

# VOLUNTARY ADMISSION BY AMGEN

## Promotion of prescription only medicine to the public

Amgen voluntarily admitted promoting Aranesp (darbepoetin alfa), a prescription only medicine, to the public.

As the matter related to a potentially serious matter, promotion of a prescription only medicine to the public, it was taken up and dealt with as a formal complaint under the Code in accordance with the Constitution and Procedure.

Amgen described events that took place at The National Kidney Foundation's (NKF's) annual conference October 2006. The NKF was a patient organisation and its conference was usually attended by patients and health professionals. Amgen had exhibited at the conference; its representative had set up the stand the night before the meeting in a room which he thought was away from the public. The representative therefore used branded material mistakenly thinking that the public would not see it. The exhibition started the next day at 9am. By 9.30am the representative realised that the area in which his stand was displayed was accessible to the public. He removed the branded material and telephoned head office to explain his mistake.

The Panel noted that Aranesp branded material had been displayed for a short time at a meeting of the NKF. The NKF was a UK charity run by kidney patients for kidney patients although its annual conference was usually also attended by health professionals. In the Panel's view the representative should have known that the conference audience in the area where he had his stand would have included patients/public and so he should have taken extra precautions to ensure that they did not see any branded material. It was not acceptable to assume when a mixed audience was present that a particular exhibition space would only be accessible to health professionals. As acknowledged by Amgen, a prescription only medicine, Aranesp, had been promoted to the public. The representative had thus not maintained a high standard of ethical conduct. Breaches of the Code were ruled. The Panel noted the representative's prompt action in removing branded items from his stand once he realised his mistake. The Panel considered that the circumstances thus did not warrant a ruling of a breach of Clause 2 of the Code.

Amgen Limited made a voluntary admission concerning the promotion to the public of Aranesp (darbepoetin alfa), a prescription only medicine.

Paragraph 5.4 of the Authority's Constitution and Procedure stated that the Director should treat such an admission as a complaint if it related to a serious breach of the Code. Promotion of a prescription only medicine to the public was regarded as a serious matter and the Director accordingly decided that the admission must be treated as a complaint.

### COMPLAINT

Amgen described events that took place at the National Kidney Foundation (NKF) national conference on 14 October 2006, involving one of its representatives.

The NKF was a patient organisation that held an

annual conference supported by the pharmaceutical industry. The conference was usually attended by patients and health professionals. It was common practice for this event to be attended by representatives as long as there was no marketing, in any form, of medicines to the public. However, Amgen's representative had inadvertently used branded materials and a branded exhibition banner in an area open to the general public. This was corrected immediately upon learning that the area was not restricted to health professionals.

The representative had set up his stand the night before the meeting, under the impression that company exhibition stands were in a separate room away from the public, whilst the patient advocacy group stands were set up in the main foyer. The representative therefore used a branded exhibition banner mistakenly thinking that the public would not see it. The exhibition started the next day at 9am. By 9.30am the representative realised that the area in which his stand was displayed was accessible to the public. He removed the branded material and branded banner and telephoned Amgen head office to explain his mistake.

Amgen apologised for potentially exposing members of the public attending the conference to branded materials and noted that it strove to abide by the Code in all matters. Amgen would make every effort to ensure that such a mistake did not happen again.

When writing to Amgen, the Authority asked it to respond in relation to Clauses 2, 15.2 and 20.1 of the Code.

### RESPONSE

Amgen explained that the conference facilities were arranged in such a way that the industry stands were in a room that appeared to be completely separate from the rest of the meeting. Therefore, the representative was under the erroneous impression that the room with the stands in was for health professionals only, and would not be accessed by the general public. Given that the NKF meeting focussed not only on patients but also on health professionals this was not an unreasonable assumption.

The representative arrived at 9am to a stand that had been erected the night before. Shortly before 9.30am, the representative was asked to pose in front of his stand for some NKF publicity photographs. This made him carefully reassess the contents of the stand and also made him look, for the first time, at the contents of other stands in the room. He immediately realised that branding had been excluded from other stands because the room was, indeed, accessible to all conference delegates, including members of the general public. The banner and promotional materials were removed immediately; this was

approximately half an hour after the start of the meeting, and only a few minutes after the main conference start time of 9.30am.

In the short period of time that the banner had been in place, the representative was confident that only a handful of delegates had passed by the stand.

Although it was not possible to state how many of these delegates were health professionals or patients, Amgen could verify that exposure of branded material to the public was very limited.

With regard to Clause 20.1, Amgen fully understood that prescription only medicines must not be promoted to the public. It noted that there was no malice aforethought on its part and the philosophy behind Clause 2 was reinforced during its sales training.

Amgen was aware that, under Clause 2, promotional activities must not be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry.

Whilst Amgen recognised that promotion to the public was a serious matter, it was confident that, in this case, only a limited number of people passed through the room during this period (single figures). The branded materials in question were displayed inadvertently and the error was corrected as soon as it was recognised. Therefore Amgen did not believe the inadvertent display of branded materials, an error that was corrected as soon as it was recognised, had, in this case, brought the industry into disrepute.

All Amgen representatives were fully conversant with the Code and aware of the need to maintain high ethical standards as outlined in Clause 15.2; indeed, the representative's remedial/corrective action to remove the offending materials was entirely consistent with someone upholding Amgen's high ethical standards.

The items on display at the Amgen stand included materials for both patients and health professionals. Patient materials were displayed so that health professionals could see what materials Amgen provided patients with kidney disease.

#### **PANEL RULING**

The Panel noted that Aranesp branded material had been displayed for a short time at a meeting of the National Kidney Foundation. The NKF was a UK charity run by kidney patients for kidney patients although its annual conference was usually also attended by health professionals. In the Panel's view the representative should have known that the conference audience in the area where he had his stand would have included patients/public and so he should have taken extra precautions to ensure that they did not see any branded material. It was not acceptable to assume when a mixed audience was present that a particular exhibition space would only be accessible to health professionals. As acknowledged by Amgen, Aranesp branded material had been on open view in an exhibition area accessible to the public; a prescription only medicine had thus been promoted to the public. A breach of Clause 20.1 was ruled. The representative had thus not maintained a high standard of ethical conduct, a breach of Clause 15.2 was ruled. The Panel noted the representative's prompt action in removing branded items from his stand once he realised his mistake. The Panel considered that the circumstances thus did not warrant a ruling of a breach of Clause 2 of the Code which was reserved to indicate particular censure.

**Proceedings commenced**      **15 November 2006**

**Case completed**                      **10 January 2007**