

VOLUNTARY ADMISSION BY ROCHE

Failure to sit ABPI Medical Representatives Examination

Roche Products voluntarily advised the Authority that one of its promotional employees had not taken the ABPI Medical Representatives Examination, in breach of the Code. The employee had originally undertaken a non-promotional role but moved into a promotional role (relations manager) in December 2010.

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 Roche is given below.

The Panel noted that the employee at issue had started the promotional role in December 2010 and in May 2013 had not yet taken the ABPI Medical Representatives Examination.

The Panel noted that the employee's role and responsibilities, as acknowledged by Roche, satisfied those of a representative as set out in the Code. The employee had not passed the examination contrary to the requirements of the Code. A breach of the Code was ruled as acknowledged by Roche.

The Panel noted that Roche had no process for checking the ABPI examination status of staff that transferred roles within the company and the error was only identified due to a complaint about another matter. In that regard the Panel considered that the company had not maintained high standards and a breach of the Code was ruled. Although concerned about Roche's lack of process, the Panel ruled no breach of Clause 2.

Roche Products Limited voluntarily advised the Authority that one of its promotional staff members had not taken the ABPI Medical Representatives' Examination. Roche submitted that it had failed to check the ABPI examination status of the employee when they had transferred roles internally within the company.

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

Roche stated that during its investigation in order to respond to Case AUTH/2603/5/13, it discovered that one of its employees in a promotional role (relations manager) had not taken the ABPI Medical Representatives Examination.

The employee had originally been engaged by Roche in a non-promotional role. In December 2010 she moved to the position of relations manager. A copy of the job description was provided.

Roche stated that the employee's role was field-based but unusually reported to a head office manager. The normal process to verify the ABPI qualification of a field-based role was undertaken by the field-based manager. Roche noted that unfortunately due to the unusual reporting line, the check had not taken place in this case.

Roche immediately instructed its employee to cease all promotional activity and the employee had now been transitioned to another non-promotional role.

Roche submitted that it had failed to comply with the requirements of Clause 16.3 and to maintain high standards in breach of Clause 9.1 because it had not checked the ABPI examination status of the employee in question when the employee had moved from a non-promotional to a promotional role. Roche recognised that given the length of time its employee had been in a promotional role before the error was discovered the Panel might want to consider Clause 2.

In summary, Roche recognised the seriousness of the omission but considered that it had, upon discovery of the oversight, acted immediately and appropriately to address the issue. Roche submitted that the relations manager job description would be revised to ensure it was clear that success in the ABPI Medical Representatives Examination was a requirement of the role. The current job description provided listed ABPI qualified under desirable knowledge and experience.

When writing to Roche, the Authority asked it to respond in relation to Clauses 2, 9.1 and 16.3 of the Code.

RESPONSE

Roche provided a copy of its standard operating procedure (ABPI Code SOP UK 112 Representatives Training) which outlined the process regarding checking the ABPI examination status of relevant employees.

Roche required its representatives (including contract representatives) to pass the appropriate ABPI examination in line with the Code. The requirement extended to sales managers and suchlike whose duties comprised or included either calling upon doctors and/or other prescribers (albeit as business managers within the NHS) and/or the

promotion of medicines on the basis, *inter alia*, of their therapeutic properties (which also included discussions around cost).

The SOP noted that representatives were accountable for providing the human resources/recruiting manager or initial training course coordinator with a copy of their ABPI examination certificate. Human resources was accountable for keeping records of ABPI examination results and certificates, flagging those who had not passed the examination to the training department and terminating the contracts of those who did not pass the examination within the appropriate time limit.

Roche submitted that if an existing employee moved from a non-promotional to a promotional role, as in this case, human resources confirmed that the process was for the head office assessment team to check the ABPI examination status of head office-based roles and field-based line managers to check the status of field-based roles. However, this process was not documented.

Roche noted that the relations manager was a field-based role that reported in to a head office manager. The normal verification of the ABPI qualification of a field-based role was undertaken by the field-based manager, as described above. Unfortunately in this case, due to the role reporting into a head office-based position rather than a field-based manager, the check had not taken place.

Roche confirmed that it discovered the lack of an ABPI examination qualification for the individual whilst investigating the complaint in Case AUTH/2603/5/13, wherein the Authority asked whether Roche staff who had paid for hospitality for health professionals at a UK congress had passed the ABPI examination.

On discovering this oversight, Roche immediately instructed the employee in question to cease all promotional activity and the employee had now moved to a non-promotional role. In addition the ABPI examination status of all Roche relations managers had been checked and Roche confirmed that all (except the individual in question) had successfully completed the ABPI examination.

With regard to the clauses raised in this voluntary admission, Roche submitted that it had failed to comply with the requirements of, and was therefore in breach of, Clause 16.3. In addition, Roche considered that, given the length of time that its employee in question was in a promotional role before this error was discovered, it had failed to maintain high standards and was therefore in breach of Clause 9.1.

Roche considered that, on discovering this error, it acted swiftly and appropriately to address the situation by instructing its employee to cease all promotional activity. In addition, Roche had verified the ABPI examination status of the remaining relations managers as successfully completed and would revise its representative training SOP to ensure that checks of this status for internal moves into a promotional role were performed with the

same rigour as those for new employees beginning a promotional role. Roche had no further comments in relation to the requirements of Clause 2 beyond that set out above.

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 no 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 a representative was defined in Clause 1.6 as someone who called on members of the health professions and administrative staff in relation to the promotion of medicines. In the Panel's view such people would often have job titles other than 'representative'. The term promotion was defined in Clause 1.2 as any activity undertaken by a pharmaceutical company or with its authority which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply, or use of its medicines. Clause 16.4 stated that the ABPI Medical Representatives Examination must be taken by representatives whose duties comprised or included one or both of calling upon, *inter alia*, doctors and/or other prescribers; and/or the promotion of medicines on the basis of their particular therapeutic properties.

The Panel noted that the relations manager, had started in that role in December 2010 and in May 2013 had not yet taken or passed the ABPI Medical Representatives Examination.

The Panel noted that certain performance standards/indicators of the relations manager role referred to 'marketing strategy, 'promotional objectives' and 'product information in line with strategy'. In that regard, the Panel considered that the role and responsibilities of the relations manager as acknowledged by Roche satisfied those of a representative set out in the Code (Clauses 1.6 and 16.4). The relations manager had not passed the examination contrary to the requirements of the Code and a breach of Clause 16.3 was ruled as acknowledged by Roche.

The Panel considered that the failure of the relations manager to pass the ABPI Medical Representatives Examination despite the fact the company's SOP required such an employee to do so was because the company had no process for checking the ABPI examination status of staff who transferred roles within the company. The Panel also noted that the error was only identified due to a complaint about another matter. The Panel considered that the lack of process amounted to a failure to maintain high standards and ruled a breach of Clause 9.1.

The Panel was concerned about Roche's lack of process to check the ABPI examination status of staff transferring roles internally within the company. However, taking all of the circumstances in to account, the Panel did not consider that a breach of Clause 2, a sign of particular censure, was warranted and no breach of that clause was ruled.

Complaint received **7 June 2013**

Case completed **11 July 2013**
