much greater detail than was covered in a 45 minute presentation covering the breadth of emerging therapies. The alirocumab studies presented had also been published in high-impact medical journals with which the UK health professional would have been fully familiar through his/her professional and academic standing. To suggest that the presentation promoted the use of alirocumab to this UK health professional was to imply that he/she would have limited prior knowledge of the product, which was clearly not the case.

In summary Sanofi submitted that the UK health professional's engagement as a service provider for the full meeting, at which there was presentation of data concerning a Sanofi product with which he/she was already deeply familiar could not be considered promotion to him/her. Sanofi therefore submitted that there was no breach of Clause 3.1.

Having reviewed the events preceding the APEX meeting and of the meeting itself, Sanofi submitted that it had followed the requirements of the Code. The UK affiliate had no involvement in the organisation of the meeting and did not allow UK health professionals to form part of the audience as arrangements for the meeting could not be provided sufficiently in advance.

The single UK attendee was present as an appropriately-contracted service provider for the duration of the meeting, was not required to (nor did he/she) deliver any promotion concerning Sanofi products. As a member of the organising committee, he was exposed to data on a Sanofi product in development on which he/she was already deeply familiar.

Sanofi submitted that no breach of Clauses 3.1, 18.1 or 23.1 occurred, and in consequence no breach of Clauses 9.1 or 2.

PANEL RULING

The Panel noted Sanofi's submission that the UK affiliate had no involvement in the organisation of and arrangements for the APEX meeting held in Barcelona in July 2015 which was organised by Sanofi's European Medical Affairs group for cardiovascular disease based at Sanofi's Paris office. The audience included 60 participants from Europe and 3 from China; Sanofi UK did not invite any UK health professionals to attend either as delegates or speakers. Nor did any Sanofi UK staff attend. The Panel did not have a delegate list but noted that according to Sanofi there were no UK delegates in the audience. The Panel noted that a single UK health professional was contracted directly by the Sanofi European office to be present for the duration of the meeting as a steering committee member which brought the complaint within the scope of the Code.

In this regard the Panel noted that the UK company would be responsible for any acts and omissions of its overseas affiliate in relation to the speaker. Sanofi UK reviewed and confirmed that the Sanofi contractual arrangements were satisfactory.

The Panel noted that the UK health professional's role was to oversee the delivery of the meeting which included co-chairing, acting as a moderator/facilitator for two workshops and delivering two presentations titled 'What are the challenges of diagnosing and treating familial hypercholesterolaemia in the real world' and 'Moving to absolute risk assessment to guide clinical decision making'. The health professional was selected on the basis of his expertise in atherosclerosis; he had also had a role for Sanofi's alirocumab studies and had attended advisory boards concerning the alirocumab clinical trial programme.

The Panel noted the complainant's allegation that the meeting promoted alirocumab. Alirocumab did not have a marketing authorization at the time of the meeting. The Panel noted Sanofi's submission that the objectives of the meeting were to share knowledge and experience on the clinical management of patients at high cardiovascular risk, and to provide a forum for exchange on how to facilitate the implementation of guidelines and latest evidence into clinical practice. Contrary to Sanofi's submission two of the five presentations mentioned alirocumab. 'The holistic management of patients with dyslipidaemia and high cardiovascular risk: the exciting future' provided an overview of the various medicines and treatments currently in development for the management of dyslipidaemia/atherosclerosis including alirocumab. The UK health professional's presentation 'Moving towards absolute risk assessment to guide clinical decision making' (presentation 5) included a slide on the ODYSSEY trial and alirocumab. This was also inconsistent with Sanofi's submission that the UK health professional was not speaking about any Sanofi product.

The Panel had to consider whether alirocumab had been promoted to the UK health professional, prior to receiving a marketing authorisation. The Panel noted Sanofi's submission that at the time of the meeting alirocumab was under review by the EMA and subsequently received a positive opinion from the CHMP on 23 July 2015 and a European marketing authorisation in September 2015. In these circumstances and given Sanofi's role and commercial interest, the Panel queried whether such a meeting could be considered as anything other than promotional. The Panel noted the UK health professional's role at the meeting and that the contractual responsibilities required attendance for the entire time. The Panel noted Sanofi's submission that the health professional's expertise was such that he was already very familiar with all of the

material presented. In the Panel's view the UK health professional was not present at the meeting at any point as a delegate. Given the health professional's role at the APEX meeting and his involvement with the alirocumab studies, the Panel did not consider that alirocumab had been promoted to the UK health professional and thus on the narrow grounds of the complaint it had not been promoted prior to the grant of its marketing authorization. The Panel ruled no breach of Clause 3.1. The Panel consequently ruled no breach of Clause 12.1 in relation to the allegation of disguised promotion to the UK health professional. The Panel considered that there was no evidence to show that the health professional had not been suitably qualified to provide the services contracted or that his/her engagement had been an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. The Panel therefore ruled no breach of Clause 23.1 and consequently no breach of Clause 18.1. The Panel noted its rulings above and did not consider that Sanofi UK had failed to maintain high standards or brought discredit upon and reduced confidence in the pharmaceutical industry. No breach of Clause 9.1 and consequently Clause 2 was ruled.

Complaint received **29 September 2015**

Case completed **28 October 2015**