CASE AUTH/2493/3/12

GENERAL PRACTITIONER v ASTRAZENECA

Invitation to an advisory board

A general practitioner complained about an invitation to participate in an AstraZeneca advisory board. The invitation consisted of three pages which had been faxed to the complainant's practice.

The complainant noted that page 2 of the facsimile was addressed to 'All GP's' [sic] and the letter (page 1 of the facsimile) was addressed to 'Dr X'. The complainant considered that this implied that invitees had not been specifically selected for their relevant expertise. It further implied that the facsimile was sent to multiple practices, such that the number of consultants was not limited to what might be reasonably necessary for the purpose of the advisory board.

Pages 1 and 2 of the facsimile referred to a £300 honorarium but on page 3 £125 was offered. Either way, the complainant considered this could be regarded as an incentive to attend without regard for the level of expertise non-specified GPs might be able to contribute.

The detailed response from AstraZeneca is given below.

The Panel noted the complainant had provided copies of three invitations to an AstraZeneca advisory board, one addressed to 'Dear Dr X'; one to 'All GP's' [sic] and the other with no stated addressee; the latter invitation was, according to AstraZeneca, intended for the practice manager. The Panel noted that the invitation to 'Dear Dr X' stated that the objective of the meeting was to gain advice and feedback on new educational materials to help GPs more effectively diagnose bipolar disorder and how best to discuss these materials via a team of telephone-based service agents. Given the broad stated objectives the Panel noted that AstraZeneca aimed to recruit GPs from across the mental health and commissioning spectrum. The meeting objectives stated in the invitation for practice managers were similar to those above, with the additional objective of gaining advice and feedback on how the educational materials might support the practice and patients by achieving targets through increased and more accurate diagnosis. AstraZeneca also wanted to assess criteria upon which a practice manager might permit access to speak to a GP directly. The Panel noted the broad objectives of the advisory board and the aim to recruit managers from a broad spectrum of practices including those with no mental health lead.

The Panel noted that what appeared to be the covering letter referred only to the GP advisory board on 26 March. The practice manager invitation bore no addressee and did not make it at all clear that invitees had to be practice managers. The Panel noted the objectives of the advisory boards and consequently the broad selection criteria for participants. Given such broad selection criteria the Panel did not consider the use of the term 'All GPs' and 'Dear Dr X' in relation to a GP surgery was unreasonable, or that on the specific facts of this case the GP advisory board invitation implied that no selection had taken place as alleged. No breach of the Code was ruled in that regard. In relation to the practice manager invitation the Panel considered that the absence of any addressee, the failure to identify the status of consultants within the letter and the absence of any relevant covering letter gave a poor impression and implied that no specific selection of consultants had or would take place. A breach of the Code was ruled.

The Panel noted that although the educational module to be discussed at the advisory boards related to mental health, it would be made available to all GPs regardless of their expertise in that therapy area. The GP advisory board, if it had gone ahead, would have consisted of six GPs, one clinical commissioning group mental health lead, one GP that saw his own mental health patients and a mental health locality cluster lead. The practice manager advisory board, if it had gone ahead, would have consisted of five managers from practices where GPs had no special interest in mental health, three from practices where there was a mental health lead and two from practices where there was a clinical commissioning group mental health lead. In the Panel's view, the attendees at each advisory board had ultimately been selected such as to fairly represent the target audience for the educational materials under discussion. The Panel did not consider that an advisory board of nine or ten was a number greater than that reasonably necessary to achieve the objectives outlined above in the 3 hours available. No breach of the Code was ruled in that regard.

The Panel noted its comments and rulings above about the meetings' objectives and the consultants' honoraria. The Panel did not consider that the honoraria were an inducement to prescribe or recommend any medicine and consequently ruled no breach of the Code.

A general practitioner complained about an invitation which he had received from a market research company to take part in an AstraZeneca advisory board. The invitation consisted of three pages which had been faxed to the complainant's practice. The matter was taken up with AstraZeneca UK Limited.

COMPLAINT

The complainant noted that page 2 of the facsimile was addressed to 'All GP's' [sic] and the letter (page 1 of the facsimile) was addressed to 'Dr X'. The complainant considered that this implied that invitees had not been specifically selected for their relevant expertise. It further implied that the facsimile was sent to multiple practices, such that the number of consultants was not limited to what might be reasonably necessary for the purpose of the advisory board.

The complainant submitted that it was unclear how his practice had been selected, or whether specific GPs were being invited.

Pages 1 and 2 of the facsimile referred to a £300 honorarium but on page 3 it was stated that £125 was offered as a fee for attendance and contribution at the advisory board. Either way, the complainant considered this could be regarded as an incentive to attend without regard for the level of expertise non-specified GPs might be able to contribute.

As such, the complainant alleged that this activity was in breach of Clause 20.1 on the use of consultants and Clause 9.1, failing to maintain high standards.

When writing to AstraZeneca, the Authority asked it to respond in relation to Clauses 2 and 18.1 in addition to Clauses 9.1 and 20.1 cited by the complainant.

RESPONSE

AstraZeneca noted that the complaint centred around the selection and compensation of attendees invited to participate in an advisory board. Although the complaint was about an advisory board on 26 March 2012, another advisory board planned for the 29 March 2012 was relevant and there was further explanation below.

AstraZeneca submitted that it had worked with a third party to develop educational modules to help GPs better diagnose bipolar and unipolar depression. This was an important educational need because a depressed patient's first contact with the health service was his/her GP and misdiagnosis was common. The educational modules were written by an independent clinician chosen by the third party and were not product related, but were in the process of being certified according to AstraZeneca procedures. AstraZeneca intended the educational modules to be accessed electronically and to tell GPs about them via its TeleReach service - a service whereby ABPI qualified representatives telephoned general practices at allotted times to speak to either a practice manager or a relevant health professional to discuss a proposed non-promotional patient- or disease-centered offering. Many practices preferred the TeleReach representatives to speak to the practice manager to discuss the offering before allowing them to speak to a relevant health professional.

Given the need to understand how to correctly position a new educational service offering for serious mental health with a primary care audience and how to offer this with a new service team, AstraZeneca had organised advisory boards with the appropriate stakeholders. This need arose because with previous offerings in different therapy areas there had been a variance on how often the TeleReach team had had a telephone conversation with a GP with little insight as to why this variance might occur.

AstraZeneca submitted that the objective of the advisory board in question was to gain advice from GPs about the value of these non-promotional educational modules to their ongoing clinical practice and to gain clarity on the optimal way to explain these modules during a telephone conversation, with the aim of maximising the educational benefit of the modules and optimising the telephone interaction with the GP. Another objective for the advisory board was to discuss the TeleReach service and gain the GPs' advice and feedback on the service in general, how it might be best used and the type of services they would be interested in finding out about by this method. The advisory board was to last 3 hours on the evening of 26 March. There was no intended pre work but attendees were expected to be engaged and contribute advice for the majority of those 3 hours, which was reflected in the agenda.

However, on the day before receiving the complaint there was an announcement of a High Court decision that resulted in the unexpected loss of the Seroquel XL (long acting quetiapine) patent formulation in the UK, which was AstraZeneca's only promoted mental health product. Therefore any activities in development that related to the brand and the mental health therapy area were immediately stopped, and as this included the educational modules about depression it would have been inappropriate to continue with the advisory board which was thus cancelled. This decision was communicated to attendees on 22 March.

AstraZeneca stated that on 29 March 2012 another advisory board was planned with similar objectives but different attendees; GP practice managers. The intention of this advisory board was to discuss similar topics as outlined above but to gain specific advice from practice managers. This was because most of the time the TeleReach representatives had to speak to a practice manager before being allowed to speak to a health professional or they might only ever get to speak to the practice manager. This telephone conversation needed to be framed differently to that with a GP. Therefore it was appropriate to gain the advice of practice managers and their input into what they would want to know about these educational modules to ensure that AstraZeneca was able to communicate their benefit for GPs and ultimately patient care in their practice. In addition, it was important for AstraZeneca to gain advice on the TeleReach service from these important stakeholders. This advisory board, however, was also cancelled for the reasons stated above.

AstraZeneca submitted that it engaged a market research agency to recruit for both advisory boards. AstraZeneca gave the agency a written brief detailing the purpose of the advisory boards, including the criteria for the recruitment of attendees. The brief contained sufficient background to ensure that the agency understood the TeleReach service and the rationale behind why AstraZeneca produced educational modules about the correct diagnosis of depression. To give full context there was a brief synopsis of AstraZeneca's relevant medicine and how the brand strategy was relevant to the educational modules. The agency was not expected to mention the brand whilst recruiting, particularly as there would be no brand discussion in the advisory board.

AstraZeneca explained that it had asked the agency to recruit 8-10 GPs with differing experience and areas of interest for the advisory board. Due to the nature of the advice being sought in relation to the broad applicability of the educational materials and how best to deliver them through a TeleReach channel, it was not necessary to select individuals with significant clinical experience in mental health. Instead, the recruitment strategy required GPs from across the mental health therapeutic interest and commissioning spectrum; 1 or 2 GPs who were clinical commissioning group (CCG) mental health leads, 2 or 3 GPs who were the mental health leads for their GP practice and 4 or 5 GPs with no specific interest in mental health. AstraZeneca requested this participant breakdown because the educational modules would be available to all GPs and this proportion represented the likely final audience. This breakdown also met the requirements of the second objective of the advisory board; to obtain feedback about the TeleReach service in general. The final attendance list consisted of 9 GPs of which 3 had a particular interest in mental health because of responsibilities in their practice or CCG.

AstraZeneca stated that the briefing for the practice manager advisory board stated that 8-10 practice managers should attend; the practice managers should have worked in practices with GPs who occupied roles as CCG mental health leads (1 or 2), in GP practices with a mental health lead (2 or 3) and in GP practices where there was no mental health lead (4 or 5) in order to gain a broad spectrum of advice. Of the 10 practice managers due to attend the advisory board, 5 either had a mental health lead GP within the practice or one of their GPs was the CCG mental health lead.

AstraZeneca submitted that therefore during the recruitment process, GP practices were contacted not only to assess suitability of the GPs but also the practice manager, and the final attendee lists demonstrated that the agency worked within its brief. Unfortunately, as neither advisory board met, there were no outputs to share. However, AstraZeneca considered that it had demonstrated a strong rationale and robust reasoning for the choice and number of attendees in direct relation to the identified need, and it therefore refuted the alleged breach of Clause 20.1.

With regard to Clause 18.1 AstraZeneca submitted that attendees at an advisory board routinely received an honorarium for the provision of advice and feedback. AstraZeneca policy required the honorarium to reflect fair market value for the role and time spent, and it must not be used as an undue incentive to attend. As there was no intent to discuss an AstraZeneca product at the advisory board in question AstraZeneca considered that the reasonable honorarium offered could not be deemed an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.

AstraZeneca stated that it made no attempt to target prescribers of any particular product; the recruiting agency was not given any criteria to recruit based on any sales or potential sales.

AstraZeneca submitted that the proposed honoraria took into account the professional standing of the two groups recruited and were based on AstraZeneca's fair market value in both cases. It was also appropriate to reimburse reasonable travel expenses incurred in attending the advisory board meeting. For GPs the honorarium was £300 and reimbursement of reasonable travel expenses. This was in line with AstraZeneca's fair market value table.

AstraZeneca had limited experience of engaging practice mangers for their services but it was initially considered that £125, with reasonable travel expenses, was an appropriate fair market value for a three hour advisory board. However the agency suggested that £150 would be more appropriate and this was to be reflected in the confirmatory invitation.

Thus AstraZeneca considered that it had demonstrated a clear rationale related to identification and calculation of a suitable fair market value honorarium, which was not an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. AstraZeneca refuted the alleged breach of Clause 18.1.

AstraZeneca submitted that usually the recruiting agency initially tried to telephone GPs at their practices to establish their interest and relevant experience for an advisory board, using a company's recruitment criteria. If the GP was appropriate for the advisory board and indicated that he/she would be able to attend, the agency emailed him/her a formal invitation. This email had been reviewed and certified by AstraZeneca signatories for this purpose.

AstraZeneca stated that practice receptionists did not always let the agency talk to the GP or practice manager directly, but instead asked for details to be either faxed or emailed for them to pass onto the relevant person, with a brief explanation of what it related to. In cases where there was more than one

eligible GP in the practice, receptionists frequently asked for only one invitation and not one per GP. In such cases, the facsimile would be addressed to 'All GPs'. This scenario was routine practice for this agency as receptionists often limited access to GPs, to protect their time for patient care.

AstraZeneca submitted that as stated above, during this recruitment process, GP practices were contacted not only to assess the suitability of the GP but also the practice manager. If the agency could not speak to the practice manager then both invitations (GP and practice manager) would be faxed or emailed to the receptionist to pass onto the relevant people. The agency produced a covering letter to go with the invitation(s) to ensure the receptionist could identify the documents. The covering letter also contained the agency's contact details in case the GP or practice manager wanted to participate in the advisory board.

AstraZeneca stated that the agency contacted 80 GP practices to obtain approximately 20 attendees who met the pre-specified criteria. The final list of attendees for both advisory boards fulfilled the pre-specified criteria given to the agency which demonstrated that by this process it was able to identify eligible people and screen out when appropriate.

AstraZeneca submitted that it was difficult to know how the situation arose with the complainant as the complaint was anonymised. The agency was very clear that the process was as outlined above and it was possible that the complainant's practice received two invitations (GP and practice manager), one of which was addressed to 'Dr X' and another with no addressee, as a result of this being requested by the receptionist when telephoned by the agency. The agency was aware that the intention was to personalise the invitation with the recipient's name and did so in cases where it had spoken directly to the intended recipient. In cases where the receptionist had requested it to be sent for him/her to pass on to the relevant person, the agency admitted that due to an oversight on its part it had either not put a recipient's name on the invitation or had left it blank.

AstraZeneca accepted full responsibility for the actions and oversight of its third parties but contended that there had not been a breach of high standards in this case given the full explanation above and the validity of the advisory board. It was unfortunate that the complainant received the invitations with no context or explanation from the receptionist. AstraZeneca had described a clear rationale for the advisory boards and demonstrated that it sought to recruit a limited number of appropriate attendees using a robust recruitment strategy; the attendees were offered honoraria for their services based on the AstraZeneca fair market value for their role. AstraZeneca refuted the alleged breach of Clause 9.1.

In conclusion, AstraZeneca accepted that the complainant had experienced unintentional confusion and concern about the advisory boards but, based on the above, it refuted the alleged breaches of Clauses 9.1, 18.1 and 20.1. In addition, the company confirmed that neither the agency nor it had received a complaint from any of the other practices contacted. AstraZeneca considered that high standards were maintained when recruiting for and organising the advisory boards and that the agency followed a correct process. Also, as demonstrated, this was a legitimate advisory board, with appropriate invitees being offered honoraria that reflected their professional standing and fair market value. AstraZeneca thus refuted the alleged breach of Clause 2.

PANEL RULING

The Panel noted that 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.

To be considered a legitimate advisory board the choice and number of participants 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 participants at a meeting should be limited so as to allow active participation by all. The agenda should allow adequate time for discussion. The number of meetings and the number of participants 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, the expected advisory role and the amount of work to be undertaken.

The Panel noted the complainant had provided copies of three invitations to an AstraZeneca advisory board, one addressed to 'Dear Dr X'; one to 'All GP's' [sic] and the other with no stated addressee; the latter invitation was, according to AstraZeneca, intended for the practice manager. The Panel noted that the invitation to 'Dear Dr X' stated that the objective of the meeting was to gain advice and feedback on new educational materials to support GPs with more effective diagnosis of bipolar disorder and how best to discuss these materials via a team of telephone-based service agents. Given the broad stated objectives the Panel noted that AstraZeneca aimed to recruit GPs from across the mental health and commissioning spectrum. The meeting objectives stated in the invitation for practice managers were similar to those above, with the additional objective of gaining advice and feedback on how the educational materials might support the practice and patients by achieving targets through increased and more accurate diagnosis. AstraZeneca had also submitted that it wanted to assess criteria upon which a practice

manager might permit access to speak to a GP directly. The Panel noted the broad objectives of the advisory board and the aim to recruit managers from a broad spectrum of practices including those with no mental health lead. According to AstraZeneca these selection criteria were met in relation to each advisory board.

The Panel noted AstraZeneca's submission that the agency initially contacted practices by telephone, but if they were not permitted to speak to a GP or practice manager then a facsimile or email was sent to the receptionist to be passed on to the relevant person. AstraZeneca submitted that in these instances the agency produced a covering letter which was sent with the invitation to ensure that it was passed to the intended recipient. The Panel noted that the two documents received by the complainant in relation to the GP advisory board were addressed to 'Dear Dr X' and 'All GP's' [sic]. The latter appeared to be a covering letter produced by the agency although the position was unclear. It did not appear to be part of the approved material for the advisory board provided by AstraZeneca. The third document, an invitation to the practice manager advisory board, did not bear an addressee. The Panel noted AstraZeneca's submission that faxes were sometimes not addressed to an individual at the request of the practice receptionist, and considered that this was unsatisfactory. The selection of participants must stand up to scrutiny. In this regard the Panel noted AstraZeneca's acknowledgement that there was an unfortunate oversight on the part of its agency in either not putting a recipient's name on the invitation or leaving it blank. The Panel noted that the identity of the complainant had not been disclosed and thus AstraZeneca was unable to comment on the arrangements in place at the complainant's practice.

The Panel noted that what appeared to be the covering letter referred only to the GP advisory board on 26 March. The practice manager invitation bore no addressee and did not make it at all clear that invitees had to be practice managers. The Panel did not know whether AstraZeneca's agency had had a telephone conversation with the complainant's receptionist about this letter and, if so, what was said. However, it would not be unreasonable for a receptionist to mistakenly assume that it was intended for any health professional or senior administrative staff employed at the practice. Indeed the complainant appeared to view the practice manager invitation as part of the information about the GP meeting.

The Panel noted the objectives of the advisory boards and consequently the broad selection criteria for participants. Given such broad selection criteria the Panel did not consider the use of the term 'All GPs' and 'Dear Dr X' in relation to a GP surgery was unreasonable, or that on the specific facts of this case the GP advisory board invitation implied that no selection had taken place as alleged. No breach of Clause 20.1 was ruled in that regard. In relation to the practice manager invitation the Panel considered that the absence of any addressee, the failure to identify the status of consultants within the letter and the absence of any relevant covering letter gave a poor impression and implied that no specific selection of consultants had or would take place. A breach of Clause 20.1 was ruled.

The Panel noted that although the educational module to be discussed at the advisory boards related to mental health, it would be made available to all GPs regardless of their expertise in that therapy area. In that regard the written brief provided to the agency engaged to recruit for the advisory boards required it to ensure that the GP advisory board was made up of 8-10 GPs, to include 1-2 clinical commissioning group mental health leads, 2-3 practice mental health leads and 4-5 GPs with no specific interest in mental health. The practice manager advisory board was to consist of those who worked in practices with GPs who had similar roles to those described above. The GP advisory board, if it had gone ahead, would have consisted of six GPs, one clinical commissioning group mental health lead, one GP that saw his own mental health patients and a mental health locality cluster lead. The practice manager advisory board, if it had gone ahead, would have consisted of five managers who worked in practices where GPs had no special interest in mental health, three who worked in practices where there was a mental health lead and two who worked in practices where there was a clinical commissioning group mental health lead. In the Panel's view, and irrespective of its ruling above about the practice manager advisory board invitation, the attendees at each advisory board had ultimately been selected such as to fairly represent the target audience for the educational materials under discussion. The Panel did not consider that an advisory board of nine or ten was a number greater than that reasonably necessary to achieve the objectives outlined above in the 3 hours available. No breach of Clause 20.1 was ruled in that regard.

The Panel noted that it was a legitimate activity for pharmaceutical companies to engage health professionals as consultants for a range of activities, including as advisory board members, and that health professionals could be paid a fee for such services. The Panel noted that both meetings had been scheduled to run from 6.30 – 9.30pm with one 15 minute break. Each agenda item outlined the discussion and feedback expected from participants. The honorarium offered in the invitation to GPs was £300 and for practice managers the honorarium offered in the invitation was £125. The Panel did not consider that these were unreasonable fees for 2 ¾ hours' work and did not consider that either payment was, in itself, an incentive to attend either meeting as alleged. No breach of Clause 20.1 was ruled.

The Panel further noted that the agency brief stated that one of the objectives of both advisory boards was to 'Gain feedback on the Seroquel offering'. The Panel assumed that this referred to the educational materials described above. The Panel considered that this was unfortunate wording to describe such materials, which should be non-promotional.

The Panel noted its comments and rulings above about the meetings' objectives and the consultants' honoraria. The Panel did not consider that the honoraria were an inducement to prescribe or recommend any medicine and consequently ruled no breach of Clause 18.1.

The Panel noted its rulings above and subsequently ruled no breach of Clauses 9.1 and 2.

Complaint received **23 March 2012**

Case completed **30 May 2012**
