

VOLUNTARY ADMISSION BY JANSSEN

Failure to sit the examination for representatives within one year

Janssen voluntarily admitted that one of its sales managers failed to take the required examination within one year of commencing that role.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Janssen.

Janssen explained that in Autumn 2014, one of its employees became a first line sales manager. Details of the manager's previous roles (which did not include sales), qualifications and training were provided.

In June 2015, the learning and development (L&D) department was asked to clarify whether the manager needed to complete the ABPI representatives examination. The advice was 'No' given the employee's qualifications and training to date. This was an error. In April 2016 this advice was re-questioned and the L&D team raised the matter with the medical director, who confirmed the examination was required.

Janssen stated that these events amounted to a breach of the Code, since the individual had been in a sales management role for more than 12 months without sitting the ABPI examination.

The detailed response from Janssen is given below.

The Panel noted that Janssen made no submission that the manager's role was not within the definition of a representative. It therefore followed that the sales manager in question, who commenced employment in that role in Autumn 2014, should have taken an appropriate examination for the first time by Autumn 2015.

The requirement of the Code to take an examination within 1 year had not been met as acknowledged by Janssen and the Panel ruled a breach of the Code.

The Panel was concerned that neither an experienced manager nor Janssen's L&D department were clear about the requirement to take an examination. It did not appear that anyone had referred directly to the Code. The Panel further noted that Janssen's procedure for training employees on the Code did not cover the situation where an existing employee moved to a role which newly required them to take an appropriate examination. On balance the Panel decided that the failure to take the examination or recognise that the employee needed to take an appropriate examination amounted to a failure to maintain high standards and thus a breach of the Code was ruled.

Janssen voluntarily admitted that one of its sales managers failed to take the required examination within one year of commencing that role.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Janssen.

VOLUNTARY ADMISSION

Janssen stated that in September 2014, one of its employees moved into a sales management role, responsible for leading a team of sales representatives. The employee had previously worked as a product manager, in Janssen medical affairs, for other pharmaceutical companies and prior to that as a health professional.

During time in Janssen medical affairs the employee completed signatory training but before formally becoming a Janssen signatory moved to another role in Janssen. Details of the manager's qualifications and training were provided.

In June 2015 the learning and development (L&D) department was asked to clarify whether the manager needed to complete the ABPI representatives examination. Janssen had no written record of a follow up conversation but later that year after being prompted by its learning management system (LMS) to provide a copy of his/her ABPI certificate, the manager again contacted L&D and was advised that the examination was not required given his/her qualifications and training to date. This was in error and based on a misunderstanding that given the manager's background (as a health professional and signatory training), the ABPI representative's examination was not needed. The manager had been trained on the company's work instruction (WI) on a number of occasions but the WI was followed based on the incorrect advice received.

In April this advice was re-questioned within the L&D team, prompted by a gap in the training records on the company LMS, and L&D raised the question of exemption with the medical director, who confirmed the examination was required.

Janssen stated that these events amounted to a breach of Clause 16.3, since the individual had been a sales manager for more than 12 months without sitting the ABPI examination.

Janssen was asked to provide the PMCPA with any further comments in relation to the requirements of Clauses 9.1 and 16.3.

RESPONSE

Janssen stated this was a case of an experienced employee with significant relevant training (registered health professional and signatory-trained) moving into a sales management role from within the company. The company's standard operating procedure (SOP) indicated that anyone in a sales role must have taken the ABPI Medical Representatives Examination. On this occasion, given the employee's background, the SOP was unfortunately incorrectly interpreted by L&D and incorrect advice given. This was an isolated incident and one of low risk to Code compliance given the individual's training on the Code and as a health professional; and his/her pharmaceutical industry experience. In this context Janssen submitted that it had not failed to maintain high standards.

The employee did not take the ABPI Medical Representatives Examination within one year of being a sales manager.

The manager's email to the company's L&D department was provided. The gap in timelines from June to October 2015 reflected the verbal discussion that took place during this period between the representative and an L&D manager. The manager's October email was prompted by his/her training on the Work Instruction WI08558, Procedure for Training Employees on the ABPI Code of Practice, issued as training by Janssen's learning management system. The manager referred to this training in an email as 'ABPI requirement training'. The response from the L&D manager detailed the incorrect advice.

Following an internal audit of training records, the individual was flagged as the company did not have a record of his/her ABPI Medical Representatives Examination certificate on file. The response to the request to provide the certificate to L&D, caused L&D to review the original advice given in 2015. Further advice on whether, given the manager's training and background, an exemption was possible was then discussed with the medical director who confirmed the examination certification requirement. Janssen then duly reported a potential breach of Clause 16.3 to the PMCPA.

PANEL RULING

The Panel noted that Clause 16.3 stated that representatives must take an appropriate

examination within the first year of their employment as a representative and pass it within two years of starting such employment. A representative was defined in the Code as someone who called on members of the health professions and others in relation to the promotion of medicines.

The Panel noted that Janssen made no submission that the manager's role was not within the definition of a representative. It therefore followed that as the sales manager in question commenced employment in that role in Autumn 2014 he/she should have taken an appropriate examination for the first time by Autumn 2015.

The Panel noted that the manager in question had been in post for over 18 months and had not yet taken an examination. The requirement of Clause 16.3 to take an examination within 1 year had not been met as acknowledged by Janssen and the Panel ruled a breach of that clause.

With regard to Clause 9.1, the Panel was concerned that neither an experienced manager nor the L&D department were clear about the requirement to take an examination. It did not appear that anyone had referred directly to the Code. The Panel further noted that the work instruction detailing the procedure for training employees on the Code did not cover the situation where an existing employee moved to a role which newly required them to take an appropriate examination. The exemptions to taking the ABPI examination were removed from the Code in 2006 and so in that regard the examination requirements of the Code were very simple. The Panel noted an email in 2016 referred to 'exemption criteria' and implied that the manager's need to take an appropriate examination might be 'a local decision'. On balance the Panel decided that the failure to take the examination or recognise that the employee needed to take an appropriate examination amounted to a failure to maintain high standards and thus a breach of Clause 9.1 was ruled.

Complaint received **23 May 2016**

Case completed **4 July 2016**