

# ANONYMOUS v ALLERGAN

## Meeting arrangements

An anonymous, non-contactable complainant alleged that Allergan had inappropriately approved materials for, and selected delegates to attend, a neuroscience meeting.

The complainant explained that the meeting was put through as a stand meeting at which other companies would be present in order to circumvent the approval requirements. The complainant alleged that the meeting was advertised as a funded training course rather than a meeting solely sponsored by Allergan which had selected the attendees and had possibly paid their travel costs. The complainant named three senior employees who he/she alleged were all complicit in the wrong doing.

The complainant further explained that the slides used were approved by the medical department on the basis that exhibiting costs were shared with other companies, however no other companies were present and slides, which did not go through Allergan's Zinc approval system, were used for an Allergan engineered meeting.

The detailed response from Allergan is given below.

The Panel noted that the complainant was anonymous and non-contactable. A complainant had the burden of proving their complaint on the balance of probabilities. Anonymous complaints were accepted and like all complaints were judged on the evidence provided by the parties. The weight to be attached to any evidence might be adversely affected if the source was anonymous.

The Panel noted that the parties' accounts of the meeting differed. The complainant had referred to a meeting held at a named hospital with a named consultant in October 2013. The only meeting which Allergan could identify which involved the same hospital and consultant, was held in May 2013. The complainant had alleged that the meeting was solely sponsored by Allergan whereas Allergan submitted that this was not so, there were two other sponsors. The complainant had referred to an Allergan engineered meeting and alleged that the company had selected the attendees. Allergan submitted that the meeting was organised by a third party; its only involvement was to provide part sponsorship, it did not select attendees or pay their travel costs as surmised by the complainant. The complainant had referred to training slides being submitted to Allergan for approval. Allergan submitted that it did not receive any slides or materials associated with the meeting as it was an independent, third party course. The company stated that as it had had no involvement or influence on the content of the meeting and it had not

provided any speakers, there was no requirement to review slides and materials used at the meeting.

The Panel noted that the complainant had named three senior employees who he/she alleged were complicit in the alleged wrong doing. However, according to Allergan only one of those named had been involved with the meeting and the role of one of the employees within the company had been incorrectly cited by the complainant.

The Panel noted the substantial differences in the parties' accounts and that no evidence had been provided by the complainant to support his/her allegations. The Panel considered that the nature of these differences and the evidence provided by Allergan was such that there were grounds to doubt the veracity of the complaint. The Panel noted its statement above about the burden of proof.

The Panel considered that there was no evidence before it to indicate that the slides required certification as alleged. Allergan's sponsorship of the meeting was approved in Zinc using the company's meeting approval process. No breach of the Code was ruled.

The Panel noted that the meeting was a one day training course on the pharmacology of botulinum toxins and their use around the eye. In that regard the Panel considered that it was not an unreasonable educational meeting for Allergan to sponsor. The Panel noted Allergan's submission that it had not provided any support to any delegates attending the meeting with regard to registration or travel as alleged and had not provided any subsistence. It paid for the exhibition stand fee alone. In the Panel's view Allergan's involvement with the meeting was not unacceptable. No breach of the Code was ruled.

The Panel did not know what the complainant meant when he/she alleged that the meeting was advertised as a funded training course rather than a meeting sponsored by Allergan. The complainant had not provided a copy of the advertisement to support his/her allegation. The Panel thus ruled no breach of the Code.

The Panel noted its rulings above and considered that there was no evidence to show that either the company or its representatives had failed to maintain high standards. No breach of the Code were ruled. The Panel consequently ruled no breach of Clause 2.

An anonymous, non-contactable complainant alleged that Allergan Ltd had inappropriately approved materials for, and selected delegates to attend, a neuroscience meeting.

## COMPLAINT

The complainant explained that the meeting was initially entered as a training meeting, however due to poor planning and a delay in getting speaker/trainer slides approved the meeting was put through as a stand meeting at which other companies would be present in order to circumvent the approval requirements. The meeting was advertised as a funded training course rather than a meeting solely sponsored by Allergan. The complainant alleged that no other companies were present or ever invited and attendees were selected by Allergan. This information was only shared by management; those involved were three named senior employees; the complainant provided details of each employee's role within the company.

The complainant stated that the meeting was held in October 2013 at a named hospital and the trainer, a consultant ophthalmologist, was unaware of the inappropriate approval. The complainant alleged that details of the course, agenda items, venue and content were emailed to the sales team who forwarded the details to prospective delegates. The course had around ten UK attendees and although unsure, the complainant alleged that it was more than conceivable that Allergan had covered their travel costs. The complainant was unsure of how the sales team was told to record the meeting but it would be in the call report history.

The complainant further explained that there had been issues with the course as the slides used were not deemed suitable for medical approval. The trainer was asked to resubmit his slides but he declined and in the end the course was approved on the basis that exhibiting costs were shared with other companies and slides, which did not go through Allergan's Zinc approval system, were used for an Allergan engineered meeting.

The complainant alleged that the three named senior employees were all complicit in the wrong doing and the meeting was held with the particular support of one of those named. The complainant stated that this was perhaps one example of other similar activities and needed highlighting as it was a clear breach. Given it occurred during Allergan's audit phase, the complainant questioned how seriously some took the audit and adherence to the Code.

The complainant stated that he/she did not write in malice but in exasperation that some flexed the rules to suit themselves; their false claims of being compliant made it unacceptable. The complainant was concerned that if this matter was reported directly, the individuals involved would brush it under the carpet, place blame elsewhere and claim no knowledge. The complainant alleged that for the meeting to be signed off and go ahead, all of the named senior employees were fully involved and aware.

When writing to Allergan, the Authority asked it to respond in relation to Clauses 2, 9.1, 14.1, 15.2 and 19 of the Code.

## RESPONSE

Allergan submitted that although the complaint referred to a meeting held in October 2013, it could not identify any meeting that corresponded to that date; it had, however, found an event sponsored in May 2013 which formed the basis of the response below.

Allergan explained that the trainer named by the complainant was a consultant ophthalmologist with a special interest in neuro ophthalmology; he/she was the clinical lead of the botulinum toxin service at the named NHS foundation trust. Along with another named consultant who was an oculoplastic surgeon, he/she ran a number of independent courses and training events.

In response to a request that Allergan sponsor one of his/her independent courses, the consultant ophthalmologist was asked to send a request in writing which was duly received. Allergan agreed to co-sponsor the event and to have a promotional stand at the meeting held in May 2013, paying a sponsorship fee of £1,200. As there was no local Allergan representative, no stand was placed at the meeting and no Allergan employees attended.

Allergan considered the following points which in its view confirmed the appropriateness of the meeting arrangements:

- The meeting, held in May 2013 and not October 2013 as alleged, took place in appropriate healthcare premises, the postgraduate education centre of the named hospital, and ran from 10am to 4pm with registration at 9:30am. The postgraduate centre catering service provided a sandwich lunch and there were morning and afternoon coffee breaks. Allergan did not provide any subsistence beyond the agreed sponsorship fee and did not cover any travel costs for the delegates.
- It was a third party meeting, a verbal request for stand sponsorship was made to the representative followed by an email from the course organizers. Allergan was also informed that the course had received CPD accreditation. The course organizers engaged two other sponsors for the meeting one of which was a competitor to Allergan in ophthalmology. According to the information provided to Allergan by course organizers, all companies sponsored the event for the same amount. In preparing this response Allergan contacted both of these companies directly to confirm that they had indeed sponsored the event. One confirmed that it had sponsored the meeting with £300 and a representative attended with a small table stand.
- There was a clear educational objective to the meeting as evidenced by the agenda (copy provided) and provided by the course organizers.
- The meeting participants were neither selected nor invited by Allergan, this was the responsibility of the course organizers. The number of attendees was restricted to ten health professionals and there was no registration cost to the delegates according to the information provided to Allergan by course organizers at the time of the

sponsorship request. Physicians working in ophthalmology and managing blepharospasm were expected to attend.

- Allergan had no involvement or influence on the content of the meeting other than to review the agenda provided by the organizers as part of the stand meeting approval process and noted that it had sufficient educational content to justify a full day meeting. The agenda was titled 'Management of Blepharospasm Training Meeting'. It included sessions on 'Pharmacology of Botulinum Toxin, Anatomy around the Eyes, Common conditions of the eyelids and orbits, Practical aspects of Botulinum toxin use, Common Injection techniques and How to set up an audit of toxin service'. It was not specific to a brand or product.
- The meeting went through the Allergan approval process, a meeting request form was raised, reviewed in Zinc and signed off. The copy approval certificate was provided. The payment was made following the receipt of appropriate documentation from the course organizers.

Allergan submitted that according to the supplementary information to Clause 19.1, 'Pharmaceutical companies may appropriately hold or sponsor a wide range of meetings'. The Code described a range of meetings and principles which applied to sponsorship or holding those meetings.

Allergan noted that the complainant named three of its employees who were alleged to have been involved in the activity. Allergan submitted that one employee (and the only one available for interview as the other two had since left the company) was neither involved in the setting up nor review/approval of the meeting. Allergan was satisfied that he/she had no knowledge of the meeting in question. The second employee received the request from the organizers and initiated the job bag and provided the information to reviewers. The third employee was neither involved in the review nor the sign off of the meeting. He/she never worked in medical as cited in the complaint.

According to Allergan's customer relations management (CRM) system, the Allergan representative covering the territory met the consultant ophthalmologist who organized the meeting in mid January 2013 along with one of the named senior employees to introduce the representative who had returned from extended leave. The representative saw the consultant again in February and March 2013 to discuss the training course and finalize the details of Allergan's support. There were no further notes in the call system. No exhibition stand was set up at the meeting and no Allergan employee attended the meeting due to absence of a territory sales representative. The representative had left the company, therefore it had not been possible to interview him/her with regard to this complaint.

Allergan submitted that it did not receive any slides or materials associated with the meeting as it was an independent course and Allergan's involvement was limited solely to sponsorship. There was no requirement to review any materials that were to be presented at the meeting. As part of Allergan's

investigation, it noted that the meeting as advertised on the Royal College of Ophthalmologists' website confirmed the CPD accreditation and third party nature of the meeting. Allergan submitted that the meeting was neither engineered nor solely sponsored by Allergan as alleged by the complainant.

Allergan was not involved in the planning, organization and conduct of the meeting, therefore it did not produce any invitations. The agenda provided by the organizers, along with their request for sponsorship, was used for the approval of the stand meeting via Allergan's meeting approval process in Zinc. As sponsorship of a local stand meeting, it required examination under Allergan's meeting approval process. The job bag in Zinc was created nine days before the meeting was scheduled to take place and was reviewed two to three days later by two different reviewers who requested further information before receiving final approval in Zinc the day before the meeting. This would not be an unusual situation as for third party organized meetings, company representatives would pursue provision of information and details from organizers before creating a job bag. The certificate was signed by two named Allergan employees on the day the meeting was scheduled to take place.

Allergan submitted that it did not promote the meeting. Allergan did not have information on who attended the meeting. As there was no sales representative on the territory at the time, Allergan did not attend the meeting or put up a stand. Therefore no records existed of the meeting attendees in the CRM system.

Allergan submitted that its payment for sponsorship was made to a company of which the consultant ophthalmologist was an executive, on receipt of appropriate documentation.

Allergan submitted that it maintained high standards while sponsoring this meeting and acted appropriately in the review, approval and overall support of this meeting. Allergan submitted that there was no deviation from company procedures or any breach of Clause 9.1.

The meeting was appropriately reviewed and approved according to company procedures. On receipt of a written request, a meeting request form was created and the review of the job bag occurred within the Zinc system. The approval was granted considering the different requirements of the Code as noted above. Allergan co-sponsored a third party organized meeting and was not involved in organizing or promoting the meeting, selecting or inviting the attendees, or determining the agenda or content. There were no promotional materials linked to the meeting and as a third party organized stand meeting Allergan was not required to review and approve slide decks. Therefore no requirement for certification of any materials and thus no breach of Clause 14.1.

Allergan submitted that it had already clarified the role and involvement of the three senior employees named in the complaint. In addition,

the involvement of two representatives, the Zinc reviewers and two signatories in the meeting had also been addressed. Allergan submitted that there were no concerns with regard to the behaviour of the named employees or any indication that they failed to maintain a high standard of ethical conduct with regards to the sponsorship of the meeting at issue. Allergan further submitted that all of the employees complied fully with the company's procedures and relevant Code requirements in this instance. Therefore Allergan denied a breach of Clause 15.2.

With regard to the requirements of Clause 19, several points had been addressed above under overall conduct of the meeting. The third party organized meeting was held in May 2013 and not in October 2013 as alleged. Allergan co-sponsored the meeting to the value of £1,200 and it planned to have a promotional stand. No hospitality was provided by Allergan. There was a clear educational objective as evidenced by the agenda. The venue, the postgraduate education centre, was an entirely appropriate healthcare premises for this type of meeting. Participants were neither selected nor invited by Allergan, this was the responsibility of the course organizers. Allergan understood that the number of attendees was restricted to ten health professionals and there was no registration cost to the delegates according to the information provided by the organizers at the time of the sponsorship request. The meeting was for physicians who worked in ophthalmology and managed blepharospasm. It was a full day meeting from 10am to 4pm with registration at 9:30am. Allergan denied a breach of Clause 19.1.

Allergan submitted that the subsistence as detailed above was linked to an educational meeting in an appropriate venue with appropriate duration to justify the arrangements. Allergan did not provide any subsistence beyond the stand fee which was paid to the meeting organizers and it thus denied a breach of Clauses 19.2 or 19.3.

As this was a third party organized meeting, Allergan had no involvement or influence on the content of the meeting. As part of company policy, Allergan reiterated the need for organizers to declare sponsorship received from pharmaceutical companies. This was approved as a stand meeting therefore the presence of the stand would be obvious to the attendees with regard to the sponsors of the meeting. Allergan had tried to get a final agenda and materials from the course organizers which unfortunately they had not been able to provide to date. Allergan submitted that to the best of its knowledge, there were no papers or published proceedings from this meeting. Allergan stated that it did not invite or select prospective delegates and did not provide any support with regard to registration or travel. Allergan denied a breach of Clause 19.4.

Considering all of the above Allergan denied a breach of Clause 2.

In conclusion, Allergan was both surprised and concerned to receive this anonymous complaint which appeared to have manipulated some limited

facts and concocted others to malign the company and three named employees. Allergan noted that the complainant had not provided any clear evidence of the incidents that he/she alleged, and that fundamental details such as the date and nature of the meeting were incorrectly cited.

#### **PANEL RULING**

The Panel noted that the complainant was anonymous and non-contactable. A complainant had the burden of proving their complaint on the balance of probabilities. Anonymous complaints were accepted and like all complaints were judged on the evidence provided by the parties. The weight to be attached to any evidence might be adversely affected if the source was anonymous.

The Panel noted that the parties' accounts of the meeting differed. The complainant had referred to a meeting held at a named hospital with a named consultant in October 2013. The only meeting which Allergan could identify which involved the same hospital and consultant, was held in May 2013. The complainant had alleged that the meeting was solely sponsored by Allergan whereas Allergan submitted that this was not so, there were two other sponsors. The complainant had referred to an Allergan engineered meeting and alleged that the company had selected the attendees. Allergan submitted that the meeting was organised by a third party; its only involvement was to provide part sponsorship and it did not select attendees nor pay their travel costs as surmised by the complainant. The complainant had referred to training slides being submitted to Allergan for approval. Allergan submitted that it did not receive any slides or materials associated with the meeting as it was an independent, third party course. The company stated that as it had had no involvement or influence on the content of the meeting and it had not provided any speakers, there was no requirement to review slides and materials used at the meeting.

The Panel noted that the complainant had named three senior employees who he/she alleged were complicit in the alleged wrong doing. However, according to Allergan only one of those named had been involved with the meeting and the role of one of those employees within the company had been incorrectly cited by the complainant.

The Panel noted that there were substantial differences in the parties' accounts and no evidence had been provided by the complainant to support his/her allegations. The Panel considered that the nature of these differences and the evidence provided by Allergan was such that there were grounds to doubt the veracity of the complaint. The Panel noted its statement above about the burden of proof.

The Panel considered that there was no evidence before it to indicate that the slides required certification as alleged. Allergan's sponsorship of the meeting was approved using the company's meeting approval process in Zinc. No breach of Clause 14.1 was ruled.

The Panel noted that the meeting held in May 2013 was a one day training course on the pharmacology of botulinum toxins, anatomy around the eyes, common conditions of the eyelids and orbits and the use of botulinum toxin around the eyelids, eyebrows and orbit. In that regard the Panel considered that the educational content was appropriate and did not consider that it was an unreasonable meeting for Allergan to sponsor. The Panel noted Allergan's submission that it had not provided any support to any delegates attending the meeting with regard to registration or travel as alleged and had not provided any subsistence. It paid for the exhibition stand fee alone. In the Panel's view Allergan's involvement with the meeting was not unacceptable. No breach of Clause 19.1 was ruled.

The Panel did not know what the complainant meant when he/she alleged that the meeting was advertised

as a funded training course rather than a meeting sponsored by Allergan. The complainant had not provided a copy of the advertisement to support his/her allegation. The Panel thus ruled no breach of Clause 19.4.

The Panel noted its rulings above and considered that there was no evidence to show that either the company or its representatives had failed to maintain high standards. No breach of Clauses 15.2 and 9.1 were ruled. The Panel consequently ruled no breach of Clause 2.

**Complaint received**      **29 May 2014**

**Case completed**        **26 June 2014**