CASE AUTH/2290/12/09

ANONYMOUS CLINICIAN v ASTELLAS PHARMA

Mycamine advisory board

An anonymous and uncontactable 'concerned' hospital clinician complained on behalf of himself and his colleagues about a Mycamine (micafungin) advisory board conducted by Astellas Pharma.

The complainant noted that he was invited to a series of advisory boards in June/July 2009 which he believed were held all over the country. He attended one of these meetings in good faith. The complainant had no particular issue with the agenda on the day but got the feeling that he was being promoted to, more than having his advice sought. It was not entirely fair to say that the whole advisory board was promotional though he thought it had too many presentations.

The complainant noted that after the meeting a member of the Astellas team visited him. The complainant glimpsed a document with his name on it and those of a few other clinicians who had attended the meeting. He insisted on viewing it. Much to his distaste, there was clear detailing of various attendees and what they thought about Mycamine. It further analysed and detailed who should be promoted to and whose opinion had been changed by the advisory board with regard to prescribing Mycamine. The complainant wondered whether the entire point of the advisory board was to promote Mycamine.

The Astellas employee refused to give the complainant a copy of the document. He was taken into 'confidence' and pleaded with not to take this further. The employee told the complainant that Astellas had asked an agency to draw up the document but there had been an issue at the Astellas head office. The employee had stated that a medical manager had lost her job because she had not wanted the document to be distributed but the medical director had agreed to the document being distributed and so the employee did not feel that he was doing anything wrong. The complainant was shocked at the unethical behaviour of the company and he and his colleagues were annoyed that such information about consultants was compiled and distributed. They attended advisory boards to give an expert opinion with the hope that the information was used in a productive manner, not to have detailed profiles on themselves drawn up and distributed. Furthermore this advisory board was clearly intended to be promotional as the outcomes from it as noted in the document clearly detailed prescribing inclination before and after the advisory board.

The detailed submission from Astellas is given below.

The Panel noted that the advisory board programme consisted of three pairs of regional meetings with each meeting chaired by either by Astellas' previous interim medical director or the current medical director. The plan was for twelve advisors from each region to attend both meetings.

Each meeting began at 8.45am with tea and coffee and finished at 4.30pm. The agenda for the first meeting detailed six presentations of varying length totalling 5 hours; some of the presentations incorporated short group exercises. Round table introductions and feedback were each allocated 30 minutes. The rest of the agenda was taken up with refreshment breaks of 75 minutes. The agenda for the second meeting was similar to that of the first; again, some of the presentations included breakout or group exercises. However from the slides provided it appeared that much of the time at both meetings would be spent on presentations.

The invitation to participate in the advisory boards was signed by a senior brand manager. The letter stated that the company was seeking guidance and support in the future development and marketing of Mycamine; active participation was sought. £1,000 would be paid. The company wanted to understand local issues and work on better management solutions. The letter confirming engagement as an advisory board member stated that the recipient had been approached on the basis of their professional skills, expertise and knowledge of the therapeutic area, specifically candida infections. The letter set out the terms and, *inter alia*, asked participants to agree to the meetings being recorded and that material being used for the company's own business purposes. Participants also consented to use of their details in an internal database for business purpose use.

Advisors were selected for invitation largely on the basis of recommendation from key account managers (KAMs) and in that regard advice to the KAMs from the senior brand manager referred to the potential advisors as 'Mycamine advocates'. The KAMs were told that, *inter alia*, nominees had to have a belief in Mycamine, a sphere of influence including drugs and therapeutics, previous experience in getting drugs onto a formulary and a desire to work with Astellas and become a brand advocate. Brand advocacy was not referred to in the invitation to advisors nor in the letter confirming engagement. The email from the senior brand manager to the KAMs also referred to the importance of maintaining momentum if the

uptake of Mycamine was to be increased through quarter 4 and beyond.

The Panel noted that the purpose of any advisory board meeting was for a company to collect health professionals' views and advice; it was not an opportunity to promote medicines. In that regard the Panel questioned the appropriateness of the advisors being nominated by members of the field force, supervised by the national sales manager. The agenda should allow adequate time for discussion and participation by all. The Panel queried whether that was so. The Code required that there must be a legitimate need for the services and the criteria for selecting consultants must be directly related to the identified need. The hiring of health professionals must not be an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.

The Panel was concerned that Astellas had used the pre-advisory board dinners as an opportunity for its medical and scientific liaison (MSL) staff to build relationships with the health professional attendees. It did not appear that participants were aware that their personal views would be provided to the MSLs and others to enable subsequent relationships to be built. The document setting out the views of participants was headed that the document was for MSL managers and not intended for use by sales representatives given that the content was obtained in an advisory board setting and it was not appropriate to take comments or recommendations and apply them in an alternative context.

MSL managers were advised that they could contact any advisory board member who had informally suggested another meeting or who had given them their business card; they were not to contact anyone who did not know them and when making contact MSLs were to develop relationships to expand their knowledge in the treatment area. MSLs were not to request visits to speak about Mycamine as this would make the visit promotional. Such visits should be carried out separately by the sales force.

The Panel was concerned about the role of the MSLs in that the Code defined a representative as anyone who called upon health professionals and/or administrative staff in relation to the promotion of medicines. Involving the MSLs in the advisory board meetings and follow-up meant that any subsequent discussion was not reactive ie not in response to a specific unsolicited enquiry and thus unable to take the benefit of the exemption to the definition of promotion as set out in the Code.

As part of the follow-up participants were asked by letter to discuss any further points with the KAMs who had been provided with details of the named individual participants' contributions and views relevant to the KAM's geographical area. This material appeared to be similar to that circulated to the MSL managers but without the heading stating, *inter alia*, that the material was not intended for use by sales representatives. Astellas had approved circulation of this material to the representatives and had considered that it did not need certification. A presentation had been prepared for the KAMs' internal use only. This had been certified. A spreadsheet setting out participants' views had also been circulated to the KAMs. Astellas had not approved circulation of this material to the representatives and it had not been certified. The Panel was very concerned at the nature and level of the detail provided to the KAMs. It did not consider that providing such reports to the sales force was consistent with the agreement that transcripts from the meetings could be used for Astellas' internal business purposes. The presentation and spreadsheet detailed feedback ranking ie from 0, limited use of echinocandins (caspofungin only); ignorant of Mycamine to 10, Mycamine on formulary; use of Mycamine; on message; willing to advocate to others. The data showed that compared to baseline the ranking had improved after the first advisory board and further gains had been made following the second meeting. The feedback ranking summary slide was headed 'Raise awareness and create motivation to support/prescribe Mycamine' and stated '93% positive shift of opinion towards Mycamine'. The Panel considered that the data produced as an outcome of the advisory board and shared with the sales force reinforced the impression that the purpose of the advisory board was, at least in part, to change the views of participants regarding Mycamine ie to promote the product rather than just elicit views and advice. The Panel acknowledged that any advisory board on a particular medicine would inevitably have some promotional impact on the participants. In the Panel's view, however, that such impact was evaluated and then communicated to the field force demonstrated an intention to promote Mycamine and positively change participants' views about the product.

The agenda and objectives as described to participants were not necessarily unacceptable. The selection criteria communicated to the KAMs, ie that the company expected advisory board members to *inter alia*, become brand advocates, was not an acceptable outcome for a genuine advisory board. The Panel considered that the provision of detailed information regarding advisory board members' position with regard to their personal use of Mycamine to the MSL managers and the KAMs (who promoted the medicine) was unacceptable as was the failure to certify briefing material for the representatives. The Panel also considered that the roles of the KAMs and MSLs before and after the meetings were inappropriate and inconsistent with the non-promotional purpose of an advisory board. In the Panel's view the overall arrangements for the advisory boards showed that they had, at least in part been held for a promotional purpose and to develop brand advocates/opinion leaders rather than solely for gathering expert advice and opinion.

Thus the Panel ruled that the overall arrangements for the advisory boards were disguised promotion in breach of the Code. The payment of a fee to attend a promotional event was unacceptable and in effect an inducement to prescribe, administer or recommend a medicine. A breach of the Code was ruled.

The Panel considered that, given the overall arrangements for the advisory boards, Astellas had failed to comply with the requirements of relating to consultants. It was not a genuine consultancy arrangement given the discrepancy between internal and external documents and the involvement of the KAMs and MSLs. The Panel was also concerned that the hiring of the health professional might be in effect an inducement to prescribe, administer or recommend Mycamine. A breach of the Code was ruled.

The Panel considered that the overall arrangements had not maintained a high standard and thus a breach of the Code was ruled. With regard to Clause 2, the Panel noted that this was reserved for use as a particular sign of censure. The Panel considered that the overall arrangements, particularly the development of brand advocates under the guise of an advisory board, brought discredit upon and reduced confidence in the pharmaceutical industry and in that regard ruled a breach of the Code.

An anonymous and uncontactable 'concerned' clinician complained about a Mycamine (micafungin) advisory board conducted by Astellas Pharma. The complainant stated that he wrote on behalf of himself and his colleagues. He wished to remain anonymous to protect an Astellas employee and to avoid any further uncomfortable dealings with the company.

COMPLAINT

The complainant noted that he was invited to a series of advisory boards in June/July 2009 which he believed were held all over the country. He attended one of these in good faith, believing that they would be like the many other advisory boards he had attended over the years. The complainant had no particular issue with the agenda on the day but got the feeling that he was being promoted to, more than having his advice sought. It was not entirely fair to say that the whole advisory board was promotional though he thought it had too many presentations.

The complainant noted in particular that after the advisory board a member of the Astellas team visited him at the hospital. The complainant glimpsed a document with his name on it and those of a few other clinicians who had attended the advisory board. He insisted on viewing it. Much to his distaste, there was clear detailing of various attendees and where they were with regard to their opinion of Mycamine. It further analysed and detailed who should be promoted to and whose opinion had been changed by the advisory board with regard to prescribing Mycamine. Given this detailed information on what had ensued in the advisory board, the opinions and perceived status of consultants and their willingness to prescribe and get the medicine on formulary, the complainant wondered whether the entire point of the advisory board was to promote Mycamine.

The complainant asked the Astellas employee for the document as it had detailed information about himself and several of his colleagues. The employee absolutely refused. He was taken into 'confidence' and pleaded with not to take this further. The employee told the complainant that the document had been drawn up by an agency on instruction of Astellas but there had been an issue at the Astellas head office. A medical manager had lost her job because she had shown some resistance to them being distributed. The complainant was further told by the employee that the medical director whom he had met at the advisory board, had said that they were fine to be distributed and used so the employee did not feel that he was doing anything wrong. The complainant was shocked at the unethical behaviour of the company.

The employee was fearful of being sacked. The complainant discussed this issue with his colleagues and they decided that to protect the employee they would complain anonymously. They were, however, absolutely annoyed that information of such a nature on consultants was compiled and distributed. They attended advisory boards to give companies an expert opinion with the hope that the information was used in a productive manner, not to have detailed profiles on themselves drawn up and distributed. Furthermore this advisory board was clearly intended to be promotional as the outcomes from it as detailed in the document clearly showed which consultant had changed his mind about Mycamine after the advisory board. It detailed prescribing inclination before and after the advisory board.

When writing to Astellas, the Authority asked it to respond in relation to Clauses 2, 9.1, 12.1, 18.1 and 20 of the Code.

RESPONSE

Astellas stated that the complainant had referred to an advisory board programme that was held in June and July 2009, and a subsequent conversation between the complainant and an unidentified Astellas employee. The complainant's letter and the allegations therein had been carefully investigated by Astellas.

The advisory boards were planned and conducted as non-promotional activities. As such, the agreements between Astellas and the paid consultant attendees represented business transactions and would thus, together with the meeting content, not normally be subject to the Code. However, in the interests of transparency,

Astellas provided a full account of the programme content and outcome. As indicated in the complainant's letter, an agency had helped Astellas run the meetings.

Following its review Astellas confidently denied any breaches of Clauses 2, 9.1, 12.1, 18 and 20. However, during its investigation Astellas discovered an email sent to the sales team with a document attached that was not approved for distribution. As a consequence Astellas acknowledged that inappropriate material was given to its sales representatives. This action served no apparent purpose and was the result of the unilateral action of one employee, who had subsequently left the company. Astellas acknowledged a breach of Clauses 14 and 15.9, for which it apologised unreservedly.

Astellas submitted that the advisory board programme had a clear purpose. A year after its UK launch in August 2008, Mycamine's adoption in the UK had been significantly below expectation and out of keeping with its overall global commercial performance. Further Astellas was relatively new to the specialist therapy area of anti-infectives in the UK (Mycamine was the only agent that Astellas currently marketed in this therapy area in the UK) and opportunities to gather constructive comment on the product, its attributes and the marketing approach from relevant external sources had been limited. It was, therefore, clearly commercially important to try to calibrate the marketing campaign against the needs and expectations of UK infection specialists and their patients.

The advisory board programme consisted of three pairs of non-promotional meetings, each meeting (of the pair) having separate content. The second meeting essentially built on what was discussed at the first. Meetings were held in Edinburgh, Birmingham and London and each was chaired by senior Astellas medical personnel. The first two meetings were chaired by a senior external consultant who had previously been an interim medical director at Astellas. The remaining meetings were chaired by the current medical director. Astellas medical was closely involved with planning for the meetings and attended the meetings themselves.

The meeting programme comprised a balance of presentations (some by practising clinicians). Case presentations were included to help ensure discussions were clinically focussed and a number of other interactive discussion sessions and small group work featured prominently in the agenda. Overall the programme was specifically designed to stimulate discussion and allow the advisors (or attendees) to contribute their views and opinions.

The phase 1 meetings began with a candid summary of Astellas' position in the anti-infectives market and the adoption of Mycamine. The meeting objectives were clearly laid out in this context.

The agency that helped Astellas run the meetings had run scientific and commercial advisory boards for many years and had developed a format that engaged participants in a manner that enhanced the quality of the meeting outputs. The precise format had been used in meetings by other UK pharmaceutical companies. The programme objectives were agreed by the agency with Astellas in February 2009. The agency staff were highly experienced in this work and well aware of the Code and other regulations governing pharmaceutical company activity in the UK.

The aim was to recruit 12 advisors to participate at each meeting location and the eventual attendance approximated this number. This size of programme (number of meetings and advisors) was not out of keeping with the objectives of the advisory boards and their advisory nature. The meeting objectives included identification of regional differences in views obtained. It was important to ensure that the advice obtained was valid as far as was reasonably possible across the UK.

Advisors were selected for invitation largely on the basis of recommendations from the key account managers (KAMs) for anti-infectives – senior field based employees whose job was to know those involved in local decision making regarding medicines usage. KAMs were highly experienced and well versed in company protocols and procedures, as well as being ABPI trained and certified. The KAMs were given clear and appropriate guidance from the senior product manager in order to recommend advisors. The national sales manager also supervised the recommendation of advisors.

The invitation to potential advisors clearly laid out the meeting objectives and was examined by an Astellas medical advisor in line with the requirements of the Code and Astellas company policy. Advisors were mainly microbiologists but senior laboratory mycologists, senior pharmacists and intensive care physicians also attended. Each advisor had relevant specialist knowledge and insight into clinical care of patients, and their professional standing was respected and valued by Astellas.

Each advisor signed a consultancy agreement with the company prior to the meetings as required under Clause 20.1. The agreement allowed Astellas and its affiliates to use a recording of the meetings for internal business purposes. Microphones and a medical writer from the agency were present.

Advisors received an honorarium of £500 for each of the two advisory boards attended in recognition of the significant time and effort given. In addition accommodation (which was optional and only provided on the evening before the meetings when advisors indicated this was required) and subsistence were provided before and during the meetings. Details were provided. Reasonable travel expenses were also reimbursed.

The objectives of the advisory boards were clearly stated in the invitation sent to the advisors. These were similar and related to the objectives agreed between the agency and Astellas in the Statement of Work dated 24 February 2009. The central purpose was to gather advice on how Astellas could optimise the marketing campaign for Mycamine.

Advisors were asked to fill out questionnaires in order to generate objective feedback on the advisory board programme. Astellas noted that 93.5% of advisors gave 4/5 or 5/5 ratings when asked (immediately after each phase 1 meeting) how well they considered the meeting programme met the outlined objectives. The percentage after the phase 2 meetings was 92.6%. In addition the vast majority of advisors considered that they had been given adequate opportunity to contribute: 96.7% of advisors gave a 4/5 or 5/5 rating in response to a question addressing this point on the evaluation forms after the phase 1 meeting. After the phase 2 meetings the figure was 96.3%.

Following each phase of advisory board meetings, summary and full reports were prepared to document the advice and opinion offered at the meetings. These were commissioned by Astellas in advance of the meetings and a medical writer, who had been introduced appropriately, typed notes during the meeting. After the conclusion of the advisory board programmes, an Astellas senior brand manager also requested two additional reports for which the agency performed a post-hoc analysis which required a further review of audio recordings, identification of individual opinions and provision of the documents which were clearly marked as being for internal information only. The first additional report was a summary of views and advice given to Astellas by each advisor during the meeting. The reports, although clearly for internal company use only, were prefaced with a statement that they were for the use of Astellas medical and scientific liaison (MSL) staff.

MSLs were non-promotional staff, who were managed, trained and briefed by the Astellas medical team to respond to the specific requests of health professionals. Such briefings could include providing information on important clinical issues in the therapy area, where the regional KAMs were not able to do this either because it would be inappropriate or if/when they did not have the depth of knowledge required. MSLs were not incentivised on sales.

In line with their non-promotional role, the principles by which the MSLs could therefore approach advisory board members were carefully proscribed by their medical manager. MSLs attended some pre-advisory board dinners in order to build relationships. They did not attend the meetings themselves.

In addition to these summary sheets, the medical writer was asked to review the audio again to create a spreadsheet that captured individual advisors' views on micafungin as a way of summarising opinions throughout the meeting. Advisors were asked their general views on micafungin during the advisory board meeting and this was considered entirely appropriate. The 'benchmarking' of views performed to generate the supplementary report was performed on subjective review of the entire audio by the medical writer after the conclusion of the programme. The views of each advisor would thus equally have been known to all who attended the advisory board.

With any meeting or discussion, an individual's views might change (positively or negatively) or stay the same. The analysis was subjective and was conducted after reflection on the views given and comments expressed by advisors throughout the meetings. This analysis was not intended for use in a promotional context. The document would assist Astellas in the future when organising speaker meetings since it was normal, and indeed good practice, for companies to know the views of their speakers before asking them to speak.

At an Astellas senior management team meeting the spreadsheet was used to present an analysis showing the generally positive nature of the feedback along with identification of other important learnings from the advisory board programme. Astellas contended that the existence of the documents did not undermine or contradict the established objectives of the advisory board programme, and these supplementary documents were prepared as an afterthought.

The comment and advice given in the meetings was generally seen as extremely encouraging. The feedback to Astellas was therefore of vital importance, given the company's investment in marketing Mycamine in the UK. The comment, advice and support for Astellas and Mycamine had been gathered in a robust and credible manner.

The company also had an understandable desire, when reviewing the feedback from advisors, for the open relationship, dialogue and collaboration with advisors to continue where this was appropriate and when there was mutual consent for this on the part of the company and the advisors.

Astellas was always sensitive to the requirements of the Code and respectful of its advisory board members. Such respectful and ethical conduct was pivotal to success in any therapeutic area.

Any breach of the Code that occurred in company activities following the advisory board programme should be seen as an isolated departure from not only from the requirements of the Code, but also the company's own high standards.

Follow up of advisors

It was agreed that the KAMs would continue to liaise with advisors in an appropriate professional capacity assisted, where appropriate, by the MSLs.

Advisors were therefore invited in a letter (that thanked them for their contribution to the advisory boards) to discuss any further thoughts and advice they had with the KAMs. It was made clear in the letter that the granting of such an appointment with the KAMs would be at their discretion. Thus the desire for follow up of the advisory boards, as well as the intended nature of this follow up (and the potential role of the KAM) was clear and transparent.

In addition, and in agreement with the Astellas medical team, it was agreed that the additional reports provided by the agency could be provided to the KAMs to aid their discussions with advisors outside of the advisory board setting. Comments relating to off-licence indications for Mycamine were blacked out of these reports by the Astellas medical advisor. No effort was made to elicit advice on the off-licence use of Mycamine during advisory boards, but advisors occasionally spontaneously referred to such.

The Astellas medical advisor sent a copy of these reports to the KAMs who operated in the territory in which each respective advisor worked, together with the template of the letter that had been sent to the advisors on 11 September 2009. It was considered appropriate for the KAMS to receive these reports, and the action was considered to be consistent with the terms of consultancy agreement, which allowed Astellas to use the transcripts for internal business purposes.

In a covering email the confidential nature of the reports was made clear to the KAMs. Whether this material sent to the KAMs required certification was discussed at the appropriate levels in the company. On reading the attachments however, it was clear that the nature of the comments was similar to that which KAMs would record on their electronic territory management system and it was noted that they did not mention anything about an individual advisor's intention to prescribe Mycamine. It was decided that certification was not required as the material pertained to feedback from non-promotional meetings and did not constitute a general briefing on the product or how to promote it. The decision to make the material available was consistent with the KAMs' senior role.

The feedback was also presented to the KAMs at in the national sales conference on 16 October 2009. This was in the form of a certified presentation the purpose of which was to: summarise the positive nature of the feedback given by the advisors on Mycamine and its differentiating features; encourage and motivate the KAMs; indicate where the marketing claims for the product were to be amended and the reasons for this and to stimulate discussion to enable the team to move forward in a positive and appropriate manner.

The basis for the complaint

Given that the complainant was anonymous, Astellas had not been able to discuss the matter with its employee referred to by the complainant. However Astellas recognised that the complainant was justifiably upset - something which it very much regretted.

Astellas assumed that the complainant was specifically upset about the spreadsheet showing a post hoc benchmarking of advisors' views before, during and after the advisory boards – one of the additional reports, prepared by the agency at the senior brand manager's request, for internal use only after the meeting.

This was the only document that showed a change in views and perceptions regarding Mycamine, the central issue to the complaint. However, Astellas emphasised that it was not the purpose of the advisory boards to elicit a change in opinion, but entirely an unintended consequence. Any negative feedback from the advisory boards would have been similarly presented on the spreadsheet.

The spreadsheet was for head office use only and was not approved for promotional use. It was identified that the nature of the document could be misinterpreted. Quite deliberately it was not approved for use in the field. Astellas was initially unsure how it was obtained by one of its field-based employees and subsequently used in what the complainant judged to be a promotional context. With much regret Astellas had subsequently discovered that the spreadsheet was released on 20 October 2009 by email in an inappropriate manner, without any substantive briefing accompanying it and without consultation. This was the unilateral action of one employee who 14 days later left Astellas to work for another company, having resigned some time before. The release of this post hoc analysis served no apparent purpose and its release by the individual in question was inexplicable. Astellas was badly let down by the actions of this individual. This spreadsheet might also have coloured the complainant's perception of the 'summary of advice' documents that had been approved by the company for release to the KAMs, and which the complainant also seemed to refer to. It was possible that the complainant was only able to briefly study these documents.

Although the email referred to the sales conference where the advisory boards were discussed with the KAMs, the decision to release the email was not openly discussed at the meeting. The possibility of having additional specific information about advisors was raised in the meeting but the Astellas medical advisor in attendance clearly stated that this was inappropriate and further information beyond what had already been provided would serve no purpose. It was indicated that medical approval for release would not be given. The medical advisor consequently did not expect the document to be released against his advice.

Astellas submitted that there was little it could have done to prevent the actions of the individual who

released the document, given that he could not now be held accountable for his action since he had left the company and the company's medical team had advised specifically against release of the document. The email was not sent to any of Astellas' medical staff, and release of the document was therefore concealed from medical colleagues.

Astellas stated that once the email was discovered, the national sales manager instructed the KAMs to destroy the document and not to use it again. Because this was an email attachment there was no material to recover.

Astellas noted that a medical manager's resignation in October 2009 was unrelated to any issues about the advisory board programme or the outcomes and follow up.

Astellas admitted that the document at issue was released without the necessary approval and that this material was inappropriate. Astellas therefore acknowledged a breach of Clause 14 and 15.9. This action was extremely disappointing and had understandably led to the purpose of the advisory boards being misconstrued. However, in general the reports generated for Astellas were handled appropriately and in a manner consistent with the terms of the consultancy agreement that advisors signed.

Astellas was also disappointed with the report of the alleged behaviour of the Astellas employee referred to by the complainant. Their behaviour, once the document had been discovered by the complainant, seemed to have been a reflex reaction. Their response showed a willingness to damage the company's reputation and that of individuals therein with fabricated allegations in a misguided attempt to preserve their own standing with the complainant and with Astellas. The employee's evasion from responsible action (for example by reporting the meeting with the complainant to their manager) precluded the possibility of the company apologising for any offence caused and addressing any misunderstanding with the complainant in person.

Summary

In summary Astellas stressed the high calibre of the Mycamine advisory board meetings programme. Feedback strongly suggested that the meeting objectives were met and that advisors had enough opportunity to contribute. In addition the detailed reports prepared by the agency showed that advice given was painstakingly gathered and analysed. Finally the outcomes documented in Astellas' response showed that it considered the advice carefully and as a result changed the way that Mycamine was marketed. Astellas therefore denied a breach of Clauses 12, 18 or 20.

The substance to the complaint concerned a misunderstanding about the nature of a report that was meant to be for internal use only and not for use in a promotional context. In that regard Astellas had been badly let down by the ex-employee who released the unauthorised material and by the unidentified representative who responded inappropriately when challenged by the complainant. Astellas acknowledged breaches of Clauses 14 and 15.9 because a post hoc analysis of advice was inappropriately released to the sales team, uncertified. The company apologised sincerely for any offence and misunderstanding caused but stressed the high ethical standards of the company and its compliance with these. Astellas denied any systematic failings in its compliance with the Code and therefore denied any breach of Clauses 2 and 9. Astellas did not consider that the reputation of Astellas should be held in disrepute.

PANEL RULING

The Panel noted that the complainant was anonymous and uncontactable. Complaints were judged on the evidence provided by the parties. In this case the complainant had described a document used by the representatives. Astellas acknowledged that inappropriate material that appeared to meet the complainant's description had been supplied to the representatives albeit without the necessary approval.

The Panel noted that the advisory board programme consisted of three pairs of meetings, held in London, Birmingham and Edinburgh, with each meeting chaired by either an external consultant who had previously been Astellas' interim medical director or the current medical director. The plan was for twelve advisors from each region to attend both meetings.

Each meeting began at 8.45am with tea and coffee and finished at 4.30pm. The agenda for the first meeting detailed six presentations of varying length totalling 5 hours; some of the presentations incorporated short group exercises. Round table introductions and feedback were each allocated 30 minutes. The rest of the agenda was taken up with refreshment breaks of 75 minutes. The agenda for the second meeting was similar to that of the first; again, some of the presentations included breakout or group exercises. However from the slides provided it appeared that much of the time at both meetings would be spent on presentations.

The invitation to participate in the advisory boards was signed by a senior brand manager. The letter stated that the company was seeking guidance and support in the future development and marketing activity for Mycamine; active participation was sought. £1,000 would be paid (£500 per meeting). The company wanted to understand local issues and work on better management solutions. The letter mentioned the need for participants to sign an agreement so that information from Astellas could be shared. The letter confirming engagement as an advisory board member stated that the recipient had been approached on the basis of their

professional skills, expertise and knowledge of the therapeutic area, specifically candida infections. The letter set out the terms and asked participants to agree to the meetings being recorded and the use of that material for the company's own business purposes provided this was not broadcast externally or published without prior written consent. Participants also consented to use of their details in an internal database for business purpose use.

Advisors were selected for invitation largely on the basis of recommendation from the KAMs and in that regard advice to the KAMs from the senior brand manager referred to the potential advisors as 'Mycamine advocates'. In nominating such advocates the KAMs were told that, *inter alia*, nominees had to have a belief in Mycamine, a sphere of influence including drugs and therapeutics, previous experience in getting drugs onto a formulary and a desire to work with Astellas and become a brand advocate. Brand advocacy was not referred to in the invitation to advisors nor in the letter confirming engagement. The email from the senior brand manager to the KAMs also referred to the importance of maintaining momentum if the uptake of Mycamine was to be increased through quarter 4 and beyond. The Panel noted that the in-house advice regarding the advisory boards given to the KAMs had a distinct commercial edge, in contrast to the clinical, professional tone of the letters sent to potential advisors as described above.

The Panel noted that the purpose of any advisory board meeting was for a company to collect health professionals' views and advice; it was not an opportunity for a company to promote medicines. In that regard the Panel questioned the appropriateness of the advisors being nominated by members of the field force, supervised by the national sales manager. The agenda should allow adequate time for discussion and participation by all. The Panel queried whether that was so. Clause 20 of the Code required that there must be a legitimate need for the services and the criteria for selecting consultants must be directly related to the identified need. The hiring of health professionals must not be an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.

The Panel was concerned that Astellas had used the pre-advisory board dinners as an opportunity for its MSL staff to build relationships with the health professional attendees. It did not appear that participants were aware that their personal views would be provided to the MSLs and others to enable subsequent relationships to be built. The document setting out the views of participants was headed that the document was for MSL managers and not intended for use by sales representatives given that the content was obtained in an advisory board setting and it was not appropriate to take comments or recommendations and apply them in an alternative context.

MSL managers were advised that they could contact any advisory member who had informally suggested another meeting or who had given them their business card (email dated 12 August 2009). MSLs were instructed not to contact anyone who did not know them and when making contact MSLs were to develop relationships to expand their knowledge in the treatment area. MSLs were not to request visits to speak about Mycamine as this would make the visit promotional. Such visits should be carried out separately by the sales force.

The Panel was concerned about the role of the MSLs in that the Code defined a representative as anyone who called upon health professionals and/or administrative staff in relation to the promotion of medicines (Clause 1.6). Involving the MSLs in the advisory board meetings and follow-up meant that any subsequent discussion was not reactive ie not in response to a specific unsolicited enquiry and thus unable to take the benefit of the exemption to the definition of promotion as set out in Clause 1.2.

As part of the follow-up participants were asked by letter (9 September) to discuss any further points with the KAMs who had been provided with details of the named individual participants' contributions and views relevant to the KAM's geographical area (email dated 11 September). This material appeared to be similar to that circulated to the MSL managers but without the heading stating, *inter alia*, that the material was not intended for use by sales representatives. Astellas had approved circulation of this material to the representatives and had considered that it did not need certification. A presentation had been prepared for the KAMs' internal use only. This had been certified. A spreadsheet setting out participants' views had also been circulated to the KAMs. Astellas had not approved circulation of this material to the representatives and it had not been certified. The Panel was very concerned at the nature and level of the detail provided to the KAMs. It did not consider that the provision of such reports to the sales force was consistent with the agreement that transcripts from the advisory board could be used for Astellas' internal business purposes. The presentation and spreadsheet detailed feedback ranking ie from 0, limited use of echinocandins (caspofungin only); ignorant of Mycamine to 10, Mycamine on formulary; use of Mycamine; on message; willing to advocate to others. The data showed that compared to baseline the ranking had improved after the first advisory board and further gains had been made following the second advisory board meeting. The feedback ranking summary slide was headed 'Raise awareness and create motivation to support/prescribe Mycamine' and stated '93% positive shift of opinion towards Mycamine'. The Panel considered that the data produced as an outcome of the advisory board and shared with the sales force reinforced the impression that the purpose of the advisory board was, at least in part, to change the views of participants regarding Mycamine ie to promote the product rather than

just elicit views and advice. The Panel acknowledged that any advisory board on a particular medicine would inevitably have some promotional impact on the participants. In the Panel's view, however, that such impact was evaluated and then communicated to the field force demonstrated an intention to promote Mycamine and positively change participants' views about the product.

The agenda and objectives as described to participants were not necessarily unacceptable. The selection criteria communicated to the KAMs, namely that the company expected advisory board members to *inter alia*, become brand advocates, was not an acceptable outcome for a genuine advisory board. The Panel considered that the provision of detailed information regarding advisory board members' position with regard to their personal use of Mycamine to the MSL managers and the KAMs (who promoted the medicine) was unacceptable as was the failure to certify briefing material for the representatives. The Panel also considered that the roles of the KAMs and MSL staff before and after the meetings were inappropriate and inconsistent with the non-promotional purpose of an advisory board. In the Panel's view the overall arrangements for the advisory boards showed that they had, at least in part been held for a promotional purpose and to develop brand advocates/opinion leaders rather than solely for gathering expert advice and opinion. Thus the Panel ruled that the overall arrangements for the advisory boards were disguised promotion in breach of Clause 12.1. The payment of a fee to attend a promotional event was unacceptable and the fee was in effect an inducement to prescribe, administer or recommend a medicine. A breach of Clause 18.1 was ruled.

The Panel considered that, given the overall arrangements for the advisory boards, Astellas had also failed to comply with the requirements of Clause 20. It was not a genuine consultancy arrangement given the discrepancy between the internal and external documentation and the involvement of the KAMs and MSLs. The Panel was also concerned that the hiring of the health professional might be in effect an inducement to prescribe, administer or recommend Mycamine. A breach of Clause 20 was ruled.

The Panel considered that the overall arrangements had not maintained a high standard and thus a breach of Clause 9.1 was ruled. With regard to Clause 2, the Panel noted that this was reserved for use as a particular sign of censure. The Panel considered that the overall arrangements, particularly the development of brand advocates under the guise of an advisory board, brought discredit upon and reduced confidence in the pharmaceutical industry and in that regard ruled a breach of Clause 2.

Complaint received **21 December 2009**

Case completed **16 March 2010**