CASE AUTH/1863/7/06 *NO BREACH OF THE CODE*

MEDIA/DIRECTOR v SANOFI-AVENTIS

Patient organisation meeting

An article in The Observer newspaper entitled 'Cancer drug firm's PR trip sparks a row' criticised the activities of Sanofi-Aventis. In accordance with established practice the matter was taken up by the Director as a complaint under the Code. The article stated that a row had broken out over a trip described as 'educational' to Budapest and Paris by the heads of most of Britain's cancer charities. Sanofi-Aventis had arranged for policymakers and patients' representatives to enjoy a weekend away while they got the chance to hear about new cancer medicines, many of which were not yet offered by the NHS.

The article stated that a leaked draft of the itinerary described the meeting as a 'parliamentary and stakeholder working group'. It began with a flight to Budapest for the opening of the European Association of Cancer Research (EACR) conference. There was 'optional attendance' at the lectures and an exhibition, followed by dinner. Participants were also to visit a hospital in Paris to see the 'gold standard' treatment received by French patients in contrast with that experienced by NHS patients. The most senior cancer official within the Department of Health (DoH) was attending, paid for by the government, and two MPs were going, courtesy of a firm of political lobbyists. However, the chairman of the all-party parliamentary group on cancer declined the invitation stating, 'I didn't want to go because it was funded by a drugs company. There are other ways of finding out how other countries' cancer plans work without taking a weekend in Budapest and Paris. If I want to learn more about a particular cancer therapy, I can talk to doctors here who know about it. I really feel that these charities should pay for themselves – or if they can't, the company should hold the meeting in London'.

One insider who saw the draft itinerary was reported as saying, 'This kind of trip gives the company a chance to point out that other countries are spending more on new cancer drugs than the NHS. What it does is give charities the ammunition to go back to the UK and say, well the French are prescribing this new drug, so why is it being denied to our patients?'

In the article the charity bosses defended their roles, one of whom stated 'We've fully discussed this trip with our trustees and the board, and felt it was of value. If we paid, then it would come out of the charity's fund for research, which would be very wrong'.

The article reported growing concern about how 'Big Pharma' was influencing patients' groups and noted that The Lancet had called for greater transparency from the charities over where their sponsorship money came from.

The Panel noted from Sanofi-Aventis' submission that the reason for visiting France was to learn about the differences between the UK and French cancer plans and to see why there was such a difference in survival rates between the two countries.

The initial invitation sent on 12 April stated that the study group would attend the EACR conference in Budapest and then meet with key decision makers involved in the development of the French Cancer Plan. The group would include parliamentarians, patient group representatives, DoH officials and clinical leaders. It would explore best practice in cancer prevention, research and treatment.

A draft agenda had been sent to all invitees on 20 June. This stated that the group would attend the opening ceremony of the EACR conference followed by 'optional attendance at lectures, poster sessions and exhibition'. The final agenda stated that there was a choice of sessions at the EACR conference not that attendance was optional. According to the draft agenda the working group was to fly to Budapest early on 1 July. Delegates were to attend the opening ceremony of the EACR conference. An evening seminar with EACR was followed by a working dinner to discuss 'Advances in Cancer: making it a reality in the NHS'. On 2 July delegates were to attend the plenary lecture at the EACR conference at 9am and subsequently arrived in Paris at around 3pm with free time until dinner at 8pm with pan-European cancer groups to discuss improvement in survival rates, preventing cancer,

tackling health inequalities, increasing spending on cancer and access to new cancer treatments. On 3 July there would be a visit to a cancer clinic/unit (yet to be confirmed), lunch with a representative from the French Cancer Research Association to discuss what the UK could learn from France with regard to making and maintaining progress and a seminar and discussion in the afternoon to learn more about the French approach. The working group was due to arrive back in London later that evening.

The final agenda differed with regard to the description of attendance at the EACR conference as noted above, a seminar with an adviser to the French health minister was arranged for 6pm on 2 July and there was no mention of free time although there was a little spare time between arriving in Paris at 3.20pm and the 6pm seminar. The tour of the cancer department the next day was confirmed. The attendees included MPs, advisers, patient groups in the cancer area and DoH officials.

The Panel considered that both the draft and the final agenda were very full with little free time given the number of meetings and working meals. The prime reason for attending the meeting would be educational including meeting experts and discussing differences between France and the UK.

The Panel noted that the EACR conference provided a valid and cogent reason for travelling to Budapest. It would be much more difficult to hold the meetings and discussion about the French arrangements in the UK. The relevant resource or expertise was in France thus there were valid and cogent reasons to travel there.

With regard to the comments made by an 'insider' in the article, the Panel did not consider that the Code prevented companies discussing spending on cancer medicines and if other countries prescribed medicines which were licensed for use in the UK but were not prescribed in the UK it was not necessarily a breach of the Code to make this known.

With regard to the concerns in the article about pharmaceutical companies' relationships with patients' groups, the Panel noted that the supplementary information to the Code stated that any involvement a pharmaceutical company had with a patient organisation must be declared and transparent. Companies must make public by means of information on their websites or in their annual report a list of all patient organisations to which they provided financial support. This might include sponsoring materials and meetings. There was no specific criticism of Sanofi-Aventis in this regard.

The Panel considered that the meeting had a clear educational purpose such as to justify the hospitality. The hotels were described as standard business hotels. Most of the meals were working discussions. The hospitality was secondary to the education. The cost of attending the meeting at £1,508 per person was not unreasonable given there were two European destinations and the registration fee for EACR conference was £310.

Overall the Panel considered that the arrangments were not unreasonable. No breach of the Code was ruled.

An article entitled 'Cancer drug firm's PR trip sparks a row' which appeared in The Observer newspaper of 2 July 2006 criticised a Sanofi-Aventis organised trip to Budapest and Paris, Saturday 1 July to Monday 3 July, for the heads of most of Britain's cancer charities.

COMPLAINT

The author of the article stated that a row had broken out over a trip described as 'educational' to Budapest and Paris by the heads of most of Britain's cancer charities that had been funded by a major drugs company.

The article reported that Sanofi-Aventis had arranged for policymakers and patients' representatives to enjoy a weekend away while they got the chance to hear about new cancer medicines, many of which were not yet offered by the NHS.

A draft of the itinerary, leaked to The Observer, described the meeting as a 'parliamentary and stakeholder working group'. It began with a flight to Budapest and incorporated the opening of the European Association of Cancer Research (EACR) conference. There was 'optional attendance' at the lectures and an exhibition, followed by a dinner. Participants were also going to a hospital in Paris where they were seeing the 'gold standard' treatment received by French patients in contrast with that experienced by NHS patients.

The most senior cancer official within the Department of Health (DoH) was attending, although her costs were being met by the government, and two MPs were going on the trip, courtesy of a Westminster firm of political lobbyists. However, the chairman of the all-party parliamentary group on cancer, declined the invitation stating, 'I didn't want to go because it was funded by a drugs company. There are other ways of finding out how other countries' cancer plans work without taking a weekend in Budapest and Paris. If I want to learn more about a particular cancer therapy, I can talk to doctors here who know about it. I really feel that these charities should pay for themselves – or if they can't, the company should hold the meeting in London'.

One insider who saw the draft itinerary was reported as saying, 'This kind of trip gives the company a chance to point out that other countries are spending more on new cancer drugs than the NHS. What it does is give charities the ammunition to go back to the UK and say, well the French are prescribing this new drug, so why is it being denied to our patients?'

In the article the charity bosses defended their roles one of whom stated: 'We've fully discussed this trip with our trustees and the board, and felt it was of value. If we paid, then it would come out of the charity's fund for research, which would be very wrong'.

The article reported that there was growing concern about how 'Big Pharma' was influencing patients' groups. The medical journal The Lancet had called

for greater transparency from the charities over where their sponsorship money came from.

The communications director for Sanofi-Aventis, said, 'This is a purely educational trip. It enables the MPs and the patients' groups representatives to look at best practice that is happening; I can't see the harm in this'.

When writing to Sanofi-Aventis, the Authority asked it to respond in relation to Clauses 2, 9.1 and 19.1 of the Code and its supplementary information as well as the supplementary information to Clause 20.2 of the Code which stated that meetings for member of public, journalists and patient organisations must comply with Clause 19.

RESPONSE

Sanofi-Aventis submitted that the trip was educational, organised in the context of the annual congress of the EACR, in Budapest. The EACR supported research in cancer through scientific meetings and fellowships and independently arranged its annual meeting at locations which it selected; it received no sponsorship from Sanofi-Aventis UK. The agenda for the Budapest conference covered all areas of cancer research, including epidemiology, cell and tumour biology, signalling pathways, tumour immunology, oncogenomics, apoptosis and medicine related research.

Sanofi-Aventis submitted that the UK delegates then travelled to Paris, in order to learn from senior French policy markers about the French Cancer Plan, both in theory and practice. The location was prompted by the 'Karolinska Report' (A pan-European comparison regarding patient access to cancer medicines originating from the Karolinska Institutet, Stockholm, Sweden, September 2005) which reviewed cancer care across Europe and identified France as demonstrating best practice – in direct contrast to the UK. On this basis, Sanofi-Aventis considered that there was a need in the UK to enhance awareness and understanding of current and future best practice in cancer prevention, research, and treatment amongst stakeholders. The Sanofi-Aventis programme was entirely non-promotional and encompassed a wide range of topics including epidemiology, genetics, new treatment modalities, organisation of cancer services and commissioning. There was no promotion of the company's products or services. A detailed agenda was provided.

Attendees

Sanofi-Aventis submitted that 58 delegates were invited on the basis of their experience or interest in oncology research and management of cancer services; 13 initially accepted but two withdrew at the last minute leaving 11 delegates. They were not approached as potential prescribers, and indeed the majority were not health professionals with prescribing powers or influence. Sanofi-Aventis was represented by three of its staff; no sales personnel were involved.

The initial part of the trip incorporated the official EACR meeting for the afternoon of 1 July and early morning of 2 July, plus two Sanofi-Aventis organised meetings. The first meeting concerned research in cancer and was led by EACR officials. The second meeting was with prominent UK researchers (all of whom were attending the EACR independently) during the evening of 1 July.

With regard to the statement in the Observer article that there was 'optional attendance' at the [EACR] lectures followed by a dinner', Sanofi-Aventis submitted that an initial draft of the programme, clearly marked as such, indicated that there were options available for the first part of the EACR meeting on the afternoon of 1 July; however, this was never intended to imply that the options extended beyond the EACR itself. The ambiguity of wording was subsequently recognised and it was altered accordingly before the final programme was distributed.

Sanofi-Aventis submitted that the latter part of the trip involved direct contact with senior French policymakers and patient group representatives, and a visit to a major Paris hospital in order to gain a practical view of the French approach to management of cancer services. As detailed in the agenda, the first meeting in France on 2 July was a seminar with an adviser to the French Health Minister. The second meeting on 2 July was a pan-European patient group discussion with Europa Uomo and Europa Colon.

Sanofi-Aventis submitted that on 3 July the first meeting was held at the Georges Pompidou European Hospital, where a presentation on the hospital was given. Following a front-line tour of the specialist cancer department, presentations on the implementation of the French Cancer Plan were delivered by local experts at the hospital.

In the afternoon of 3 July two further meetings were held. One was with the Association pour la Recherche sur le Cancer and the Europa Donna. The second meeting was a seminar with the Institut National du Cancer. Other speakers were also French Cancer Plan policy experts.

Sanofi-Aventis submitted that the total cost per delegate was £1,508; this included transport, accommodation and subsistence at £845 per person and an EACR registration fee of £310. A detailed breakdown of all of the costs associated with the meeting was provided. Further evidence of the modest nature of the costs incurred was also provided in the delegates' expenses claims. One flight was economy class, and the other was a budget air-line. The Eurostar journey returning to London was in standard class, and all group transfers were by bus.

Hotels with standard business facilities were used in both locations and both these and the restaurants to which delegates were taken were of a standard appropriate to the delegates without being lavish or luxurious. Sanofi-Aventis noted that most of the meals taken during the trip were working discussions, and the programme did not include any leisure component or free time.

In support of the utility and appropriate nature of this trip, correspondence from delegates and aggregated feedback on the content quality and relevance of the meeting was provided.

The invitation, agenda and programme for this trip, including detailed arrangements for travel and

hospitality, were reviewed, approved and certified as required by the Code and the company's standard operating procedure.

Compliance with the ABPI Code

Sanofi-Aventis submitted that, in light of the details provided above, there had been no breach of the Code in either letter or spirit. The hospitality was associated with an educational and scientific meeting, secondary to the main purpose of the meeting, in proportion to the occasion and cost what the recipients would reasonably pay themselves (Clause 19.1). The arrangements and programme were the same for health professionals, policy-makers and patient organisation representatives, and complied with Clause 19 (Clause 20.2).

Sanofi-Aventis submitted that the programme and arrangements recognised the commitment and professionalism of the delegates; there was no social programme and the scientific and educational content extended throughout the available time. The delegates were senior managers, patient group representatives, MPs, policymakers and clinical oncologists and researchers who were prominent and highly involved in the subjects covered.

Sanofi-Aventis submitted that high standards were therefore maintained (Clause 9.1) and that no aspect of the meeting had brought discredit upon, or reduced confidence in, the pharmaceutical industry (Clause 2).

Sanofi-Aventis provided additional information including the draft programme (sent on 20 June), and a list of all those invitees who received it. A working document which pre-dated the draft programme (dated 15 June), and was sent to a single recipient was also provided.

PANEL RULING

The Panel noted that Clause 20.3 of the Code stated, *inter alia*, 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. The supplementary information to this clause stated that meetings organised for or attended by members of the public, journalists and patient organisations must comply with Clause 19 of the Code.

Clause 19.1 stated that companies must not provide hospitality to members of the health professions and appropriate administrative staff except in association with scientific meetings, promotional meetings, scientific congresses and other such meetings. Meetings must be held in appropriate venues conducive to the main purpose of the event. Hospitality must be strictly limited to the main purpose of the event and must be secondary to the purpose of the meeting ie subsistence only. The level of subsistence offered must be appropriate and not out of proportion to the occasion. The costs involved must not exceed that level which the recipients would normally adopt when paying for themselves.

The supplementary information stated the provision of hospitality was limited to refreshments/subsistence (meals and drinks), accommodation, genuine registration fees and the payment of reasonable travel costs which a company might provide to sponsor a delegate to attend a meeting.

With any meeting, certain basic principles applied:

- The meeting must have a clear educational content
- The venue must be appropriate and conducive to the main purpose of the meeting; lavish or deluxe venues must not be used and companies should avoid using venues that were renowned for their entertainment facilities
- The subsistence associated with the meeting must be secondary to the nature of the meeting, must be appropriate and not out of proportion to the occasion.

Meetings orgainsed by pharmaceutical compaines which involved UK health professionals at venues outside the UK were not necessarily unacceptable. There had to be valid and cogent reasons for holding meetings at such venues. These were that most of the invitees were from outside the UK and, given their countries of origin, it made greater logistical sense to hold the meeting outside the UK or given the location of the relevant resource or expertise that was the object or subject matter of the meeting, it made greater logistical sense to hold the meeting outside the UK. As with meetings held in the UK, in determining whether such a meeting was acceptable or not, consideration must also be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience, subsistence provided and the like. As with any meeting it should be the programme that attracted delegates and not the associated hospitality or venue.

The Panel noted that the Karolinska Report did not conclude that France demonstrated best practice as submitted by Sanofi-Aventis. With regard to adoption of the newest cancer medicines made available between 1999 and 2004, France was described as an average adopter of new cancer medicines for breast cancer, colorectal cancer, lung cancer, non Hodgkin's lymphoma and supportive care. Austria, Spain and Switzerland were the top three countries in this regard. The UK was below average. The one year and five year survival rates for all tumour types in France was 81% and 61% respectively. Only Sweden was better (81% and 62%). The relevant data for the UK was 67% and 48%.

The Panel noted from Sanofi-Aventis' submission that both the UK and France had a cancer plan and the reason for visiting France was to learn about the differences in the plans and to see why there was such a difference in survival rates between the two countries. Sweden did not have a national cancer plan.

The initial invitation sent on 12 April stated that the study group would attend the EACR conference in Budapest followed by a series of meetings with key decision makers who had been involved in the development of the French Cancer Plan. The group would include parliamentarians, patient group representatives, DoH officials and clinical leaders. It would explore best practice in cancer prevention, research and treatment.

A draft agenda had been sent to all invitees on 20 June. This stated that the group would attend the opening ceremony of the EACR conference followed by 'optional attendance at lectures, poster sessions and exhibition'. The final agenda stated that there was a choice of sessions at the EACR conference not that attendance was optional. According to the draft agenda the working group was to fly to Budapest early on 1 July. Delegates were to attend the opening ceremony of the EACR conference and welcome reception. An evening seminar with EACR was arranged with officials of the EACR speaking. This was followed by a working dinner with UK researchers attending the EACR conference to discuss 'Advances in Cancer: making it a reality in the NHS'. The draft agenda listed four speakers at this dinner. On 2 July delegates were to attend the plenary lecture at the EACR conference at 9am and subsequently arrived in Paris at around 3pm with free time until dinner at 8pm with pan-European cancer groups to discuss improvement in survival rates, preventing cancer, tackling health inequalities, increasing spending on cancer and access to new cancer treatments. On 3 July there would be a visit to a cancer clinic/unit (yet to be confirmed), lunch with a representative from the French Cancer Research Association to discuss what the UK could learn from France with regard to making and maintaining progress and a seminar and discussion in the afternoon to learn more about the French approach. The working group was due to arrive back in London later that evening.

The final agenda differed with regard to the description of attendance at the EACR conference as noted above, a seminar with an adviser to the French health minister was arranged for 6pm on 2 July and there was no mention of free time although there was a little spare time between arriving in Paris at 3.20pm and the 6pm seminar. The tour of the cancer department the next day was confirmed. The attendees included MPs, advisers, patient groups in the cancer area and DoH officials.

The Panel considered that both the draft and the final agenda were very full with little free time given the number of meetings and working meals. The prime reason for attending the meeting would be educational including meeting experts and discussing differences between France and the UK.

The Panel considered that it was not necessarily inappropriate for a pharmaceutical company to fund an educational meeting provided the requirements of the Code were met. Of course there were other ways of finding out about how other countries' cancer plans worked but given the location of the experts it was not unreasonable to travel outside the UK. The EACR conference was in Budapest which provided a valid and cogent reason for travelling to Budapest. It would be much more difficult to hold the meetings and discussion about the French arrangements in the UK. The relevant resource or expertise was in France thus there were valid and cogent reasons to travel there.

With regard to the comments made by an 'insider' in the article, the Panel did not consider that the Code prevented companies discussing spending on cancer medicines and if other countries prescribed medicines which were licensed for use in the UK but were not prescribed in the UK it was not necessarily a breach of the Code to make this known.

With regard to the concerns in the article about pharmaceutical companies' relationships with patients' groups, the Panel noted that the supplementary information to Clause 20.3 stated that any involvement a pharmaceutical company had with a patient organisation must be declared and transparent. Companies must make public by means of information on their websites or in their annual report a list of all patient organisations to which they provided financial support. This might include sponsoring materials and meetings. There was no specific criticism of Sanofi-Aventis in this regard.

The Panel considered that the meeting had a clear educational purpose such as to justify the hospitality. The hotels were described as standard business hotels. Most of the meals were working discussions. The hospitality was secondary to the education. The cost of attending the meeting at £1,508 per person was not unreasonable given there were two European destinations and the registration fee for EACR conference was £310.

Overall the Panel considered that the arrangments were not unreasonable. No breach of Clause 19.1 of the Code was ruled. The Panel considered that there was also no breach of Clause 9.1 of the Code and ruled accordingly. Given its rulings above the Panel ruled no breach of Clause 2 of the Code.

Proceedings commenced 4 July 2006

Case completed 26 September 2006