

# CONSULTANT PHYSICIAN v SANOFI

## Arrangements for a meeting

A consultant physician, complained about the arrangements for a meeting organised by Sanofi.

An email from Sanofi invited the recipient to attend the Lyxumia Speaker Club to discuss the key data for Lyxumia with one of the lead investigators followed by an afternoon of professional development. The email also stated that the company was able to offer to pay £1000 for attending as it viewed the meeting as preparation for any Lyxumia talks to be delivered at meetings which the local sales team would organise. Payment would be made in 2 equal amounts at the first 2 talks delivered along with honoraria.

The complainant noted that he had been offered £1,000 to attend a class on Sanofi's new medicine, Lyxumia. This was justified on the grounds that it was training to allow him to deliver talks about Lyxumia in the future. The complainant stated that he had never had any plans to talk about Lyxumia and had not requested such training. The complainant alleged that the activity was a thinly-veiled attempt to pay him to attend a meeting with the primary purpose of marketing.

The detailed response from Sanofi is set out below.

The Panel noted that according to the agenda, the meeting commenced with coffee at 9.45am. 'Workshop 1 – Lyxumia slide kit' ran from 10.00am-12.30pm, a Q&A session with the training faculty after lunch from 1.15pm-1.45pm. The development workshops ran from 1.45pm to 4.15pm with a 15 minute coffee break and included conflict management, critical appraisal of clinical papers, health economics for non economists, media training and writing successful business cases.

The Panel noted that the complainant's submission that he/she had no, nor had ever stated any, plans to talk about Lyxumia. This appeared to be contrary to Sanofi's submission that those invited had either given verbal agreement prior to being sent the email or had shown interest in being a speaker for Sanofi on another diabetes topic.

The Panel queried why Sanofi had not contracted specific speakers before inviting them to attend one of the speaker club meetings rather than broadly inviting a mixture of health professionals, some of whom might go on to carry out speaker services and some of whom might not. Nonetheless, the Panel noted that payment for attending the Lyxumia speaker club meeting would only be made to the health professional on completion of the first two speaking engagements. The payment was a fee for service. It had not been offered or promised to those attending the meeting in connection with the promotion of Lyxumia as alleged. The Panel, on this narrow ground, ruled no breach of the Code.

The Code required that the hiring of a consultant to provide a relevant service must not be an inducement to prescribe, supply, administer, recommend buy or sell a medicine. The Panel noted its comments and the ruling above of no breach in relation to the payment. Whilst the Panel had some concerns about the arrangements it did not consider that the arrangements had failed to satisfy these requirements on the narrow ground alleged. No breach was ruled.

The Panel queried whether the invitation was sufficiently clear about the arrangements. The subject title of the email read 'Lixisenatide data review meeting' and this in the Panel's view implied that it was referring to a normal promotional meeting. This impression was compounded by the first two paragraphs which described the speaker club as a discussion of the key Lyxumia data with a lead investigator. It only became clear in the third paragraph that invitees were being asked to attend as consultants and they would be paid as such. A reader glancing at the email might get the impression that a £1000 fee was payable for attending a Lyxumia promotional meeting. Indeed this was the complainant's impression. Such an impression was unacceptable. The Panel considered that Sanofi had failed to maintain high standards and a breach was ruled.

The Panel noted its rulings above and did not consider the circumstances warranted a ruling of a breach of Clause 2 which was reserved as a sign of particular censure. No breach of Clause 2 was ruled.

A consultant physician, complained about the arrangements for a meeting organised by Sanofi.

An email from a Sanofi scientific advisor, diabetes, invited the recipient to attend the Lyxumia Speaker Club, which provided an opportunity to discuss the key data for Lyxumia with one of the lead investigators followed by an afternoon of professional development. The development workshops offered to attendees were conflict management, critical appraisal of clinical papers, health economics for non economists, media training, and writing successful business cases.

The email also stated that the company was able to offer to pay £1000 for attending as it viewed the meeting as preparation for any Lyxumia talks to be delivered at meetings which the local sales team would organise. Payment would be made in 2 equal amounts at the first 2 talks delivered along with honoraria.

## COMPLAINT

The complainant provided a copy of an email invitation sent by Sanofi. The complainant noted

that he had been offered £1,000 to attend a class on Sanofi's new medicine, Lyxumia. This was justified on the grounds that it was training to allow him to deliver talks about Lyxumia in the future. The complainant stated that he had never had any plans to talk about Lyxumia and had not requested such training.

The complainant alleged that the activity was a thinly-veiled attempt to pay him to attend a meeting with the primary purpose of marketing.

When writing to Sanofi the Authority asked it to respond in relation to the requirements of Clauses 2, 9.1, 18.1 and 20.1 of the Code.

## RESPONSE

Sanofi explained that the Lyxumia Speaker Club was a national medical education programme designed to help and support health professionals to credibly and confidently present the clinical data and evidence for Lyxumia when engaged as speakers at Sanofi organised meetings. The particular challenge was that when Lyxumia was launched, much of the clinical data was awaiting publication. It was clear that those whom Sanofi contracted as Lyxumia speakers needed to be able to understand and articulate all of the published and unpublished data within the marketing authorization. Therefore the Speaker Club programme was devised to ensure that any speakers engaged had all the information available regarding the data and could articulate it in an appropriate way.

The identified health professionals attended a full day of training (9.45am – 4.30pm) and the agenda was identical for each meeting. The morning session related purely to Lyxumia clinical data and the afternoon session related to skills which would support the speakers in their professional capacity. The Lyxumia workshop was facilitated by a member of the training faculty, who were external experts in diabetes and experienced academic speakers. All trainers were fully conversant with the Lyxumia clinical trial data. No sales personnel attended the meetings; they were attended only by members of the medical, marketing and professional relations teams.

Sanofi provided a representatives' briefing document which outlined the process for the Speaker Club including details of how to contract the speakers and also how to identify suitable attendees. These were nominated from those areas which were most likely to have speaker meetings rather than from all areas of the UK.

There had been five meetings since March 2013 and four more were planned. Details of the venues, trainers and numbers of attendees were provided.

There was no meeting invitation for this programme as it was intended only for those who would be engaged as speakers at Sanofi meetings. It was expected that a conversation between the customer and a member of the field or medical team would take place to explore whether a given health professional would wish to speak at Sanofi meetings.

Subsequent correspondence was then sent by the head of professional relations to confirm details such as date and development course preferred, the invitation to present at two subsequent local meetings and a clear indication that payment for undertaking those engagements would be made, alongside payment for preparation time in attending the speaker training session, on completion of the speaker engagements (as per the brief).

Meeting confirmation letters were sent to health professionals who had confirmed they would like to attend before each meeting. These were personalised for the recipient by the head of professional relations and emailed to the customer.

Sanofi submitted that attendance at the Lyxumia Speaker Club was preparation for delivering subsequent talks on Lyxumia to other health professionals. Lyxumia was a new product which had recently been launched in the diabetes market of which there was little knowledge or clinical experience. The rationale for providing training was so that the clinical trial programme could be discussed and any questions the speakers might have be confidently answered by the independent external experts who made up the training faculty. Payment was offered for the time spent in the data sessions of the Speaker Club in preparation for subsequent engagements (payment was only made when the engagements had been conducted). The amount to be paid varied per health professional depending upon his/her tier of expertise using the company's UK health professional fee grid. The amount to be paid was provided to the head of professional relations once the customer was confirmed. The amount was validated against the fee grid. Therefore whilst in this case the complainant could have received £1,000, this amount could be different for other attendees. All payments offered were calculated to cover the time spent in the Lyxumia data session at the Speaker Club; it did not cover any time the speaker might have spend at any of the development sessions associated with those meetings.

Reasonable travel to attend the Speaker Club was provided as per the Sanofi UK expenses policy and was paid at the first speaker engagement the health professional undertook on the production of valid receipts.

Sanofi recognised that it was normal practice for the pharmaceutical industry to engage specialists to speak at educational events to educate other health professionals about new products. It wanted to ensure that any health professionals who spoke at Sanofi-organised and sponsored events were confident in the newly available clinical data and the evidence base for Lyxumia. It was reasonable to pay health professionals who spoke on the company's behalf for the time it took them to prepare for such meetings and Sanofi classified attendance at the morning session of this educational meeting as preparation for future speaking engagements.

No individuals were paid to merely attend the meeting. Payment was only made upon subsequent delivery of services in the form of presentation at

a Sanofi-sponsored meeting. A payment of half the allowable fee was made for each of the first two occasions the health professional spoke for the company. Any subsequent meetings (beyond the first two) would attract purely a speaking fee.

Sanofi provided a copy of its relevant standard operating procedure (SOP).

Sanofi submitted that the training faculty had all extensively been involved in Lyxumia, either as an advisory board member (UK and/or global), involved in global educational presentations or as an investigator on the ELIXA study. There was one exception to this and details were provided as were details of the possible trainers.

Some of the trainers had attended a train the trainer workshop before the first speaker workshop took place where the scientific slide deck was developed by them to ensure that it supported the clinical evidence for the product and was deemed to be credible. The initial slide kit was certified in accordance with Clause 14 for the first Speaker Club in March 2013 (GBIE.LYX.13.01.06). This set was used at the three March and April Speaker Club meetings and provided to all attendees.

Following feedback at these meetings and subsequent publication of some of the data, the slide kit was updated. A replacement slide kit (ref GBIE.LYX.13.07.08 (1)) was to be used at the September and subsequent Lyxumia speaker meetings.

The field team member in question sent emails to eight customers and had initially spoken to six out of the eight customers and gained a verbal agreement before emailing to outline the details of the Speaker Club initiative. The local Sanofi diabetes specialists had also spoken to the customers about the Speaker Club before the emails were sent. Two of the doctors had previously given consent to speak for Sanofi, not related specifically to Lyxumia, but for another diabetes topic. Details of the customers contacted were provided: six had given verbal agreement prior to sending the email.

In summary, Sanofi stated that whilst it was concerned that a health professional had gained the impression that the meeting was '... a thinly-veiled attempt to pay me to attend a meeting with the primary purpose of marketing...' it was confident that the meeting and the arrangements relating to it complied with the Code.

The meeting had significant educational content both in terms of the Lyxumia session and the afternoon sessions. The objective of the meeting was not to market the product but to ensure full understanding of the complete data set for Lyxumia, a new product, (including published and unpublished data as well as summary of product characteristics requirements) to ensure that the clinicians engaged at Sanofi-organised meetings could present data in a way that reflected the evidence base for the medicine in line with the marketing authorization. No payment was made solely to attend the meeting; payment was linked to and only paid upon provision of speaker

services. As such Sanofi did not consider that the meeting breached Clauses 2, 9.1, 18.1 or 20.1.

## PANEL RULING

The Panel noted that Sanofi had not been provided with the identity of the complainant. It noted the complainant's allegation that the Lyxumia speaker club meeting was a thinly-veiled attempt to pay him to attend a meeting with the primary purpose of marketing.

The Panel examined the invitation which described the objective of the meeting as giving the health professional the opportunity to have a half day discussion on the key data for Lyxumia with one of the lead investigators and an afternoon of professional development of his/her choice. The agenda for the meeting was attached and the development workshops that could be signed up for were listed. The invitation explained that Sanofi would pay the health professional £1000 for attending as it was classed as preparation for any Lyxumia talks, organised by local sales teams, that would be delivered by the health professional. This would be paid in two equal amounts at his/her first two speaker meetings in addition to the honoraria. Travel expenses related to the Lyxumia speaker club meeting would also be paid at the first speaker meeting.

According to the agenda, the meeting commenced with coffee at 9.45am. 'Workshop 1 – Lyxumia slide kit' ran from 10.00am-12.30pm, a Q&A session with the training faculty after lunch from 1.15pm-1.45pm. The development workshops ran from 1.45pm to 4.15pm with a 15 minute coffee break. The development workshops included conflict management, critical appraisal of clinical papers, health economics for non economists, media training and writing successful business cases.

The Panel noted Sanofi's submission that attendance at the Lyxumia speaker club was preparation for speakers engaged to deliver talks on Lyxumia at Sanofi organised meetings. The Panel noted Sanofi's submission that payment was offered for time spent in the data session of the Lyxumia speaker club meeting in preparation for subsequent engagements in the form of a presentation at a Sanofi sponsored meeting and was only made in two equal amounts upon completion of each of the first two engagements.

The Panel noted the complainant's submission that he/she had no, nor had ever stated any, plans to talk about Lyxumia. This appeared to be contrary to Sanofi's submission that those invited had either given verbal agreement prior to being sent the email or if prior verbal agreement had not been given the relevant recipient had shown interest in being a speaker for Sanofi on another diabetes topic.

The Panel noted that engaging health professionals as consultants to speak at meetings was a legitimate activity. However, the arrangements had to fulfil certain criteria and otherwise comply with the Code.

The Panel noted Sanofi's submission that the objective of the meeting was not to market Lyxumia but was to ensure full understanding of the data set for Lyxumia to ensure that those clinicians that were engaged at Sanofi organised meetings could present the data in a way that reflected the evidence for the medicine in line with its marketing authorization. The Panel noted that Sanofi had run five Lyxumia Speaker Club meetings with 73 attendees and it intended to run four similar events with 3 attendees confirmed thus far. Venues included Birmingham, London, Scotland, Bristol and Leeds. The number of health professionals attending each event varied from 1 to 32. The agenda for all of the meetings were the same. The Panel queried whether the company needed in excess of 73 speakers nationally.

However, whilst at least 76 health professionals in total would have attended a Lyxumia speaker club meeting by the 5 November, not all would definitely go on to speak at a Sanofi organised meeting. With such a mixed audience Sanofi had to ensure that all of the material was appropriate for those health professionals who were not consultants; that it was all within licence and complied with the Code. The Panel queried why Sanofi had not contracted specific speakers before inviting them to attend one of the speaker club meetings rather than broadly inviting a mixture of health professionals, some of whom might go on to carry out speaker services and some of whom might not. Nonetheless, the Panel noted that payment for attending the Lyxumia speaker club meeting would only be made to the health professional on completion of the first two speaking engagements. The payment was a fee for service. It had not been offered or promised to those attending the meeting in connection with the promotion of Lyxumia as alleged. The Panel, on this narrow ground ruled no breach of Clause 18.1.

Clause 20.1 required that the hiring of a consultant to provide a relevant service must not be

an inducement to prescribe, supply, administer, recommend buy or sell a medicine. The Panel noted its comments and the ruling above of no breach of Clause 18.1 in relation to the payment. Whilst the Panel had some concerns about the arrangements it did not consider that the arrangements had failed to satisfy the requirements of Clause 20.1 on the narrow ground alleged. No breach of that clause was ruled.

The Panel queried whether the invitation was sufficiently clear about the arrangements. The subject title of the email read 'Lixisenatide data review meeting' and this in the Panel's view implied that it was referring to a normal promotional meeting. This impression was compounded by the first two paragraphs which described the speaker club as a discussion of the key Lyxumia data with a lead investigator. It only became clear in the third paragraph that invitees were being asked to attend as consultants and they would be paid as such. A reader glancing at the email might get the impression that a £1000 fee was payable for attending a Lyxumia promotional meeting. Indeed this was the complainant's impression. Such an impression was unacceptable. The Panel considered that Sanofi had failed to maintain high standards and a breach of Clause 9.1 was ruled.

The Panel noted its rulings above and did not consider the circumstances warranted a ruling of a breach of Clause 2 which was reserved as a sign of particular censure. No breach of Clause 2 was ruled.

<b>Complaint received</b>	<b>10 September 2013</b>
<b>Case completed</b>	<b>13 November 2013</b>