

# MEMBER OF THE PUBLIC v ASTELLAS PHARMA

## Conduct of representatives

A member of the public complained that two representatives of Astellas Pharma had sponsored lunch meetings with no educational content. One of the representatives did large stand meetings where she logged a number of GPs with whom she had had no conversation whatsoever.

The detailed response from Astellas is given below.

The Panel noted that the complainant had made a very general allegation. No specific details had been provided. The Panel noted that a complainant had the burden of proving their complaint on the balance of probabilities.

The Panel noted Astellas' submission that it had examined all meetings organised since January 2009. It could find no evidence that meetings with no educational content had taken place. The Panel examined the documents generated during the meetings approval process and noted that details of the educational content of each meeting and associated expenditure were given. Since 29 June 2009 all meetings costing less than £100 did not require approval and thus no relevant documents were available. The representatives had denied organising meetings as alleged. The Panel considered that there was no evidence to support the complainant's allegation that the representatives had organised meetings without any educational content. No breach was ruled.

The Panel noted that Astellas had conceded that in contravention of its policy one of the representatives had inflated the number of contacts at exhibition stands by listing all attendees at the meeting rather than those spoken to. The Panel had not seen the relevant Astellas' policy however, Astellas representatives were not incentivised on calls or contact rates. The Panel considered that this was an in-house matter. There was no evidence that representatives had been encouraged or incentivised in relation to contact rates in a way that was contrary to the requirements of the Code. No breach was ruled.

A member of the public complained about the conduct of two representatives of Astellas Pharma Ltd.

### COMPLAINT

The complainant stated that to his knowledge the representatives in question had sponsored lunch meetings with no educational content. One of the representatives did large stand meetings where she logged a number of GPs with whom she had had no conversation whatsoever.

When writing to Astellas, the Authority asked it to respond in relation to Clauses 2, 9.1, 15.2 and 19.1 of the Code.

### RESPONSE

Astellas noted that the complainant alleged that the two named medical representatives had sponsored lunches with no educational content and that one of the representatives had falsely logged contacts at 'large stand meetings'. Astellas took the Code very seriously and it had checked its records and interviewed the representatives concerned and could find no evidence to support the allegation that meetings with no educational content had taken place.

With regard to the allegation that one individual had inflated the number of contacts made, while this was an important matter for Astellas to deal with, the company could not see how the Code would apply unless the representatives were incentivised on contact rates. Astellas did not incentivise call or contact rates and therefore it did not consider that the Code applied to such an administrative matter per se. However in the interests of transparency Astellas provided full details of all the stand meetings and the contacts logged by the representatives since 1 January 2009. In summary however Astellas could find no evidence of any Code breaches and in particular no evidence of breaches of Clauses 2, 9.1, 15.2 and 19.1.

Astellas had a thorough, electronic meetings approval process which covered all types of meetings including representative-led audio visual (AV) meetings, Astellas meetings with external speakers and stand meetings (independent NHS-led meetings).

Before 29 June 2009, all meetings (except stand meetings) with external speakers, regardless of cost, were examined by a medically qualified and Code trained individual to ensure an appropriate educational content and level of subsistence, and to check that the speakers had been provided with a written brief and a contract/agreement. These meetings were approved by the regional business manager (RBM) before submission to the medical department. From 29 June 2009 this process was amended as a result of a revised external meetings policy and currently only meetings costing more than £500 were reviewed and approved by the medical department. The RBM would, however, still review and approve all meetings costing more than £100 to ensure Code compliance. Any invitations, speaker briefs and speaker agreements used for these meetings had to be produced on Astellas' pre-

certified templates. AV meetings costing more than £50 (before 29 June 2009) and above £100 (29 June 2009 onwards) also required RBM approval. Stand meetings, regardless of costs, did not require additional medical approval however RBM approval was of course required. This was because Astellas had no input into the agenda or speaker selection.

Astellas had carefully examined all the meetings carried out by the representatives in question since January 2009. The majority of these meetings had been AV meetings where the representative had detailed products to the health professional using a detail aid or a short slide presentation although a few had been incorrectly recorded as AV meetings when they were in fact stand meetings. This was a simple misunderstanding of the term 'AV meeting' and the representative concerned had since correctly differentiated such meetings. However, as Astellas offered no incentives for running any meetings it considered that these mistakes were not directly relevant to the complaint. Subsistence at these meetings had been insignificant sandwiches or snacks. The representatives were interviewed separately and both had denied conducting any meetings without educational content.

A smaller proportion of the meetings had been stand meetings at independent educational events mostly taking place in hospital postgraduate educational centres and occasionally other appropriate locations eg a hotel. The representatives had sponsored such meetings by paying for stand space where they had detailed their products and interacted with health professionals. Four of the meetings examined had involved external speakers paid for by Astellas to discuss a particular disease and its management. In these Astellas-sponsored educational meetings, speakers had received a written speaker brief and had signed a speaker agreement/contract. From the records hospitality had been appropriate to the education provided. Therefore, Astellas had no doubts that the meetings carried out by the representatives, regardless of their type had had an educational content appropriate to the type and duration of the meeting. Hence Astellas submitted that the representatives in question had maintained high standards and had not breached Clauses 2, 9.1, 15.2 and 19.1.

Representatives sponsored independent educational meetings (NHS-led) by paying for stand space. This allowed them the opportunity to detail health professionals on their company's products before and after the meeting and during the session breaks. It would be unusual to be able to speak to every attendee at a large stand meeting but it was also not common practice to have a separate register of attendees at each representative's stand. Commonly a copy was made of the official attendance list, although for small meetings it was likely that representatives who had worked on that territory for many years would know all or nearly all of the attendees to their stands.

Astellas did not incentivise its representatives on the basis of the number of calls or contacts with health professionals. Like most pharmaceutical companies the representatives were incentivised on territory sales obtained from IMS data. There was, therefore, no benefit for representatives to log contacts with health professionals at stand meetings which had not taken place. Although contact with health professionals by representatives was a matter for the Code the recording of such contacts was not covered by the Code unless the representatives were incentivised to breach the Code by company policy. More importantly such mis-recording would be invisible to the external world and would have no impact on health professionals, patients, the NHS or the image of the pharmaceutical industry. Astellas thus believed that such administrative matters should be resolved in-house and were not covered by the Code. If purely administrative issues were indeed covered by the Code, then this would have extraordinary implications for the industry eg would representatives fraudulently claiming expenses become a matter for the Code as well as disciplinary matter?

The contact rate with health professionals by one of the representatives in question was usually above the average for Astellas medical sales representatives and there were several reasons for this. The representative was amongst Astellas' most experienced representatives and had worked on the same territory for approximately 12 years (4 years with Astellas). The individual was therefore well known and also highly regarded by the medical community locally. Understandably over the years the representative had developed a strong professional relationship with health professionals from the region and therefore at stand meetings the interaction and contact with these health professionals might be higher than the average representative.

Notwithstanding this it was clear that the representative had listed all attendees at stand meetings and company policy was that only those health professionals who were actually spoken to should be recorded. However this was a matter for Astellas internally and as stated above there were no benefits whatsoever to inflate contact rates. Additionally Astellas conceded that at large stand meetings it might not be logistically possible to accurately record all contacts and in group conversations there might not always be an appropriate opportunity to ask someone's name before they moved on to another stand. Astellas understood from personal experience in other pharmaceutical companies was that it was normal practice to record all attendees at stand meetings, usually by taking a copy of the attendance register.

Astellas stated that it faced the same dilemma as all pharmaceutical companies in ensuring that contacts logged by a representative had actually been seen by that representative. It was impossible to thoroughly police this but Astellas expected the line

manager to check the meetings records of their subordinates and to scrutinise them against the following rules:

- a person must be spoken to about a product to be counted as a contact;
- a person might be put down as a meeting contact if they were in the audience when key messages regarding promoted products were delivered and
- at stand meetings only those spoken to should be recorded as a contact.

Astellas routinely used agencies to run follow-up interviews with customers to see if the representative delivered the key messages and how they were accepted by the customers. From this Astellas had, on rare occasions, found that the customer had not been called on and it had taken the necessary actions, which on at least one occasion had resulted in dismissal. However it was not easy to perform this validation with stand attendees (contacts) since they might only have had a brief conversation and it was not likely that all messages would have been delivered, making a systematic assessment unreliable.

Astellas did not routinely ask health professionals to sign a register of attendance unless it was an Astellas-sponsored meeting with CPD accreditation. As mentioned above, validation should be the concern of the line manager when approving the meeting expenses.

There was no incentive whatsoever for a representative to list more contacts than actually seen. Astellas did not incentivise representatives for contacts (or calls) made. Astellas' incentives were based on sales results calculated from IMS data.

Astellas did not have incentives or targets for contacts made. However the main reason to put a representative on a territory was to deliver key messages about the company's products to convince the health professional to prescribe them. Therefore it might potentially be of concern if the IMS sales were below expectations and when the number of calls and contacts made on a particular geographical area fell short of historical activity. This was the only potential use of historical call and contact frequency and would be used to probe for an explanation of poor sales performance. However Astellas did not set any targets for such activity and therefore the contact rate would be that which the representative concerned had previously achieved on the territory. There were no issues with sales performance for the representatives in question.

In summary Astellas could find no evidence of any meetings taking place without educational content and Astellas did not incentivise representatives' contact rates and had no policies which might lead

to a breach of the Code. Astellas agreed that some contacts had been listed by one representative in error but it did not believe this was a matter for the Code when in these specific circumstances there were no consequences in terms of patient safety, health professionals, the NHS or the reputation of the industry. Astellas denied breaches of Clauses 2, 9.1, 15.2 and 19.1

## PANEL RULING

The Panel noted that the complainant had made a very general allegation about the sponsorship of lunchtime meetings which did not have any educational content. No specific details had been provided. The Panel noted that a complainant had the burden of proving their complaint on the balance of probabilities.

The Panel noted Astellas' submission that it had examined all meetings organised since January 2009. It could find no evidence that meetings with no educational content had taken place. The Panel examined the documents generated during the meetings approval process and noted that details of the educational content of each meeting and associated expenditure were given. Since 29 June 2009 all meetings costing less than £100 did not require approval and thus no relevant documents were available. The representatives had denied organising meetings as alleged. The Panel considered that there was no evidence to support the complainant's allegation that the representatives had organised meetings without any educational content. No breach of Clauses 15.2 and 19.1 was ruled. Consequently the Panel ruled no breach of Clauses 9.1 and 2.

The Panel noted that Astellas had conceded that in contravention of the company's internal policy one of the representatives had inflated the number of contacts at exhibition stands by listing all attendees at the meeting rather than those spoken to. The Panel had not seen Astellas' policy and procedures on contact rates and visits. The Panel noted the company's submission that representatives were not incentivised on calls or contact rates. The Panel considered that the representative's behaviour on this point was an in-house matter. There was no evidence that representatives had been encouraged or incentivised in relation to contact rates in a way that was contrary to the requirements of the Code. No breach of Clauses 9.1, 15.2, and 2 was ruled.

<b>Complaint received</b>	<b>14 July 2009</b>
<b>Case completed</b>	<b>3 September 2009</b>