ANONYMOUS v ASTRAZENECA

Promotion of Seroquel

An anonymous complainant alleged that the content of an AstraZeneca meeting was misleading and promoted Seroquel (quetiapine) outwith its marketing authorization. Seroquel was licensed for the treatment of schizophrenia and bipolar disorder.

The subject of the meeting was 'Cognitive treatment of borderline personality disorder (BPD)'. The first part concerned the use of cognitive therapy but according to the complainant soon moved onto which medicine should be used, of which Seroquel was recommended as the medicine of choice. It was not implied or stated that Seroquel was unlicensed for this diagnosis. The complainant considered that this was a contrived attempt to draw attendance on one subject then manipulate the talk to the use of an unlicensed medicine therefore deliberately misleading the audience.

The detailed response from AstraZeneca is given below.

The Panel noted that the parties' account of the meeting in question differed. The complainant alleged that the meeting, held almost 6 months' previously, was about cognitive treatment of borderline personality disorder and included a recommendation that Seroquel was the medicine of choice. The complainant had stated that the meeting was held in the last week of October or the first week of November. AstraZeneca submitted that the only meeting it had sponsored at the named venue in October/November 2009 was held on 5 November. The meeting was about schizophrenia, in line with the Seroquel summary of product characteristics (SPC), and that borderline personality disorder was only referred to by the speaker in order to answer an unsolicited question from the audience.

The Panel was very concerned to note that AstraZeneca had not been able to provide copies of the invitation, agenda or slides used at the meeting. This was wholly unacceptable. In that regard the company had no record of the proceedings and thus had been unable to provide a robust response to the complaint. The meeting had been sponsored by AstraZeneca; the local representative had briefed the speaker. The company was thus responsible for the format and content of the meeting. In that regard the Panel disagreed with AstraZeneca's submission that the presentation was educational and thus did not require certification. This submission appeared to contradict AstraZeneca's speaker guidance document which stated that meetings organised by the sales force were classified as promotional. AstraZeneca was responsible for what the speaker said on its behalf and in the Panel's view his slides should have been certified. The meeting confirmation note given to the out-patient manager stated that the meeting would comprise a presentation on an AstraZeneca product in the management of schizophrenia. The form further stated that the meeting would last 50 minutes and a simple buffet would be provided.

The agenda for the meeting as recorded on the territory management system stated that the meeting title was 'Schizophrenia case study'. The meeting approval document on the territory management system referred to Seroquel, a schizophrenia case study, acute schizophrenia and schizophrenia in the community.

The Panel noted that AstraZeneca had provided accounts of the meeting from three of the attendees. When asked what the meeting was about one person stated that it was about schizophrenia and that they thought borderline personality disorder might have been mentioned. A second person stated that the meeting topic was the management of borderline personality disorder with psychotherapy; they could not remember anything being presented on schizophrenia and they further stated that quetiapine was not mentioned. A third person also stated that the meeting was about the management of borderline personality disorder; they did not think that schizophrenia was discussed. The third person thought that, in discussion with the audience, anti-psychotics were mentioned a little but were not the main focus. Neither the Panel nor AstraZeneca knew the complainant's identity.

The Panel noted that the complainant had the burden of proving their complaint on the balance of probabilities. The complainant had provided no material to support their allegation. Two of the three witness statements, provided by AstraZeneca, however, appeared to give some support to the complainant's allegation in that both attendees thought the meeting was about borderline personality disorder. However, when one was asked if quetiapine was mentioned they said 'No, it was just an educational talk'. The other attendee thought anti-psychotics were mentioned a little but were not the main focus. When asked more generally about any discussion about pharmacotherapy, the attendee stated 'From memory the "usual thing" that although nothing is licensed in personality disorder some medications exert some useful impact'. The Panel considered

that there was no evidence to show that AstraZeneca had promoted Seroquel outwith its marketing authorization as alleged. Taking all of the circumstances into account, the Panel did not consider that on the balance of probabilities Seroquel had been promoted for borderline personality disorder. No breach of the Code was ruled. The Panel further considered that although there appeared to be some confusion about the topic of the meeting, there was no evidence to show that delegates had been misled about Seroquel. No breach of the Code was ruled. The Panel did not consider that it had any evidence to show that the meeting was disguised promotion. No breach of the Code was ruled. Similarly the Panel considered that it had no evidence to show that the representative had not maintained a high standard of ethical conduct. No breach of the Code was ruled.

The Panel noted that AstraZeneca's record of the meeting was extremely limited. This was wholly unacceptable. The company did not know what invitations had been sent on its behalf, nor had it certified the presentation delivered. In the Panel's view this was extremely poor practice. The Panel was concerned that material that would have helped AstraZeneca respond to this complaint had either not been generated or copies had not been kept. This had left the company vulnerable and unable to robustly respond to the allegations made. Nonetheless the complaint at issue was about the content of the meeting, not the arrangements for it and in that regard there was no evidence to show that high standards had not been maintained. The Panel ruled no breach of the Code.

An anonymous complainant complained about the promotion of Seroquel (quetiapine) by AstraZeneca. Seroquel was licensed for the treatment of schizophrenia and bipolar disorder.

COMPLAINT

The complainant alleged that an AstraZeneca meeting was not only misleading in its content but also blatantly promoted Seroquel outwith its marketing authorization. The complainant considered that the underhand way this meeting was held brought the pharmaceutical industry into disrepute and further weakened confidence with NHS employees.

The complainant submitted that the meeting in question was held in the last week of October or the first week in November 2009 at a named venue. The meeting was facilitated by the local AstraZeneca representative. The subject was 'Cognitive treatment of borderline personality disorder (BPD)'. The first part of the talk concerned the use of cognitive therapy but soon moved onto which medicine should be used, of which Seroquel was recommended as the medicine of choice. At no point was it implied or stated that Seroquel was unlicensed for this diagnosis.

The complainant considered that this was a contrived attempt to draw attendance on one subject then manipulate the talk to the use of an unlicensed medicine therefore deliberately misleading the audience.

When writing to AstraZeneca the Authority asked it to respond with regard to the requirements of Clauses 2, 3.2, 7.2, 9.1, 12.1 and 15.2 of the Code.

RESPONSE

AstraZeneca acknowledged that a meeting had taken place at the named venue on 5 November 2009. It was an educational speaker meeting organized by the local representative with support and assistance from an NHS out-patient manager of a partnership NHS foundation trust who coordinated meetings between pharmaceutical companies and the doctors' diaries. The representative discussed the arrangements with the out-patient manager which included potential invitees. The representative then sent the out-patient manager a meeting confirmation note to confirm their discussion. The local NHS standard practice was that the out-patient manager populated a standard NHS meeting form with the relevant details of the meeting and then sent the invitation to those health professionals that they knew would educationally benefit from pharmaceutical company speaker meetings. AstraZeneca stated that its meeting records indicated that six general adult psychiatrists and one doctor on a GP rotation attended the meeting. Prior to the meeting the out-patient manager also sent a reminder to the attendees of the logistical details of the meeting and confirmed attendees.

AstraZeneca submitted that the venue was selected as it was conveniently located for the intended audience and had a private function room away from the public where the educational meeting was held.

The speaker was a general adult consultant psychiatrist. The representative asked him to present a schizophrenia case study entitled 'Management of Schizophrenia'. The representative visited the speaker three times and briefed him on the educational requirements of the meeting and the Code in line with the AstraZeneca Speaker Briefing Guidance document. The representative asked the speaker to discuss a real life schizophrenia patient case study with relevance to Seroquel, based on the speaker's experience as reflected in the meeting confirmation note. In response to this brief, the speaker prepared and presented an anonymised patient case study in schizophrenia and discussed the disease area and various treatment options, including Seroquel, which was the medicine used to manage the patient in question. The treatment of a patient with schizophrenia was in line with the marketing authorization and in accordance with the summary of product characteristics (SPC) for Seroquel. The

speaker was not briefed to discuss the use of Seroquel in patients with borderline personality disorder. Therefore, AstraZeneca denied a breach of Clause 3.2.

There was no evidence to suggest that the information presented in the case study was not factual, accurate or balanced or was misleading. Therefore, AstraZeneca did not believe there had been a breach of Clause 7.2.

The meeting started at 7.30pm and finished with questions and discussions at 8.45pm when an evening meal was served. Seven health professionals (including the speaker) and two AstraZeneca representatives attended.

During the presentation, one of the attendees asked the speaker an unsolicited question about borderline personality disorder and schizophrenia. The speaker answered the question using a separate presentation saved on his laptop which the AstraZeneca representative was unaware of. The speaker had created and used this presentation with his own medical team earlier that month. In the presentation he referred to guidance from the National Institute for Health and Clinical Excellence (NICE) in order to answer the question. In answering the question, the speaker stated that atypical anti-psychotics should not be used for borderline personality disorder. The question about borderline personality disorder was not solicited by either the speaker or the AstraZeneca representative. After answering the question the speaker returned to the agreed presentation to proceed with the talk. The second presentation was not planned by the speaker or AstraZeneca and was only used to effectively reply to a question from the audience. The content of the main presentation was educational and any reference to therapy areas that were outside the licence for Seroquel was as a legitimate, professional and independent response to an unsolicited question in that area. Therefore, AstraZeneca did not believe there had been a breach of Clauses 3.2 or 12.1.

The representative followed a local procedure adopted by the NHS for organising local speaker meetings. The representative had visited the speaker three times to brief him on the requirements of the meeting including Code requirements and had briefed the meeting organiser with a written agenda. Therefore, AstraZeneca did not believe there had been a breach of Clause 15.2.

The meeting was an educational meeting based on a real life case study of a patient with schizophrenia and treatment options. It was consistent with the Seroquel marketing authorization. The speaker's reference to borderline personality disorder was in direct response to an unsolicited question from the audience. This was not planned and as such the response was neither briefed by the representative nor encouraged and was only a very small proportion of the overall education supplied by the speaker. As detailed above, AstraZeneca did not believe there was a breach of Clauses 3.1, 12.1, 7.2 or 15.2. Therefore AstraZeneca did not believe that high standards had been compromised or that the industry had been brought into disrepute and therefore denied a breach of Clauses of 2 and 9.1.

The representative had passed the ABPI Medical Representatives Examination and all AstraZeneca internal codes and policies. AstraZeneca did not intend to apply for a licence for borderline personality disorder and correspondingly there were no representatives' briefing materials on this matter.

AstraZeneca noted that the presentation was created independently by the speaker in response to a briefing from the representative and as such was intended to be an educational presentation and therefore it did not require certification. The company was unable to provide a copy of the presentation as it was the speaker's own slide deck which had since been deleted.

In response to a request for further information AstraZeneca stated that it had requested copies of the invitation from the representative who organized the meeting, the out-patient manager as well as the presenter and attendees. However, due to the time delay between the meeting date and the complaint the company had not been able to obtain a copy of the invitation. The information AstraZeneca had on its territory management system was the meeting confirmation note and the template invitation. Copes of both were provided.

In response to a request for a written agenda used by the representative to brief the meeting organiser, AstraZeneca referred to the meeting confirmation note previously provided. AstraZeneca provided a copy of the agenda as recorded on the territory management system but could not confirm whether the latter was sent by the representative to the out-patient manager.

AstraZeneca submitted that no written communication took place between the parties involved. Speaker briefing meetings took place as detailed above.

It appeared that no materials or agendas were distributed at the meeting.

The meeting was approved by the representative's manager and a copy of the relevant entry to the territory management system was provided.

AstraZeneca provided witness accounts from three delegates, although since the meeting took place about six months' ago recollection of specific details was sparse. One delegate recollected the meeting focussed on a schizophrenia case where mention might have been made of borderline personality disorder. This account was in line with the account above. Another delegate recollected that the meeting concentrated on the management

of borderline personality disorder although did not remember Seroquel being recommended for borderline personality disorder. The third delegate remembered that the presenter had technical difficulties with his presentation so had to use a draft slide presentation. He stated the presentation focused on borderline personality disorder and that pharmacological treatments might have been discussed during the group discussion but any such discussion was not the primary purpose of the meeting and was not initiated by the representative or the presenter.

AstraZeneca stated that after such a period of time had elapsed between the meeting and the complaint being received, the parties involved had different recollections of the event. AstraZeneca referred to the documentation in the territory management system and to its comments above. It appeared that the meeting was developed to cover a case of a patient with schizophrenia rather than borderline personality disorder however, during the meeting it appeared that in order to answer a question the presenter switched to a presentation on borderline personality disorder.

AstraZeneca denied a breach of Clauses 2, 3.2, 7.2, 9.1, 12.1, and 15.2 of the Code. AstraZeneca took any complaint seriously and so was reviewing internal procedures to ensure that processes were as robust as they needed to be to withstand any future complaints of this nature.

PANEL RULING

The Panel noted that the parties' account of the meeting in question differed. The complainant had alleged that the meeting, held almost 6 months' previously, was about cognitive treatment of borderline personality disorder and included a recommendation that Seroquel was the medicine of choice. The complainant had stated that the meeting was held in the last week of October or the first week of November. AstraZeneca submitted that the only meeting it had sponsored at the named venue in October/November 2009 was one held on 5 November. The meeting was about schizophrenia, in line with the Seroquel SPC, and that borderline personality disorder was only referred to by the speaker in order to answer an unsolicited question from the audience. It was difficult to know what had happened at the meeting.

The Panel was very concerned to note that AstraZeneca had not been able to provide copies of the invitation, agenda or slides used at the meeting. This was wholly unacceptable. In that regard the company had no record of the proceedings and thus had been unable to provide a robust response to the complaint. The meeting had been sponsored by AstraZeneca; the local representative had briefed the speaker. The company was thus responsible for the format and content of the meeting. In that regard the Panel disagreed with AstraZeneca's submission that the presentation was educational and thus did not require certification. This submission appeared to contradict AstraZeneca's speaker guidance document which stated that meetings organised by the sales force were classified as promotional. AstraZeneca was responsible for what the speaker said on its behalf and in the Panel's view his slides should have been certified. The meeting confirmation note given to the out-patient manager stated that the meeting would comprise a presentation on an AstraZeneca product in the management of schizophrenia. The form further stated that the meeting would last 50 minutes and a simple buffet would be provided. The template invitation, however, (to be completed by the out-patient manager) referred to 'Dinner' and the acceptance/rejection form attached appeared to allow those accepting the invitation to state which starter, main course and dessert they would like.

The AstraZeneca Speaker Briefing Guidance document referred extensively to the requirements of the Code and stated that the main focus of any meeting organised by AstraZeneca sales teams must be within licence. Such a meeting was classified as promotional and no data on unlicensed products or unlicensed uses of licensed products might be presented. The agenda for the meeting as recorded on the territory management system stated that the meeting title was 'Schizophrenia case study'. The meeting approval document on the territory management system referred to Seroquel, a schizophrenia case study, acute schizophrenia and schizophrenia in the community.

The Panel noted that AstraZeneca had provided accounts of the meeting from three of the attendees. When asked what the meeting was about one person stated that it was about schizophrenia and that they thought borderline personality disorder might have been mentioned. A second person stated that the meeting topic was the management of borderline personality disorder with psychotherapy; they could not remember anything being presented on schizophrenia and they further stated that quetiapine was not mentioned. A third person also stated that the meeting was about the management of borderline personality disorder; they did not think that schizophrenia was discussed. The third person thought that, in discussion with the audience, anti-psychotics were mentioned a little but were not the main focus. Neither the Panel nor AstraZeneca knew the complainant's identity.

The Panel noted that the complainant had the burden of proving their complaint on the balance of probabilities. The complainant had provided no material to support their allegation. Two of the three witness statements, provided by AstraZeneca, however, appeared to give some support to the complainant's allegation in that both attendees thought the meeting was about borderline personality disorder. However, when one was asked if quetiapine was mentioned they said 'No, it was just an educational talk'. The other attendee thought anti-psychotics were mentioned a little but were not

the main focus. When asked more generally about any discussion about pharmacotherapy, the attendee stated 'From memory the "usual thing" that although nothing is licensed in personality disorder some medications exert some useful impact'. The Panel considered that there was no evidence to show that AstraZeneca had promoted Seroquel outwith its marketing authorization as alleged. Taking all of the circumstances into account, the Panel did not consider that on the balance of probabilities Seroquel had been promoted for borderline personality disorder. No breach of Clause 3.2 was ruled. The Panel further considered that although there appeared to be some confusion about the topic of the meeting, there was no evidence to show that delegates had been misled about Seroquel. No breach of Clause 7.2 was ruled. The Panel did not consider that it had any evidence to show that the meeting was disguised promotion. No breach of Clause 12.1 was ruled. Similarly the Panel considered that it had no evidence to show that the representative had not maintained a high standard of ethical conduct. No breach of Clause 15.2 was ruled.

The Panel noted that AstraZeneca's record of the meeting was extremely limited. This was wholly unacceptable. The company did not know what invitations had been sent on its behalf, nor had it certified the presentation delivered. In the Panel's view this was extremely poor practice. The Panel was concerned that material that would have helped AstraZeneca respond to this complaint had either not been generated or copies had not been kept. This had left the company vulnerable and unable to robustly respond to the allegations made. Nonetheless the complaint at issue was about the content of the meeting, not the arrangements for it and in that regard there was no evidence to show that high standards had not been maintained. The Panel ruled no breach of Clause 9.1.

The Panel noted its rulings above and considered that there could be no breach of Clause 2 of the Code. The Panel ruled accordingly.

Complaint received **15 April 2010**

Case completed **8 July 2010**