

# VOLUNTARY ADMISSION BY AMGEN

## Nominated signatories

**Amgen voluntarily admitted that it had failed to notify the PMCPA and the Medicines and Healthcare Products Regulatory Agency (MHRA) of two new nominated signatories resulting in material being certified by one signatory.**

**In accordance with Paragraph 5.6 of the Constitution and Procedure for the Prescription Medicines Code of Practice Authority, the Director treated the matter as a complaint.**

**The detailed response from Amgen is given below.**

**The Panel noted that the Code required that, *inter alia*, the names of those nominated as final signatories, together with their qualifications, be notified in advance to the Advertising Standards Unit, Vigilance and Risk Management of Medicines of the MHRA, and to the PMCPA. The Panel noted Amgen's submission that it had failed to notify the MHRA and PMCPA of two non-medical nominated signatories which resulted in items being certified by two signatories, only one of whom had been notified to the MHRA and PMCPA; the Panel thus ruled a breach of the Code as acknowledged by Amgen.**

**Consequently the materials that had been certified by the above two non-medical signatories who had not been notified in advance to the MHRA and PMCPA had not been certified in accordance with the Code and its supplementary information and the Panel ruled a breach of the Code.**

Amgen Limited voluntarily admitted that it had failed to notify the PMCPA and the Medicines and Healthcare Products Regulatory Agency (MHRA) of two new nominated signatories resulting in material being certified by one nominated signatory rather than two as required by the Code.

In accordance with Paragraph 5.6 of the Constitution and Procedure the admission was treated as a complaint and the matter was taken up with Amgen.

## COMPLAINT

Amgen explained that it had breached Clauses 14.1 and 14.4 due to an administrative error in dispatch of notification of two non-medical nominated signatories to the MHRA and PMCPA, resulting in promotional material being certified by one nominated signatory (a registered medical practitioner), rather than two nominated signatories as required by the Code.

Amgen stated that upon discovering the error, immediate measures were taken to ensure that no certification of any further promotional materials by the two signatories in question occurred.

Certification of fifteen current promotional items by a second nominated signatory occurred with no change of material content; seventeen promotional items no longer in use were retrospectively reviewed by a second nominated signatory without identifying any content that was considered to be non-compliant with the Code. The PMCPA and MHRA were notified of the two new nominated signatories.

Amgen stated that it took its obligations for compliance with the Code very seriously and apologised for the administrative oversight.

The Authority asked Amgen to consider this matter in relation to Clauses 14.1 and 14.4 of the Code.

## RESPONSE

Amgen explained that two non-medical signatories certified material for approximately five months (January – June 2014) prior to PMCPA and MHRA notification of their names and qualifications (20 June). Amgen submitted that it reviewed its internal record of promotional materials and was confident that only thirty four promotional items were approved during that time and were impacted by the voluntary admission, a list of which was provided; two additional materials no longer in use had been identified since the initial voluntary admission. No change to the content of fifteen items in current use was required upon certification by a second nominated signatory. The content of nineteen items no longer in use was considered to be Code compliant upon retrospective review by a second nominated signatory.

Amgen submitted that the breach was discovered as a result of routine review of promotional material. A reviewer accessed promotional material certified in 2014 in order to assess consistency of content; the certificate included the name of one of the non-medical signatories in question. The reviewer was unsure whether the non-medical signatory had been added to the list of signatories notified to the PMCPA and MHRA, resulting in a review of that list. It was at that point that the administrative error in the notification of the two new signatories became apparent.

Following identification of this breach, Amgen implemented the following process to ensure documented and timely notification of signatories in accordance with Clause 14:

- Addition of suitably qualified new signatories to be agreed by an internal compliance committee (including senior leadership team members, the majority of whom were existing nominated signatories) and the decision documented in the meeting minutes.

- Compliance lead to promptly notify the PMCPA and MHRA of updated nominated signatories list and send confirmation to the compliance committee when completed.
- Following dispatch of communication, compliance lead to communicate the updated list of nominated signatories to all reviewers, approvers, and administrative support involved in the examination and certification of company material. In addition, the current list of nominated signatories would be uploaded to Amgen's intranet site accessible by all employees.

#### **PANEL RULING**

The Panel noted that Clause 14.4 required that, *inter alia*, the names of those nominated as final signatories, together with their qualifications, be notified in advance to the Advertising Standards Unit, Vigilance and Risk Management of Medicines of the MHRA and to the PMCPA. The names and

qualifications of designated alternative signatories must also be given. Changes in the names of nominees must be promptly notified. The Panel noted Amgen's submission that it had failed to notify the MHRA and PMCPA of two non-medical nominated signatories which resulted in thirty four items being certified by two signatories, only one of whom had been notified to the MHRA and PMCPA as required by the Code; the Panel thus ruled a breach of Clause 14.4 as acknowledged by Amgen. Consequently the materials that had been certified by the above two non-medical signatories who had not been notified in advance to the MHRA and PMCPA had not been certified in accordance with Clause 14.1 and its supplementary information. The Panel thus ruled a breach of Clause 14.1.

**Complaint received**                      **20 June 2014**

**Case completed**                              **21 July 2014**