

VOLUNTARY ADMISSION BY ABBOTT LABORATORIES

Medical Representatives Examination

Abbott Laboratories advised the Authority that one of its representatives had not taken the ABPI Medical Representatives Examination, in breach of the Code.

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.

Abbott stated that a review of representatives' certificates for passing the ABPI representatives examination showed a representative who entered the industry ten years before starting work with Abbott in the early 1990s, had not taken the examination. All other representatives were compliant with the Code requirement.

When the Code changed in 2006 the representative's manager stated in an email that the representative had sat the examination. This was incorrect.

The detailed response from Abbott is given below.

The Panel noted that the representative had a nursing qualification and had entered the industry at a time when this qualification exempted the representative from having to take the examination. That exemption, however, was removed in 2006 and all representatives who had previously been exempt had then to be entered for the examination by January 2007 and pass it by January 2008.

The Panel noted that the representative had received training on the Code and related company policies and procedures. The representative had not, however, passed the examination contrary to the requirements of the Code. A breach of the Code was ruled as acknowledged by Abbott.

Abbott Laboratories Limited advised the Authority that one of its representatives had not taken the ABPI Medical Representatives Examination, in breach of Clause 16.3 of the Code.

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.

COMPLAINT

Abbott stated that following a recent review of representatives' certificates for passing the ABPI

representatives examination it became apparent that one of its representatives who entered the industry ten years before starting work with Abbott in 1992, had not taken the examination. As soon as this information was discovered the representative stopped working in the field until some resolution could be found.

When the Code changed in 2006 the representative's manager stated in an email that the representative had sat the examination. This now appeared to be incorrect and the manager no longer worked for Abbott.

All other representatives were compliant with the Code requirement.

When writing to Abbott, the Authority asked it to provide any further comments in relation to Clause 16.3 of the Code.

RESPONSE

Abbott stated that on investigation it became apparent that the representative believed a nursing qualification meant he/she was exempt. Abbott could not find formal documentation in relation to the representative's examination status when the representative joined the company. In 2006, with the Code change, Abbott carried out a review. At this point the representative was on leave and it was the duty of the manager to have followed up on the representative's qualifications. However, it appeared that this was not completed. The manager no longer worked for Abbott and thus the company was unable to investigate further.

In summary, Abbott had failed to appropriately check and document the representative's examination status. A full review had confirmed there were no other representatives who were either unqualified or not currently working towards the examination. More recent contracts of employment for representatives had included a clause that all representatives must pass the ABPI examination within the allotted time frame; however, this was not the case when the representative at issue was employed. Following this incident, discovered during an internal compliance check, a more formal checking and documentation process was being implemented.

PANEL RULING

The Panel noted that Clause 16.3 stated that representatives must pass the appropriate ABPI representatives' examination. They must take the appropriate examination within their first year of

such employment. Prior to passing the appropriate examination, they might be engaged in such employment for not more than two years, whether continuous or otherwise. The relevant supplementary information gave the Director discretion to grant an extension in the event of failure to comply with either time limit subject to the representative taking or passing the examination within a reasonable time.

The Panel noted that the representative, who had a nursing qualification, had entered the industry at a time when this qualification would have exempted the representative from having to take the examination. That exemption, however, was removed in 2006 and all representatives who had previously been exempt from the examination had then to be entered for it by January 2007 and pass it by January 2008.

The Panel noted that on 20 January 2006 an email was sent from the training department at Abbott to all regional managers, notifying them of the changes to the ABPI examination. Under a bold blue sub-heading of 'New: There are no longer any exemptions for taking and passing the ABPI Exam' it was clearly stated that previously exempt persons must now take the examination before January 2007 and pass it before January 2008. The email stated, *inter alia*: 'In order to ascertain the number of representatives (or indeed Regional Managers)

this new ruling will affect, can you please let me know the names of anyone in your region who has previously been exempt and therefore not passed the exam'.

The Panel noted that the response to this email from the then manager of the representative in question stated that all the manager's representatives were 'up to speed re changes to ABPI Exam new code 2006'. The Panel considered that this response did not clearly answer the question asked and was ambiguous in relation to whether all this manager's representatives had indeed passed the ABPI examination, and clarification should have been sought. The email did not state that the representative had sat the examination as submitted by Abbott.

The Panel noted that the representative's training record showed that she had received training on the Code and related company policies and procedures. The representative had not, however, passed the examination contrary to the requirements of Clause 16.3. A breach of that clause was ruled as acknowledged by Abbott.

Complaint received	17 November 2011
Case completed	4 January 2012
