

# DOCTOR v ASTELLAS PHARMA

## Representative call rates

A doctor queried whether Astellas Pharma was in breach of the Code by asking its representatives to see dermatology consultants four times between mid October and Christmas. The complainant considered such conduct was close to harassment.

The Panel noted that the supplementary information to the Code stated that the number of calls made on a doctor or other prescriber each year should normally not exceed three on average excluding attendance at group meetings and the like, a visit requested by the doctor or other prescriber or a visit to follow up a report of an adverse reaction. Thus although a representative might proactively call on a doctor or other prescriber three times in a year, the number of contacts with that health professional in the year might be more. In the Panel's view briefing material should clearly distinguish between expected call rates and expected contact rates.

The briefing document, given to representatives in October 2006, stated 'Your objective is to see your Senior Grade Dermatologists 4 times by December 31 2006'. There was no explanation that, as submitted by Astellas, this was meant to be the number of contacts for the whole year, not just the period October to December. The Panel considered that without further explanation the briefing document advocated a course of action which was likely to breach the Code. A breach of the Code was ruled.

The Panel took the complaint as evidence that overcalling had actually occurred and in that regard noted that the complainant had referred to harassment. A further breach was ruled.

### COMPLAINT

A doctor queried whether Astellas Pharma Ltd was in breach of the Code by asking its representatives to see dermatology consultants four times between mid October and Christmas. The complainant considered such conduct was close to harassment.

The Authority asked Astellas to bear in mind the requirements of Clauses 2, 15.4 and 15.9 of the Code.

### RESPONSE

Astellas explained that a Skinsense Briefing Document was given to representatives with hospital responsibility attending a company sales conference held in October 2006. The representatives were responsible for seeing hospital doctors in urology as well as doctors specialising in dermatology. During the earlier part of 2006 the focus had been on urology and

now the representatives were being asked to change this emphasis and ensure that they provided sufficient information to dermatology contacts particularly with regard to Protopic (tacrolimus).

In 2006 Protopic (together with the other topical calcineurin inhibitor) had been reviewed by both the European Medicines Evaluation Agency (EMEA) and the Food and Drug Administration (FDA) regarding a potential safety issue. The conclusion was that the risk:benefit ratio for Protopic remained unchanged. In particular there was no evidence of a link between the use of Protopic and certain skin cancers or lymphomas although the possibility of a link could not be completely excluded at this stage. The theoretical possibility of such a link had been postulated based on rates of malignancy in transplant patients receiving immunosuppressive agents including the systemic form of tacrolimus. Whilst the reviews were in progress, Astellas representatives had visited their dermatology contacts less often than would otherwise have been planned.

Following the publication of the reviews it was important that representatives had sufficient opportunities to discuss these complex issues with potential prescribers. Indeed several consultants had asked to see more of the Astellas sales team to discuss these issues. The launch of the Skinsense programme was an opportunity to include this type of discussion.

The representatives' briefing at the conference referred to all senior grade dermatologists of staff grade and above, including consultants and associate specialists. The briefing did not specify just consultant dermatologists. It was suggested that all senior grade dermatologists should be seen *in total* 4 times by 31 December 2006. This was an expectation for the whole year and to include all types of contacts rather than just direct calls. However Astellas accepted that this could have been made clearer in the briefing document as required by Clause 15.9 of the Code.

On reviewing call rates for 2006 thus far the average contact rate was 1.31. In 2005, Astellas had contacted senior dermatologists on average 0.73 times in the year.

Astellas expected senior grade dermatologists to be seen a total of up to 4 times by the end of the year because the company anticipated the likelihood of an additional call being requested to allow for questions and discussions in relation to the EMEA review. This represented total contacts and not just one-to-one visits. Representatives were therefore required to allow for this possible rate of contacts. The actual number of contacts would depend on the number already made up until that time. There was never any suggestion of doctors being subjected to 'harassment' and

representatives knew that the intervals between calls should also be appropriate. All calls would be made by appointment via departmental secretaries and any refusals would be respected.

Astellas had not received any negative response to the requests for appointments from any dermatologist. Indeed as mentioned above, the opportunity had been welcomed. Therefore there was no evidence whatsoever that the frequency, timing and duration of calls had inconvenienced any dermatologist. Representatives had always been careful to comply with the wishes of the dermatologists concerned and the arrangements in place at any particular establishment. In addition, although the supplementary information to the Code stated that the number of calls made on a doctor by a representative each year should not normally exceed three on average, the circumstances of 2006 together with the low contact rate in the previous year were such that additional contacts would be likely to be welcomed and in any case would not exceed three per year on average. The total number of contacts would include meetings and conferences.

Astellas therefore denied breaches of Clauses 15.4 or 2 and was disappointed that this issue should ever have been raised with the Authority.

#### **PANEL RULING**

The Panel noted that the supplementary information to Clause 15.4 stated that the number of calls made on a doctor or other prescriber each year should normally not exceed three on average excluding attendance at

group meetings and the like, a visit requested by the doctor or other prescriber or a visit to follow up a report of an adverse reaction. Thus although a representative might proactively call on a doctor or other prescriber three times in a year, the number of contacts with that health professional in the year might be more than that. In the Panel's view briefing material should clearly distinguish between expected call rates and expected contact rates.

The Panel noted that the Skinsense Briefing Document, given to representatives in October 2006, stated 'Your objective is to see your Senior Grade Dermatologists 4 times by December 31 2006'. There was no explanation that, as submitted by Astellas, this was meant to be the number of contacts for the whole year, not just the period October to December. The Panel considered that without further explanation the briefing document advocated a course of action which was likely to breach the Code. A breach of Clause 15.9 was ruled.

The Panel took the complaint as evidence that overcalling had actually occurred and in that regard noted that the complainant had referred to harassment. A breach of Clause 15.4 was ruled.

A ruling of a breach of Clause 2 of the Code was a sign of particular censure and was reserved for such circumstances. The Panel did not consider that the matter warranted such a ruling.

**Complaint received**                      **6 November 2006**

**Case completed**                              **24 January 2007**