

VOLUNTARY ADMISSION BY SANOFI GENZYME

Inappropriate hospitality

Sanofi Genzyme voluntarily admitted that it invited members of patient organisations to the Biotech Industry Association's (BIA) gala dinner in 2014 and 2015 and provided hospitality where there was no scientific meeting, promotional meeting, scientific congress or training. In addition, the subsistence exceeded £75 per person excluding VAT and gratuities.

In accordance with Paragraph 5.6 of the Constitution and Procedure for the Prescription Medicines Code of Practice Authority, the Director treated the matter as a complaint.

The detailed response from Sanofi Genzyme is given below.

The Panel noted that the BIA's gala dinners were not meetings organised for health professionals, other relevant decision makers (ORDM) or patient associations *per se*. However each company that attended could invite guests of their choosing and in that sense the Panel considered that each company's involvement had to be judged on its own merits. The Panel noted that Sanofi Genzyme's involvement in the gala dinners in 2014 and 2015 was such that it came within the scope of the Code. The Panel noted that Sanofi Genzyme referred to taking members of patient associations to the gala dinner in the years prior to 2014 but no specific details were provided.

The Panel was unsure about all the arrangements for the gala dinners. It only had the limited information provided by Sanofi Genzyme. It appeared that the event was attended by senior figures in the industry, government and the media. It appeared that speeches were given by the BIA's Chairman, chief executive officer (CEO) and others. Some attendees were possibly invited by the trade association and others by companies. There appeared to be a social element to the occasion. The Panel noted there would be some professional benefit in attending the BIA gala dinner and considered that although it was an important event with an opportunity for networking etc, it could not be described as having a clear educational content with hospitality secondary to the main purpose as required by the Code. The venue was prestigious and the level of hospitality was significant.

The Panel noted that in 2014 Sanofi Genzyme had taken a table at the gala dinner. Three Sanofi Genzyme employees attended together with seven people from various patient organisations as its guests. Accommodation and travel had been paid for at least one attendee. The Panel noted that the cost of each gala dinner ticket in 2014 was £425 plus VAT. Accommodation was paid for at least one attendee at £160. The Sanofi Genzyme submission implied it had paid for accommodation for all patient organisation attendees. The gala dinner

in 2014 was covered by the Second 2012 Code as amended. The Panel considered that by inviting only patient organisation members, Sanofi Genzyme's involvement in the 2014 dinner was such that it had organised a meeting for patient organisations and a breach of the Code was ruled.

The Panel noted that in 2015 Sanofi Genzyme had taken a table of ten. It appeared that it only had five spaces filled all of which appeared to be company employees. The list provided showed that seven people attended from Genzyme and Sanofi. One guest was from a technology organisation and the other two guests were from patient organisations. The Panel noted Sanofi Genzyme's submission that the arrangements for the two patient organisation members attending the 2015 dinner were last minute verbal invitations. The Panel noted that the cost of the tickets in 2015 was £450 plus VAT and accommodation was provided for the two patient organisation attendees at £149.99 per attendee. Although not all Sanofi Genzyme's guests were from patient associations the Panel considered that inviting one person who was not from a patient organisation did not mean that the company had organised a corporate meeting rather than one for patient organisations.

The gala dinner in 2015 was covered by the 2014 Code. The Panel therefore ruled a breach of the Code in relation to Sanofi Genzyme's involvement in inviting patient organisations to the dinner in 2015. The Panel noted that although the cost of the food and drink was not provided given the increase in ticket price to £450 and the nature of the subsistence, it was very likely that this would cost more than £75 plus VAT and gratuities and a breach of the Code was ruled as acknowledged by Sanofi Genzyme.

Sanofi Genzyme made a voluntary admission of a number of breaches of the Code relating to the same matter which had just come to its attention.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint the matter was taken up with Sanofi Genzyme.

COMPLAINT

Sanofi Genzyme stated that in January 2015 the company invited two members of patient associations to join it for a gala dinner which was organised by the Biotech Industries Association (BIA) and held in January 2015. Hospitality included tickets to the dinner and overnight accommodation.

Accordingly, Sanofi Genzyme submitted that its actions breached Clause 22.1 because it provided hospitality where there was no scientific meeting,

promotional meeting, scientific congress or training. In addition, it breached Clause 22.2 as the subsistence exceeded £75 per person excluding VAT and gratuities.

Sanofi Genzyme would disclose these transfers of value in its disclosure for 2015.

Sanofi Genzyme also voluntarily admitted that it took members of patient organisations to the BIA's gala dinner in 2014 and previous years in breach of the Code. That hospitality was disclosed in its aggregated disclosure of payments made for 2013 and 2014.

Sanofi Genzyme attended the gala dinner in January 2016. However, it did not invite any members of patient associations and it was very clear that it should not and would not invite patient association members to such events in future.

This matter was discussed with the company by those carrying out the audit of Sanofi Genzyme on 9 February 2016.

The case preparation manager pointed out that given the transition arrangements, the January 2015 BIA dinner would come within the scope of the 2014 Code and so although Sanofi Genzyme cited Clauses 22.1 and 22.2 of the 2015 Code, the relevant clauses of the 2014 Code would be 19.1 and 19.2. Sanofi Genzyme also referred to taking members of patient associations to the gala dinner in 2014 and 2013. These activities would have been covered by Clause 19.1 of the Second 2012 Edition of the Code. There was no stated upper limit for hospitality in that Code although, as now, it was stated that the costs involved must not exceed the level which recipients would normally adopt when paying for themselves.

Sanofi Genzyme was asked to provide the PMCPA with any further comments in relation to the requirements of Clauses 19.1 and 19.2 of the 2014 Code and Clause 19.1 of the Second 2012 Edition of the Code.

RESPONSE

Sanofi Genzyme provided copies of the job bags approving the invitations to the gala dinner in 2014 – it did not have job bags for 2015 as the members of the patient associations were invited at the last minute verbally and did not go through its electronic approval system. Emails confirming attendance at the 2015 gala dinner following a verbal invitation together with hotel invoices were provided. Material describing the event, a table plan for 2015, the invoice and the Sanofi Genzyme attendance list for 2016 which did not include members of any patient organisations were provided. Finally, Sanofi Genzyme provided a copy of its new standard operating procedure (SOP) which required all activities with patient organisations to be reviewed for compliance with the Code.

Sanofi Genzyme submitted that the gala dinner cost £450 per head. In addition, it paid for the members of the patient association's overnight accommodation which in 2015 cost £149.99 for each guest.

In relation to the clauses cited by the case preparation manager, Clauses 19.1 and 19.2 of the 2014 Code in respect of the gala dinner in 2015 and Clause 19.1 of the 2012 Code in respect of the gala dinner in 2013 and 2014, Sanofi Genzyme submitted that it had breached the Code by inviting members of patient organisations to such an event.

The company now had clear policies in place. It did not take members of patient organisations to the BIA's gala dinner in 2016 and had decided to stop attending the gala dinner going forward.

In 2015 Sanofi Genzyme paid for two patient associations to attend the gala dinner. Accommodation and travel was paid for two attendees. It appeared that one other patient association had been invited but did not attend.

The gala dinner 2015 was described in an email as a prestigious black tie event at the National History Museum. There was a champagne and canapé reception in the Darwin Centre where guests could meet, network and enjoy 'fabulous surroundings'. This was followed by 'a delicious four course meal' in the Hintze Hall (formerly Central Hall), 'the home of the famous diplodocus skeleton'. There was an opportunity for further networking after the meal at a bar until midnight. The cost for a table of ten was £4,250, the same as 2014, for early bookers. Individual tickets in 2014 and 2015 were £295 plus VAT. The cost for 2015 increased to £325 plus VAT after 1 September 2014. The first increase since 2008.

In response to a request for further information Sanofi Genzyme confirmed that the verbal invitations for 2015 were because it had not originally intended to invite guests from patient associations but as a few places became available the company decided to invite them.

The 2014 gala dinner was described as 'the flagship BIA Gala Dinner continues to be the premier bioscience networking event of the year' and the 2013 dinner was a chance to network with biotech companies, government and the media to meet old friends and make new business contacts. The evening started with champagne and canapés followed by a splendid four course meal in the magnificent Central Hall. There were speeches from the BIA's chief executive officer (CEO) and the chosen charity.

PANEL RULING

The Panel noted that the provisions of Clause 19 of the 2014 Code and the Second 2012 Edition of the Code applied to meetings organised for health professionals regardless of whether the meetings were promotional or not. Clause 19.1 of the 2014 Code and the Second 2012 Edition permitted companies to provide appropriate hospitality to members of the health professions and appropriate administrative staff in association with scientific and promotional meetings. Hospitality must be secondary to the purpose of the meeting and the level of hospitality offered must be appropriate and not out of proportion to the occasion. The costs incurred must not exceed the level which recipients

would normally adopt if paying for themselves. It must not extend beyond members of the health professions or appropriate administrative staff. The supplementary information stated that the impression created by the arrangements must be borne in mind. Meetings organised for groups of doctors, other health professionals and/or administrative staff which were wholly or mainly of a social or sporting nature were unacceptable. The supplementary information also stated that the requirements of the Code did not apply to the provision of hospitality other than to those referred to in Clauses 19.1 and 24.2 and the supplementary information to Clauses 20 and 23.2. Clause 24.2 stated that the requirements of Clause 19, which covered meetings for health professionals and appropriate administrative staff, also applied to pharmaceutical companies supporting patient organisation meetings.

In addition, Clause 19.2 of the 2014 Code stated that the cost of a meal (including drinks) provided by way of subsistence must not exceed £75 per person excluding VAT and gratuities. The supplementary information to Clause 19.2 stated that the maximum of £75 plus VAT and gratuities was appropriate only in very exceptional circumstances, such as a dinner at a residential meeting for senior consultants or a dinner at a learned society conference with substantial educational content. The cost of a meal (including drinks) should normally be well below this figure. The requirements relating to hospitality in Clause 19.1 and its supplementary information applied in this case.

The Panel noted a previous case, Case AUTH/1604/7/04, which included a voluntary admission by a company in relation to its invitation to health professionals to attend the ABPI Annual Dinner in 2004 as guests of the company. Whilst noting that there had been substantial changes to the arrangements for the ABPI Annual Dinner since that time, the Panel considered that this previous case had some relevance to the case now before it. There had also been changes to the ABPI Code since then including the introduction of the financial limit for subsistence.

Turning back to Case AUTH/2821/2/16, the Panel noted that the gala dinner was not a meeting organised for health professionals, other relevant decision makers (ORDM) or patient associations *per se*. However each company that attended could invite guests of their choosing and in that sense the Panel considered that each company's involvement had to be judged on its own merits. The Panel noted that Sanofi Genzyme's involvement in the gala dinner in 2014 and 2015 was such that it came within the scope of the Code. The Panel noted that Sanofi Genzyme referred to taking members of patient associations to the gala dinner in the years prior to 2014 but no specific details were provided.

The Panel was unsure about all the arrangements for the gala dinners. It only had the limited information provided by Sanofi Genzyme. It appeared that the event was attended by senior figures in the industry, government and the media. It appeared that speeches were given by the BIA's Chairman, chief

executive officer (CEO) and others. Some attendees were possibly invited by the trade association and others by companies. There appeared to be a social element to the occasion. The Panel noted there would be some professional benefit in attending the BIA's gala dinner and considered that although the gala dinner was an important event with an opportunity for networking etc, it could not be described as having a clear educational content with hospitality secondary to the main purpose as required by the Code. The venue was prestigious and the level of hospitality was significant.

2014 gala dinner

Sanofi Genzyme submitted details of the 2014 gala dinner. There were speeches from the BIA's Chairman, CEO, the Chancellor of the Exchequer and a charity.

The Panel noted that in 2014 Sanofi Genzyme had taken a table at the gala dinner. The general manager UK & Ireland, the medical director of Sanofi Genzyme, and the director of the multiple sclerosis business unit from Genzyme attended together with seven people from various patient organisations as its guests. Accommodation and travel had been paid for at least one attendee. The Panel noted that the gala dinner was a formal occasion; the cost of each ticket in 2014 was £425 plus VAT. Accommodation was paid for at least one attendee at £160. The Sanofi Genzyme submission implied it had paid for accommodation for all patient organisation attendees. The Panel considered that by inviting only patient organisation members, Sanofi Genzyme's involvement in the 2014 BIA dinner was such that it had organised a meeting for patient organisations. The Panel noted its general comments above.

The gala dinner in 2014 was covered by the Second 2012 Code as amended. The transition arrangements for the 2014 Code were such that newly introduced requirements did not apply during 1 January 2014 – 30 April 2014. As noted above Clause 19.1 in the Second 2012 Edition of the Code as amended was similar to the 2014 Code. The Second 2012 Code as amended did not limit the cost of subsistence. The Panel therefore ruled a breach of Clause 19.1 of the Second 2012 Code as amended in relation to Sanofi Genzyme's involvement in inviting patient organisations to the 2014 gala dinner.

2015 gala dinner

Sanofi Genzyme submitted details of the 2015 dinner although the material provided did not include a date. There were speeches from the BIA's CEO, the Minister for Life Sciences, the Chairman of the BIA and a charity.

The Panel noted that in 2015 Sanofi Genzyme had taken a table of ten. It appeared that it only had five spaces filled as of 15 January 2015 all of which appeared to be company employees. The list provided showed that seven people attended from Genzyme and Sanofi. One guest was from an international technology transfer organisation and the other two guests were from patient

organisations. The Panel noted Sanofi Genzyme's submission that the arrangements for the two patient organisation members attending the 2015 dinner were last minute verbal invitations. The Panel noted that the cost of the tickets in 2015 increased to £450 plus VAT and accommodation was provided for the two patient organisation attendees at £149.99 per attendee. Although not all Sanofi Genzyme's guests were from patient associations the Panel considered that inviting one person who was not from a patient organisation did not mean that the company had organised a corporate meeting rather than one for patient organisations. The Panel noted its general comments above.

The gala dinner in 2015 was covered by the 2014 Code. The Panel therefore ruled a breach of Clause 19.1 of the 2014 Code in relation to Sanofi Genzyme's involvement in inviting patient organisations to the dinner in 2015. The Panel noted that although the cost of the food and drink was not provided given the increase in ticket price to £450 and the nature of the subsistence, it was very likely that this would cost more than £75 plus VAT and gratuities. The Panel noted that Sanofi Genzyme

had admitted a breach of Clause 22.2 of the 2015/2016 Code in relation to the 2015 event on the basis that the subsistence exceeded £75 plus VAT. A breach of Clause 19.2 of the 2014 Code was thus ruled.

The Panel noted that the case preparation manager had not cited Clauses 9.1 and 2 for Sanofi Genzyme to consider. The Panel was thus unable to make a ruling on these clauses.

During its consideration of this case, the Panel noted Sanofi Genzyme's submission that the arrangements for attending the 2015 BIA dinner were last minute verbal invitations which did not go through the company's approval systems. The Panel noted that Clause 14.3 of the 2014 Code required that material related to working with patient organisations needed to be certified. It requested that its concerns were drawn to the attention of Sanofi Genzyme.

Complaint received **18 February 201**

Case completed **11 April 2016**
