

MEDIA/DIRECTOR and ANONYMOUS v SANOFI PASTEUR MSD

Promotion of Gardasil and arrangements for a meeting

Articles entitled 'Alarm at 'battering ram' tactics over cervical cancer' and 'Vaccination campaign funded by drug firm', published in The Guardian on 26 March, criticised the promotion of Gardasil (human papillomavirus (HPV) vaccine) and the activities of Sanofi Pasteur MSD. In accordance with established practice the criticisms were taken up by the Director as a complaint under the Code (Case AUTH/1980/3/07). In Case AUTH/1983/3/07, concerns about the same articles were raised by an anonymous complainant.

Among other criticisms in the articles in The Guardian a leading public health expert likened the tactics of drug companies to 'a battering ram at the Department of Health and carpet bombing on the peripheries'. She feared the push towards mass vaccination could damage the very successful UK screening programme. She said that the vaccine was scientifically brilliant, but should be introduced carefully, not least because today's women would need to be screened for the rest of their lives. She was quoted as saying that pharmaceutical companies had tried to recruit her among the many 'opinion leaders' invited to meetings which they would be paid £1,000 to attend.

She also commented on the number of letters from representatives offering to help her plan the introduction of the vaccine. 'They wrote to every doctor of public health, every chief executive, every pharmacy adviser, senior people in the faculty of public health, all infectious disease specialists and primary care staff,' she said. Where she was based the health protection department, cancer network and screening staff together urged a national policy on the vaccine and advised staff not to talk to representatives.

The articles criticised the first global summit against cervical cancer held in Paris on 22 March which launched a Coalition against Cervical Cancer with a charter signed by female celebrities. The Coalition would lobby for mass vaccination. Journalists and celebrities were paid to attend. UK freelance journalists had not only their travel, meals and accommodation but also time paid for by the pharmaceutical company. The Club Européan de la Santé (CES) organised the meeting on the condition that Sanofi Pasteur MSD paid for it. Concern was expressed that Sanofi-Pasteur MSD was the sole funder. This charitable organisation could not have been involved if Sanofi Pasteur MSD had not offered money. The anonymous complainant had similar criticisms which were conveyed by means of annotated copies of the articles.

The Panel noted that Sanofi Pasteur MSD had invited the public health expert to participate in an advisory board in June 2005. The invitation described the advisory board as a multidisciplinary advisory panel of NHS stakeholders to discuss clinical, service and funding issues relating to the introduction of HPV vaccines into the NHS. The agenda would run from 11am to 4pm. An honorarium of £500 would be paid and all travelling expenses reimbursed. Confidentiality agreements would be signed. The Panel queried whether the invitation made the amount of work required sufficiently clear given that invitees were not sent a copy of the agenda at this stage. The final agenda ran from 10.30am to 4pm and provided plenty of opportunity for participation and discussion. The agenda was not unreasonable given the stated purpose of the meeting. Overall the Panel considered that the honorarium of £500 to participate in the advisory board as described in the invitation was not unreasonable. The invitation made the role of participants sufficiently clear. The Panel noted the amount of work actually required. The payment was for genuine services. It was not inappropriate to offer to pay attendees of the advisory board in question. No breach of the Code was ruled.

In relation to the number of letters from representatives, the Panel noted Sanofi Pasteur MSD's submission that the expert had received no promotional mailings for Gardasil. A Sanofi Pasteur MSD healthcare development executive had tried to arrange a meeting with three people within the expert's local Primary Care Trust (PCT) responsible for policy decisions on budgets but the expert had written back, via the company's head office, explaining that a meeting was not necessary given the PCT's current position on vaccination policy. Despite this letter the Panel was concerned that some eight days later the same healthcare development executive sought an appointment with the expert, the company not having forwarded a copy of her earlier letter. The company also noted that subsequent to the grant of the marketing authorization in September 2006 Sanofi Pasteur MSD's medical director wrote to the expert about a position statement on HPV vaccine which she co-authored. The position statement had advised staff to decline invitations to see company representatives. No one company was identified. She responded stating that she was reassured by Sanofi Pasteur MSD's response.

Overall the Panel did not consider that the volume of mailings sent by Sanofi Pasteur MSD was unacceptable. No promotional mailings about Gardasil had been sent to the expert. Nor was the frequency of contact made by healthcare

development executives unacceptable. The Panel ruled no breach of the Code.

In relation to the meeting held in Paris, the first thing that the Panel had to consider was whether it, or any aspect of it, came within the scope of the Code. The meeting was sponsored by Sanofi Pasteur MSD's French headquarters. The article 'Vaccination campaign funded by drug firm' noted the President of CES, a public health institution, had agreed to participate only on condition that Sanofi Pasteur MSD paid. The response from the company stated that the meeting was organised by CES – implying that CES had more than a participatory role. The position was unclear. The Panel noted that the agenda featured both European and non European (US and South American) speakers and addressed global issues in relation to cervical cancer. Twenty five UK delegates attended (11 health professionals, 13 journalists and 1 representative from a patient group). The presentations were directed to all the delegates; no material was presented during the main agenda which solely addressed a UK audience. A breakfast meeting had been held solely for UK journalists. The Panel considered that the Code applied to the invitation and the hospitality (accommodation, travelling and subsistence) provided to UK delegates. The Panel considered that the Code also applied to all of the arrangements in relation to and content of the breakfast briefing.

The breakfast briefing, organised by Sanofi Pasteur MSD UK and attended by journalists from the UK and Ireland, enabled delegates to question a panel of UK experts in the field of cervical cancer. It was chaired by a medical adviser from the UK company. The Panel did not have a copy of the invitation to the breakfast briefing. No PowerPoint presentations were made and nor were any additional materials made available. The Panel considered that it had no evidence before it to show on the balance of probabilities that either the discussions or the arrangements were unacceptable under the Code.

The Panel noted that the arrangements for UK delegates should comply with the Code. The 2006 edition of the Code extended the requirements to apply to journalists and patient groups for the first time. The Panel noted that travel was economy or standard class rail travel. The meeting venue did not appear unreasonable. Overnight accommodation was offered. It was unclear how many UK delegates had been provided with accommodation. Overall the Panel did not consider that the accommodation, travel and subsistence provided were unacceptable in relation to the requirements of the Code.

UK journalists had been provided with a certified invitation by a UK agency. Due to human error UK health professionals and others had been invited using an uncertified version of the invitation by a French based agency. The uncertified two page invitation only referred to the company sponsorship at the end, as a postscript. The Code required sponsorship to be declared such that the reader was aware of it at the outset. A breach was ruled in relation to the invitation

to UK health professionals and others.

UK freelance journalists were paid 1.5 times their daily rate to attend. The supplementary information to the Code stated that funding must not be offered to a health professional to compensate them merely for the time spent in attending meetings. Meetings organised for or attended by, *inter alia*, journalists should comply with the Code. There were differences in the role played at such meetings by journalists and health professionals. There were situations where it was legitimate to pay a health professional or journalist for their time when attending meetings such as participation on advisory boards or when they were otherwise being employed to undertake a specific piece of work so long as in each case the arrangements as a whole complied with the Code. On the evidence before the Panel it appeared that the journalists were simply delegates; they were not being paid for the benefit of their expertise or to undertake a specific piece of work. In such circumstances the payments were inappropriate. Their freelance status was irrelevant. A breach of the Code was ruled. High standards had not been maintained and a further breach was ruled.

Articles entitled 'Alarm at 'battering ram' tactics over cervical cancer' and 'Vaccination campaign funded by drug firm' published in The Guardian on 26 March criticised the promotion of Gardasil (human papillomavirus (HPV) vaccine) and the activities of Sanofi Pasteur MSD Ltd. In accordance with established practice the criticisms in these articles were taken up by the Director as a complaint under the Code (Case AUTH/1980/3/07).

In Case AUTH/1983/3/07, concerns about the same articles were raised by an anonymous complainant.

Case AUTH/1980/3/07

COMPLAINT

Among other criticisms in the articles in The Guardian a leading public health expert likened the tactics of drug companies to 'a battering ram at the Department of Health and carpet bombing on the peripheries'. She feared the push towards mass vaccination could do damage to screening programmes, such as the very successful one in Britain. She said that the vaccine was scientifically brilliant, but should be introduced carefully, not least because today's women would continue to need screening for the rest of their lives. She was quoted as saying that pharmaceutical companies had tried to recruit her among the many 'opinion leaders' invited to meetings which they would be paid £1,000 to attend. She also commented on the number of letters from sales representatives offering to help her plan the introduction of the vaccine. 'They wrote to every doctor of public health, every chief executive, every pharmacy adviser, senior people in the faculty of public health, all infectious disease specialists and primary care staff,' she said. Where she was based the health protection department, cancer network and screening staff in a joint statement urged a national policy on the vaccine and advised staff not to talk to reps, 'and to let us know if they bother you'.

The articles criticised the first global summit against cervical cancer held in Paris on 22 March which launched a Coalition against Cervical Cancer with a charter signed by female celebrities. The Coalition would lobby for mass vaccination. Journalists and celebrities were paid to attend. UK freelance journalists had not only their travel, meals and accommodation but also time paid for by the pharmaceutical company. The Club Européan de la Santé (CES) organised the meeting on the condition that Sanofi Pasteur MSD paid for it. Concern was expressed that Sanofi-Pasteur MSD was the sole funder.

This charitable organisation could not have been involved if Sanofi Pasteur MSD had not offered money.

Case AUTH/1983/3/07

COMPLAINT

The anonymous complainant had similar criticisms which were conveyed by means of annotated copies of the articles.

Cases AUTH/1980/3/07 and AUTH/1983/3/07

When writing to Sanofi Pasteur MSD about the two cases, the Authority asked it to respond in relation to Clauses 7.2, 12.2, 18.1, 19.1, 19.3 and 20.3 of the Code and, in addition, Clauses 2 and 9.1 in relation to each matter and cumulatively.

RESPONSE

Sanofi Pasteur MSD noted that the two articles contained a number of inaccuracies and misleading statements, not least the headline on the front page. In brief, these were as follows.

- 1 The Coalition against Cervical Cancer was not a 'vaccination campaign' but rather a concerted effort, supported by many respected organisations, to eradicate cervical cancer worldwide through the combination of improved education, screening, treatment and implementation of vaccination. Sanofi Pasteur MSD would demonstrate that the meeting in Paris addressed this in a holistic and balanced way.
- 2 The Paris meeting did not cost one million, *let alone* 'millions', irrespective of whether the unwritten unit was pounds or euros.
- 3 HPV vaccines were not 'only effective in young girls'. The only licensed HPV vaccine, Gardasil, was indicated for the prevention of cervical cancer in females aged 9 to 26 years (summary of product characteristics (SPC)). GlaxoSmithKline was seeking a licence for its vaccine in females aged 10 to 55 years.
- 4 Club Européan de la Santé (CES) relied on external funding sources in order to hold meetings such as the one in Paris. However, it was certainly not a condition that funding came from Sanofi Pasteur MSD.
- 5 The allegations relating to the public health expert were not made about Sanofi Pasteur MSD. Indeed, as it would demonstrate later, what was described was not at all familiar to Sanofi Pasteur MSD.

- 6 The Paris meeting addressed the desire to eradicate cervical cancer worldwide through the combination of improved education, screening, treatment and implementation of vaccination. Sanofi Pasteur MSD submitted that the meeting in Paris addressed this in a holistic and balanced way.
- 7 The travel and hospitality arrangements for the Paris meeting were Code compliant and certified as such.

The first part of the article on page 6 of The Guardian contained various allegations made by a public health expert. None of the allegations were specifically about Sanofi Pasteur MSD: the article referred to 'drug firms' and 'pharmaceutical companies'. Sanofi Pasteur MSD was not the only company active in the HPV vaccine field.

Prior to the licensing of Gardasil, Sanofi Pasteur MSD had the following contact with the expert:

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| July 2004 | One to one meetings between her and Sanofi Pasteur MSD's medical director regarding cervical cancer and HPV vaccine. At this meeting, her considerable experience in the area of cervical screening was noted. She was therefore highlighted as a potential member of a future advisory board, a fact that was mentioned to her at the meeting. |
| June 2005 | Invitation from an agency working on behalf of Sanofi Pasteur MSD to her to participate in an advisory board meeting 'to discuss the clinical, service and funding issues related to the introduction of HPV vaccines into the NHS'. An honorarium of £500 was offered. She declined the invitation. |
| October 2005 | Letter sent by her to her local Sanofi Pasteur MSD healthcare development executive. At that time, healthcare development executives were making appointments with those in primary care trusts responsible for making policy decisions on budgets. Her local healthcare development executive had sought appointments with the three people copied in on this letter (a director of public health and two heads of medicines management) who had notified her, prompting this letter. |
| October 2005 | Telephone call to her secretary by her local healthcare development executive to enquire about an appointment (following the recommendation of other policy makers in that locality). At that time her letter of 17 October 2005, which had been sent to head office, had not been seen by the healthcare development executive. The secretary advised that the response would be clear from the letter and no appointment was made. |

Since Gardasil was licensed in September 2006, Sanofi Pasteur MSD had had the following contact with her:

December 2006 Letter sent to her by Sanofi Pasteur MSD's medical director, responding to a position statement on HPV vaccine she had co-authored. Of particular note was that this letter addressed claims she had made about the activities of pharmaceutical representatives. It stressed that all activities undertaken by Sanofi Pasteur MSD were reviewed to ensure compliance with the Code. Sanofi Pasteur MSD sent her a copy of the PMCPA leaflet describing the Code for health professionals and asked her to contact it if she suspected the company's activities were not Code compliant.

January 2007 Letter sent to Sanofi Pasteur MSD's medical director by her, responding to his letter of December 2006. In her response she welcomed the reassurances Sanofi Pasteur MSD had provided, to the extent that she did not feel a meeting to discuss the matter further was necessary. Sanofi Pasteur MSD therefore considered that the issue had been satisfactorily resolved.

In light of these details, Sanofi Pasteur MSD was surprised and disturbed to read the allegations made in *The Guardian*. With specific reference to Clause 18.1, she received one invitation to participate in an advisory board long before Gardasil was licensed. As part of this invitation she was offered £500 as compensation for the time she would have spent participating in the meeting. Advisory board meetings were a legitimate activity within the Code. The invitation gave no indication, either directly or implied, that its purpose was an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. This was a non-promotional activity conducted prior to Gardasil being licensed or becoming available. Sanofi Pasteur MSD therefore refuted a breach of Clause 18.1.

Referring to Clause 12.2, she had received no promotional mailings for Gardasil from Sanofi Pasteur MSD. It therefore had exercised restraint on the frequency and volume of promotional material distributed and denied a breach of Clause 12.2.

Sanofi Pasteur MSD noted that the First Global Summit on Cervical Cancer was held on 22 March 2007 at the United Nations Educational, Scientific and Cultural Organization (UNESCO) in Paris. As correctly stated in the article, the meeting was organised by CES. Financial support was provided by Sanofi Pasteur MSD headquarters in France.

The objective of the meeting, which was endorsed by UNESCO and the International Federation of Gynaecology and Obstetrics (FIGO) and held under the high patronage of the French President and the patronage of the French

Minister of Health, was to continue the fight against cervical cancer. It built on three previous events, none of which was sponsored by Sanofi Pasteur MSD:

- the 'Charter of Paris Against Cancer' signed in February 2000 at the first World Summit Against Cancer organised by UNESCO;
- the World Cancer Declaration adopted at the World Cancer Congress in Washington, July 2006;
- the 'Call of Rabat' in September 2006 which developed a policy to prevent cervical cancer in developing countries supported by the Queen of Morocco and UNESCO ambassador.

One part of the meeting to create a Coalition On Cervical Cancer formed of global and European figureheads to sign 'The Charter Against Cervical Cancer', setting out the participants' commitment to place cervical cancer high on the global health agenda. The organisation was overseen by a Scientific Committee comprised of relevant experts. The Scientific Committee, drew up an agenda to address the worldwide management of cervical cancer in a holistic and balanced way. The first part of the agenda therefore covered all aspects of the disease from its impact, treatment options, through to prevention by both screening and vaccination. The second part was focussed on defining actions for the future, which included education of health professionals and patients, as well as the role of policy makers. The agenda was certified as compliant with the Code. The slides presented further reinforced the holistic nature of the agenda. Vaccination was referred to in the context of the goal of eradication of cervical cancer and Gardasil was not mentioned by name. Indeed, the existence of two vaccines was explicit. No promotional materials for Gardasil were available at the meeting. The agenda was accurate, balanced, fair, objective, unambiguous, reflected the current state of knowledge of cervical cancer management and was not misleading. Sanofi Pasteur MSD therefore refuted a breach of Clause 7.2.

Prior to the main meeting there was a breakfast briefing for UK journalists. This was an informal session where journalists could speak about management of cervical cancer with a panel of UK experts who were present for the Global Summit. The majority were speakers during the main meeting. The session was facilitated by Sanofi Pasteur MSD UK.

Invitations to potential delegates from the UK were extended to relevant policymakers, health professionals, patient organisations and journalists. The invitation supplied by the organisers was reviewed under the Code and following this review, a UK version was certified. It was clearly mentioned in both versions that the meeting was sponsored by Sanofi Pasteur MSD. In the certified version, the sponsorship statement was included at the start and the end of the letter. The certified version was used by the UK agency that invited UK journalists. Due to a clerical error, the French agency, responsible for inviting other UK delegates, used the original version.

Copies of the invitee and attendee lists were provided. With the exception of freelance journalists and speakers, attendees (including the sportswoman from the UK) were not paid to attend the meeting. If necessary, economy air or standard class rail travel, and overnight accommodation were offered. These arrangements were certified as compliant with the Code. The speakers from the UK were two health professionals (one chairman, one speaker), one patient group representative and one patient. The health professionals were offered an honorarium but not the patient group representative or the patient. In summary, the meeting was held at an appropriate venue; travel was economy or standard class, hospitality was provided in the context of the meeting, was secondary to it and was of subsistence level. Sanofi Pasteur MSD therefore refuted a breach of Clause 19.1.

The fact that the meeting was sponsored by Sanofi Pasteur MSD was clearly stated in the invitation letter sent to the invitees in advance of the meeting. From the outset invitees were aware that the meeting was sponsored by Sanofi Pasteur MSD. Sanofi Pasteur MSD noted that the articles in The Guardian did not allege that the sponsorship was disguised. The company therefore refuted a breach of Clause 19.3. A copy of the delegate pack was provided; this was produced by the conference organisers and did not carry a sponsorship statement. When delegates entered the building, as well as the delegate pack they also received a document in French detailing the agenda and members of the Coalition; this was a requirement of the President's office.

Freelance journalists were not incentivised to attend the meeting. However, due to their employment status, they could claim expenses corresponding to 1.5 times their daily rate. These journalists signed an agreement acknowledging that they were remunerated by Sanofi Pasteur MSD for their time spent at the meeting and that the company waived the right to review any article that might arise from them having attended the meeting.

Representatives of patient groups were treated in the same way as all other attendees (with the exception of freelance journalists) with respect to travel, accommodation and lack of payment to attend. No specific activities were conducted with patient groups other than their being invited to the meeting. Sanofi Pasteur MSD therefore refuted a breach of Clause 20.3.

Logistical support was provided by four agencies, three in France and one in the UK.

In summary, Sanofi Pasteur MSD denied breaches of Clauses 18.1, 12.2, 7.2, 19.1, 19.3 and 20.3. All contact with the public health expert had been Code compliant. The Paris meeting was organised by a third party and sponsored by Sanofi Pasteur MSD, a fact that was clear from the outset and was not challenged in The Guardian. The meeting was endorsed by a number of highly respected organisations and its content was balanced, addressing multiple areas relating to the management of cervical cancer, not only vaccination.

As previously noted the two articles contained multiple inaccuracies and misrepresented the purpose and content of the meeting. Sanofi Pasteur MSD reviewed the arrangements for the meeting to ensure they were suitable and certified the documents to be supplied to UK delegates prior to the meeting, as well as the arrangements for travel and accommodation. Sanofi Pasteur MSD had maintained high standards at all times and had not reduced confidence in the pharmaceutical industry. It therefore also refuted breaches of Clauses 9.1 and 2.

In response to a request for further information Sanofi Pasteur MSD stated that the agenda for the advisory board meeting was provided at the meeting, not with the invitation. Since the expert did not attend the meeting she would therefore not have received a copy of the agenda. A copy of the evaluation form was provided.

With respect to the First Global Summit on Cervical Cancer, the revised invitee and attendee lists, including the additional information requested, were provided.

The First Global Summit on Cervical Cancer focussed on the worldwide management of cervical cancer in a holistic and balanced way. As an introduction to the day's events, Sanofi Pasteur MSD gave journalists from the UK and Ireland the opportunity to question a panel of UK experts in the field of cervical cancer, two of whom were speaking at the event. The meeting was held from 8 to 9am over breakfast. The concept and arrangements for the meeting were certified as Code compliant. The panel consisted of three experts rather than the five initially envisaged. The journalist who had written the articles in The Guardian did not attend the breakfast meeting.

In order to ensure Code compliance in a question and answer based forum, the meeting was facilitated by the Senior Medical Adviser, Sanofi Pasteur MSD, who was a registered Code signatory. She introduced the meeting, placing it within the context of the First Global Summit on Cervical Cancer, declaring the company's sponsorship of the event and explaining that the purpose of the meeting was to allow journalists to ask questions of the three UK expert participants and Summit speakers.

As the meeting was an introduction to the Summit, for which delegate materials were available, no additional materials were distributed at the breakfast meeting. No PowerPoint presentations were given; as a member of the Scientific Committee and chair of the Summit session on impact of the disease, one panellist was asked to present the background to the First Global Summit on Cervical Cancer. The two others were asked to introduce themselves by summarising their professional backgrounds in the field of cervical cancer. The journalists were then able to ask the Panel questions relating to cervical cancer prevention. All attendees went on to attend the meeting at UNESCO at 10am.

PANEL RULING

The Panel noted that it had asked Sanofi Pasteur MSD

to respond, *inter alia*, to Clauses 9.1 and 2 in relation to each matter and to the cumulative effect of the matters raised in the articles. The company had only responded to Clauses 9.1 and 2 cumulatively but not in relation to each matter. The Panel noted that the company had been given an opportunity to respond to each matter in relation to Clauses 2 and 9.1 in accordance with the Constitution and Procedure and it would thus rule on that basis.

The Panel noted Sanofi Pasteur MSD's submission that The Guardian article referred to 'drug firms' and 'pharmaceutical companies'. The Panel agreed that the section referring to the public health expert's views did refer to drug firms and pharmaceutical companies. The heading on the front page was 'Vaccination campaign funded by drug firm'. Sanofi Pasteur MSD was named in relation to the meeting in Paris. The only mention of GlaxoSmithKline, which was developing another vaccine, was in relation to whether money was sought from GlaxoSmithKline and the reply was that GlaxoSmithKline had not been approached.

The Panel also noted that there was some confusion as to whether the summit was '... on Cervical Cancer' or 'against Cervical Cancer'. The programme and documentation referred to the meeting as 'First Global Summit on Cervical Cancer'.

The Panel noted that the article headed 'Alarm at "battering ram" tactics over cervical cancer' referred to the invitation of the public health expert and others to meetings which they would be paid £1,000 to attend and to the number of letters received from representatives. The Panel noted that the comments related to the activity of more than one company. Nonetheless, Sanofi Pasteur MSD and Gardasil was the only company and product identified and thus that company was asked to respond to these comments.

The Panel noted it was acceptable for companies to arrange advisory board meetings and the like and to pay health professionals and others for advice on subjects relevant to their products. Nonetheless, the arrangements for such meetings had to comply with the Code. The choice and number of delegates should stand up to independent scrutiny. Each should be chosen according to their expertise such that they would be able to contribute meaningfully to the purpose and expected outcomes of the meeting. The number of delegates at a meeting should be limited so as to allow active participation by all. The number of meetings and the number of delegates at each should be driven by need and not the invitees' willingness to attend. Invitations to participate in an advisory board meeting should state the purpose of the meeting and the expected advisory role and amount of work to be undertaken. If an honorarium was offered it should be clear that it was a payment for such work and advice and not a payment to attend a promotional meeting. Honoraria must be commensurate with the time and effort involved and the professional status of the recipients.

The Panel noted that Sanofi Pasteur MSD invited the public health expert to participate in an advisory board

in June 2005. The invitation described the advisory board as a multidisciplinary advisory panel of NHS stakeholders to discuss clinical, service and funding issues relating to the introduction of HPV vaccines into the NHS. The agenda would run from 11am to 4pm. An honorarium of £500 would be paid and all travelling expenses reimbursed. Confidentiality agreements would be signed. The Panel queried whether the invitation made the amount of work required sufficiently clear given that invitees were not sent a copy of the agenda at this stage. The Panel noted that the final agenda ran from 10.30am to 4pm and provided plenty of opportunity for participation and discussion. The Panel considered that the agenda was not unreasonable given the stated purpose of the meeting. Overall the Panel considered that the honorarium of £500 to participate in the advisory board as described in the invitation was not unreasonable. The invitation made the role of participants sufficiently clear. The Panel noted the amount of work actually required. The payment was for genuine services. It was not inappropriate to offer to pay attendees of the advisory board in question. No breach of Clause 18.1 was ruled. The Panel accordingly ruled no breaches of Clauses 9.1 and 2.

In relation to the number of letters from representatives, the Panel noted Sanofi Pasteur MSD's submission that the public health expert had received no promotional mailings for Gardasil. The Panel noted that a Sanofi Pasteur MSD healthcare development executive had contacted three people within her local PCT responsible for policy decisions on budgets to make appointments. The expert had replied in a letter dated 17 October to the individual concerned, via the company's head office, explaining that a meeting was not necessary given the PCT's current position on vaccination policy. Despite this letter the Panel was concerned that some eight days later the same healthcare development executive sought an appointment with the expert, the company not having forwarded a copy of the expert's earlier letter. The company also noted that subsequent to the grant of the marketing authorization in September 2006 Sanofi Pasteur MSD's medical director wrote to her about a position statement on HPV vaccine which she co-authored. The position statement had advised staff to decline invitations to see company representatives. No one company was identified. She responded stating that she was reassured by Sanofi Pasteur MSD's response.

Overall the Panel did not consider that the volume of mailings sent by Sanofi Pasteur MSD was unacceptable. No promotional mailings about Gardasil had been sent to the expert. Nor was the frequency of contact made by healthcare development executives unacceptable. The Panel ruled no breach of Clauses 2, 9.1 and 12.2.

In relation to the meeting held in Paris on 22 March the first thing that the Panel had to consider was whether it or any aspect of it came within the scope of the Code. The meeting was held in France and was sponsored by Sanofi Pasteur MSD's French headquarters. The article 'Vaccination campaign funded by drug firm' noted the

President of CES, a public health institution stated that she agreed to participate only on condition that Sanofi Pasteur MSD paid. The response from the company stated that the meeting was organised by CES – implying that CES had more than a participatory role. The position was unclear. The Panel noted that the agenda featured both European and non European (US and South American) speakers and addressed global issues in relation to cervical cancer. Twenty five UK delegates attended (11 health professionals, 13 journalists and 1 representative from a patient group). The presentations were directed to all the delegates; no material was presented during the main agenda which solely addressed a UK audience. The Panel also considered that the supplementary information to Clause 1.7 Applicability of Codes was relevant. The Panel noted that a breakfast meeting had been held solely for UK journalists. The Panel considered that the Code applied to the invitation and the hospitality (accommodation, travelling and subsistence) provided to UK delegates. The Panel considered that the Code also applied to all of the arrangements in relation to and content of the breakfast briefing.

The Panel noted that the breakfast briefing, organised by Sanofi Pasteur MSD UK and attended by journalists from the UK and Ireland, enabled delegates to question a panel of UK experts in the field of cervical cancer. It was chaired by a medical adviser from the UK company. The Panel did not have a copy of the invitation to the breakfast briefing. No PowerPoint presentations were made and nor were any additional materials made available. The Panel considered that it had no evidence to show on the balance of probabilities that either the discussions that took place or the arrangements were unacceptable in relation to Clauses 2, 7.2, 9.1, 19.1 and 19.3.

The Panel noted that the arrangements for UK delegates should comply with Clause 19. The 2006 edition of the Code extended the requirements of Clause 19 to apply to journalists and patient groups for the first time. The Panel noted that travel was economy or standard class rail travel. The meeting venue did not appear unreasonable. Overnight accommodation was offered. It was unclear how many UK delegates had been provided with accommodation. Overall the Panel did not consider that the accommodation, travel and subsistence provided were unacceptable in relation to the requirements of Clause 19.1.

The Panel noted that UK journalists had been provided with a certified invitation by a UK agency. Due to human error UK health professionals and others had been invited using an uncertified version of the invitation by a French based agency. The uncertified two page invitation only referred to the company sponsorship at the end, as a postscript. Clause 19.3

required sponsorship to be declared such that the reader was aware of it at the outset. A breach of Clause 19.3 was ruled in relation to the invitation to UK health professionals and others.

The Panel noted that UK freelance journalists were paid a fee for attendance of 1.5 times their daily rate. The Panel noted that the supplementary information to Clause 19.1 stated that funding must not be offered to a health professional to compensate them merely for the time spent in attending meetings. The supplementary information to Clause 20.2 stated that meetings organised for or attended by, *inter alia*, journalists should comply with Clause 19. The Panel noted that there were differences in the role played at such meetings by journalists and health professionals. There were situations where it was legitimate to pay a health professional or journalist for their time when attending meetings such as participation on advisory boards or when they were otherwise being employed to undertake a specific piece of work so long as in each case the arrangements as a whole complied with the Code. On the evidence before the Panel it appeared that the journalists were simply delegates; they were not being paid for the benefit of their expertise or to undertake a specific piece of work. In such circumstances the payments were inappropriate in relation to Clause 19.1. Their freelance status was irrelevant. A breach of Clause 19.1 was ruled. High standards had not been maintained; a breach of Clause 9.1 was ruled. The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was reserved for particular censure.

The Panel, noting its rulings above, did not consider that the cumulative effect of the allegations was sufficient to warrant a ruling of a further breach of Clause 9.1 or a breach of Clause 2.

The Panel considered that all of its rulings applied to both Case AUTH/1980/3/07 and Case AUTH/1983/3/07.

Case AUTH/1980/3/07

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Case completed 28 June 2007

Case AUTH/1983/3/07

Complaint received 29 March 2007

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