PHARMACIST v CELGENE

Alleged promotion of Vidaza

A regional cancer hospital pharmacist complained about alleged inappropriate promotional activity by Celgene in relation to Vidaza (azacitidine). Vidaza was indicated for the treatment of certain adult patients with myelodysplastic syndromes (MDS), chronic myelomonocytic leukaemia (CMML) or acute myeloid leukaemia (AML).

The complainant stated that he was invited at the time of the submission of azacitidine to the Scottish Medicines Consortium (SMC) (around about August 2011) to attend an advisory panel meeting. Payment was to include travel plus a £600 honorarium. The meeting was to take place after the submission to the SMC and the complainant was aware that other pharmacists were also approached. Just before the British Oncology Pharmacy Association (BOPA) conference, the complainant was invited to another meeting for senior regional pharmacists post-SMC, again with a £600 honorarium. The complainant was aware that two local haematologists were also approached and they had suggested that events took place with quite a number of doctors. In September/October the local haematology pharmacist was invited to participate in an advisory panel and offered a £600 honorarium. The complainant was concerned about the advisory element of the meeting. The complainant had not been to any of the meetings but an agenda he had seen did not seem to form the requirements for a genuine review panel.

The detailed response from Celgene is given below.

The Panel noted from Celgene's submission that there was only one advisory board meeting held in relation to the use of Vidaza in Scotland. The date of the meeting had been changed and thus two invitations had been sent. The meeting was held in November and attended by four clinicians, one pharmacist and three Celgene employees. The complainant did not attend the meeting. The Panel noted that the health professional invitees were selected based on their interest and work in the area of MDS.

The Panel noted that the invitation to the advisory board meeting was clear that the meeting was an advisory board and the objectives were stated. Background information for the attendees asked them to review the information provided and questions posed so as to facilitate open, in-depth discussion. The chairman was briefed to, *inter alia*, 'help drive informative and useful discussions around the provided topics'.

The Panel considered that the fee of £600 offered to attendees reflected the time spent preparing for the meeting and expected participation on the day. The Panel considered that the invitation should have referred to the preparation work required by attendees.

The Panel noted that the advisory board meeting that took place in October was not related to Vidaza. The organisation of the meeting appeared to be similar to that of the Vidaza advisory board.

The Panel did not consider that the Vidaza advisory board meeting, the arrangements or the documentation constituted disguised promotion of Vidaza. The Panel considered that the attendees were engaged as genuine consultants; there appeared to be a legitimate need for their services, the number engaged was not unreasonable to achieve the identified objectives and the payment appeared reasonable. No breach was ruled. The Panel considered that as the payment offered to attendees reflected the services provided by each it was not a pecuniary advantage offered as an inducement to prescribe. No breaches of the Code were ruled including Clause 2.

A regional cancer hospital pharmacist complained about the activities of Celgene Limited in relation to the use of Vidaza (azacitidine) in myelodysplasia.

Vidaza was licensed for the treatment of certain adult patients who were not eligible for haematopoietic stem cell transplantation with myelodysplastic syndromes (MDS), chronic myelomonocytic leukaemia (CMML) or acute myeloid leukaemia (AML).

COMPLAINT

The complainant stated that he was invited at the time of the submission of azacitidine to the Scottish Medicines Consortium (SMC) (around about August 2011) to attend an advisory panel meeting. Payment was to include travel plus a £600 honorarium. The meeting would have taken place after the submission to the SMC and the complainant was aware that other pharmacists were also approached. Just before the British Oncology Pharmacy Association (BOPA) conference, the complainant was invited to another meeting for senior regional pharmacists post-SMC, again with a £600 honorarium. The complainant stated that he was aware that two local haematologists were also approached and they had suggested that events took place with quite a number of doctors. The complainant knew that in September/October the

local haematology pharmacist was invited to participate in an advisory panel and offered a £600 honorarium. The complainant was concerned about the advisory element of the meeting. The complainant had not been to any of the meetings but remembered seeing an agenda which did not seem to form the requirements for a genuine review panel.

The complainant alleged that this was inappropriate promotional activity.

When writing to Celgene, the Authority asked it to respond in relation to Clauses 2, 9.1, 12.1, 18.1 and 20.1 of the Code.

RESPONSE

Celgene stated that Vidaza was appraised and recommended by the National Institute for Health and Clinical Excellence (NICE) in March 2011 as a treatment option for adults who were not eligible for haematopoietic stem cell transplantation and who received the treatment as per the marketing authorization (NICE TAG 218). Documentation was submitted for the SMC review in April/May 2011 and the final decision published on 12 September 2011.

Celgene proposed to hold an advisory board in Scotland to address the challenges of making Vidaza available for Scottish patients in the event of either a positive or negative decision by the SMC. It started to plan the meeting in June 2011 with the intention of inviting 6-8 clinicians and pharmacists to discuss:

- the challenge of effectively sharing information regarding this treatment option for patients with MDS (where treatment options were limited),
- how the company could support hospitals with training needs, and
- the logistical issues that potentially might be faced with the availability of Vidaza or otherwise on the NHS in Scotland

Celgene invited a doctor to chair the meeting which was initially scheduled to be held on the 13 September 2011 (at this time, being unaware of the date of publication of the SMC guidance). The meeting however, was later rescheduled because only two invitees could make that date. The invitees were selected based on their interest and work in the area of MDS while trying to ensure there was a fair representation from different health boards in Scotland.

Celgene stated that the initial list of proposed invitees was shared with the chair and, based on his feedback, the list was refined. All but one of the initial invitees were re-invited together with a further 10 clinicians and pharmacists (of whom the complainant was one). The meeting was eventually held on 14 November 2011, the week after the complainant submitted his complaint. No advisory board relating to the use of azacitidine in Scotland had been held before the complaint was received.

In the event, nine responses were received from the invitees, and the meeting was attended by four clinicians, including the chairman, and one pharmacist. Three Celgene attendees were at the meeting to respond to questions and clarify information if required. The discussion guide and the agenda for the meeting were provided. Celgene considered that it was clear that the purpose of the meeting was to solicit advice and engage in discussions with the experts following the positive decision from the SMC. Celgene submitted that no presentations were delivered by the Celgene attendees. The chairman ran the meeting and the meeting notes (taken by one of the Celgene attendees) were to be written up and shared with the advisory board participants.

The honorarium of £600 was offered on the basis of the time required for the participants to prepare for and attend the three hour meeting. Celgene considered that this was a fair market value for the time and input required. Reimbursement of genuine travel costs was standard practice. Celgene presumed that, because the meeting was rescheduled and the invitations therefore sent twice, the complainant mistakenly believed another similar meeting had been held. The timing of the SMC advice publication and initial date of the meeting was coincidental as this date was confirmed with the chair on 1 July 2011 when the date of the SMC advice publication was unknown. Celgene was surprised that it was reported that two haematologists suggested that a meeting took place with quite a number of doctors at the time; no such meeting had taken place.

Celgene stated that a separate meeting held in October 2011, from midday until 5pm in Glasgow, was a network pharmacists advisory board which did not discuss azacitidine and was attended by six senior network pharmacists from across the UK. It was held immediately prior to the BOPA annual meeting, 14-16 October, to facilitate attendance by the invited experts. The objectives of the meeting were to understand the nature and possible UK funding pathways for Celgene's developmental product, romidepsin, and indication extensions for lenalidomide. Four Celgene employees also attended the meeting. The agenda did not include any presentations by Celgene and it was driven by the chairman. An honorarium of £500 was offered. Celgene received significant useful advice and the write up of the meeting was recently shared with the attendees. As explained above, this meeting was unrelated in any way to the activities surrounding azacitidine or the SMC. The discussion guide and the agenda for the advisory board were provided.

Celgene stated that all the materials and arrangements relating to both advisory boards were reviewed and approved. The company's standard operating procedure (SOP) relating to meetings was provided.

Celgene considered that it had always maintained the high standards expected of the pharmaceutical industry. It had not disguised its promotional activities in any way and had always ensured the purpose of its advisory boards had been clearly communicated. The remuneration to the health professionals attending the advisory boards was reasonable and reflected fair market value for the services provided. Celgene therefore submitted that it had fully complied with the Code and had not breached Clauses 2, 9.1, 12.1, 18.1, or 20.1.

There were currently no further plans for Vidaza or pharmacy advisory boards to take place in the UK, and no further SMC-related advisory boards were planned.

PANEL RULING

The Panel noted from Celgene's submission that there was only one advisory board meeting held in relation to the use of Vidaza in Scotland. The date of the meeting had been changed and thus two invitations had been sent. The advisory board meeting was held in November and attended by four clinicians, one pharmacist and three Celgene employees. The complainant did not attend the meeting. The Panel noted that the health professional invitees were selected based on their interest and work in the area of MDS.

The Panel noted that the invitation for the MDS advisory board meeting was clear that the meeting was an advisory board, and stated the objectives to be 'to review and discuss with your colleagues attending:

- Vidaza (azacitidine) and managing SMC outcome
- Scottish clinical practice and treatment pattern
- Dosing and administration challenges for Scotland and Vidaza (azacitidine)
- Cytogenic testing
- Potential opportunities for collaboration of clinicians and industry in improving care of MDS and AML patients in Scotland'

Background information for the attendees reminded them of the meeting objectives and asked them to review the information provided and questions posed so as to facilitate open, in-depth discussion. The chairman was briefed to, *inter alia*, 'help drive informative and useful discussions around the provided topics'.

The Panel considered that the fee of £600 offered to attendees reflected the time spent in preparation for the meeting and expected participation on the day. The Panel considered that the invitation should have referred to the preparation work required by attendees.

The Panel noted Celgene's submission that the meeting was run by the chairman with no presentations given at the meeting by any of the Celgene employees who had attended. The employees had been present to answer questions or provide clarification when required. One of the employees had taken meeting notes.

The Panel noted that the advisory board meeting that took place in October was not related to Vidaza. The organisation of the meeting appeared to be similar to that of the Vidaza advisory board, in that the invitation set out the objectives of the meeting. Background information was provided to attendees which included questions relating to each objective to be considered during the discussion. Again the Panel considered that the invitation should have referred to the preparation work required by attendees.

The Panel did not consider that the Vidaza advisory board was promotional. The invitation was clear that the meeting was an advisory board and included the meeting objectives. The agenda indicated a number of discussions based around the stated objectives. Background reading and preparation was required. The Panel did not consider that either the meeting or the documentation constituted disguised promotion of Vidaza. No breach of Clause 12.1 was ruled. The Panel considered that the attendees were engaged as genuine consultants; there appeared to be a legitimate need for their services, the number engaged was not unreasonable to achieve the identified objectives and the compensation provided in return for their services appeared reasonable. No breach of Clause 20.1 was ruled. The Panel noted its rulings of no breach above and thus considered that as the payment offered to attendees reflected the services provided by each it was not a pecuniary advantage offered as an inducement to prescribe. The Panel ruled no breach of Clause 18.1. Given its rulings above the Panel also ruled no breach of Clauses 9.1 and 2.

Complaint received **7 November 2011**

Case completed **20 December 2011**