

VOLUNTARY ADMISSION BY ROSEMONT

Failure to sit ABPI Medical Representatives Examination

Rosemont Pharmaceuticals voluntarily advised the Authority that five long standing members of its sales team, although previously exempt from having to take the ABPI Medical Representatives Examination, did not sit the examination when the exemption was removed in 2006. The employees involved had all passed the ABPI Generic Representatives Examination.

In accordance with Paragraph 5.6 of the Constitution and Procedure, the Director treated the matter as a complaint.

Rosemont explained that it discovered this issue following a compliance review conducted when the company was taken over by Perrigo earlier in the year. All affected staff would now sit the examinations within the next 12 months and must pass both sets of papers within the next 24 months. If they failed to do so, Rosemont would terminate their employment in a sales capacity. Rosemont assured the Authority that it had robust procedures in place for all new sales employees and was confident that this breach could not happen again.

The detailed response from Rosemont is given below.

The Panel noted that Rosemont accepted that the Code required the individuals concerned to take the Medical Representatives Examination. Due to staff turnover it was unclear why in 2006 when the staff concerned could no longer take the benefit of the exemption, the company did not require them to take the ABPI Medical Representatives Examination. The Panel noted that this particular change had been communicated to companies as an intention well ahead of time. The changes were agreed in principle by ABPI members in 2003 before becoming part of the Code in 2006. The Panel was concerned that the matter only came to light during a compliance audit when Rosemont was taken over by another company. The Panel was also very concerned about Rosemont's proposal for the employees concerned to take the examination. The Panel noted that this was contrary to the supplementary information to the Code which referred to extensions from the Director. The Panel considered that the company should ensure that the relevant employees contacted the Director forthwith and that they should not carry out the medical representative's role unless the appropriate extension had been granted.

The Panel noted that five Rosemont representatives had not passed an appropriate Medical Representatives Examination as required by the Code and that the matter was only identified during a compliance audit some seven years after the exemption was removed. High standards had not

been maintained. Breaches of the Code were ruled. On balance the Panel did not consider that the circumstances warranted a breach of Clause 2 which was used as a sign of particular censure and was reserved for such circumstances. No breach of Clause 2 was ruled.

Rosemont Pharmaceuticals Ltd voluntarily advised the Authority that five long standing members of its sales team, although previously exempt from having to take the ABPI Medical Representatives Examination, did not sit the examination when the exemption was removed in 2006. The employees involved had all passed the ABPI Generic Representatives Examination.

In accordance with Paragraph 5.6 of the Constitution and Procedure, the Director treated the matter as a complaint.

VOLUNTARY ADMISSION

Rosemont explained that following a full review of compliance which was conducted when the company was taken over by Perrigo earlier in the year, it was noted that five long standing members of its sales team who had passed the ABPI Generic Representatives Examination and who were previously exempt from taking the ABPI Medical Representatives Examination as they were nurses prior to entering the pharmaceutical industry, did not take the ABPI Medical Representatives Examination when the exemption was removed in 2006. This was an oversight by the company at that time which had only recently come to light.

Rosemont submitted that it had started to rectify the situation to ensure compliance with the Code. All of the employees in question had been asked to register to take the morning and afternoon papers (as they passed the morning papers more than 3 years ago). In line with the timings set out in the Code, they would sit the examinations within the next 12 months and must pass both sets of papers within the next 24 months. If they failed to do so, Rosemont would terminate their employment in a sales capacity.

Rosemont submitted that the breach of Clause 16.3 only affected a small number of long standing employees. Rosemont assured the Authority that it had robust procedures in place for all new sales employees and was confident that this breach could not happen again. The procedures stated that all personnel employed in sales must produce their original certificates showing that they had passed the morning and afternoon examinations or agree to undertake the examinations within their first two years of employment within the industry in line with the Code. New employees with only the Generic Representatives Examination were required to pass

the Medical Representatives Examination within two years of changing their duties. Their employment contract stated that failure to do so would result in termination of their employment in sales.

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

RESPONSE

Rosemont submitted that unfortunately no one who was in sales management from 2006 or before was still with the company, so it was difficult to determine exactly what occurred then. However, all the sales employees in question had submitted that they were not asked by anyone within the company to undertake the ABPI Medical Representatives Examination in 2006. At that time they thought that they were exempt from the need to do so (they were all qualified nurses and were sufficiently qualified as they had passed the ABPI Generic Representatives Examination. Rosemont was, and always had been, a generic company as well as a long standing member of the ABPI.

The sales force role had changed and developed over time and representatives now discussed medicines management of patients who were unable to swallow tablets and capsules. This therefore went beyond the scope of the generic representatives qualification. It appeared that in 2006, those in charge of the sales functions either considered that the generics examination was sufficient to cover the job roles or failed to recognise the need for these employees to sit the examinations.

Rosemont submitted that since 2000 it had been a stipulation that all of its new sales people must have passed the ABPI Medical Representatives Examination or would study and pass the examination as part of their employment requirements. Unfortunately the representatives in question were long standing employees and it appeared that they had not been asked to sit the Medical Representatives Examination. This was currently being rectified and all of them had been asked to register immediately to take and pass these examinations.

Rosemont provided a copy of the current job descriptions for the three different types of jobs undertaken by the employees in question. All of the job descriptions stated that the employee must have the full ABPI examination. All new employees had to sit the examination or upgrade from the generics examination within the time specified in the Code, if they did not already hold the qualification.

The introduction checklist for new employees stated that the company must see and store on their personnel records a copy of their ABPI examination certificates, which was part of the company's employment policy for sales personnel. Rosemont also provided a copy of the letter sent to all new personnel about the ABPI examination requirement.

Rosemont submitted that this had been an oversight by the company which was being rectified as a matter of urgency; the employees had been asked to sit and

pass the full examination. Rosemont accepted that it had breached Clause 16.3, but did not consider that it had brought discredit to the industry or intentionally failed to maintain standards. Rosemont held the Code in extremely high regard and endeavoured to uphold both the spirit and the letter of the Code at all times.

PANEL RULING

The Panel noted that Clause 16.3 stated that representatives must take an appropriate representatives examination within their first year of such employment and pass it within two. The relevant supplementary information stated that prior to passing an appropriate examination, representatives might be engaged in such employment for no more than two years, whether continuous or otherwise and irrespective of whether with one company or with more than one company. The Director had discretion in the event of failure to comply with either time limit to either grant an extension or agree to the continued employment of the relevant employee as a representative past the end of the two year period 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 16.3 of the Addendum to the Second 2012 Edition of the Code stated that an appropriate examination for medical representatives was one that required a broad understanding of body systems, diseases and treatments, the development of new medicines and the structure and function of the NHS and of the pharmaceutical industry. An appropriate examination for generic sales representatives was one that required a broad understanding of body systems, the structure and function of the NHS and of the pharmaceutical industry. The supplementary information to Clause 16.3 Examinations, stated that the ABPI Medical Representatives Examination was appropriate for and must be taken by representatives whose duties comprised or included one or both of calling upon, *inter alia*, doctors and/or other prescribers; the promotion of medicines on the basis, *inter alia*, of their particular therapeutic properties. The Generic Sales Representatives Examination was appropriate for, and must be taken by, representatives who promoted primarily on the basis of price, quality and availability to those who did not prescribe medicines. The supplementary information to Clause 16.3 Time Allowed to Pass an Examination, stated that service as a representative prior to 1 January 2006 by persons who were exempt from taking the appropriate examination by virtue of Clause 16.4 of the 2003 edition of the Code did not count towards the two year limit on employment as a representative prior to passing the appropriate examination.

The Panel noted that Rosemont accepted that the individuals concerned were required under the Code to take the Medical Representatives Examination. Due to staff turnover it was unclear why in 2006 when the staff concerned could no longer take the benefit of the exemption, the company did not require them to take the ABPI Medical Representatives Examination. The Panel noted that this particular change had been communicated to companies as an intention well ahead of time. The changes were agreed in principle by ABPI members in 2003 before becoming part of the Code in 2006. The Panel was concerned that the matter only came to light during a compliance audit when Rosemont was taken over by another company. The Panel was also very concerned about Rosemont's submission that the employees concerned had registered to take the examination within one year of the date of the company's response to the complaint and must pass the examination within two years of this date. The Panel noted that this was contrary to the supplementary information to Clause 16.3 which referred to extensions from the Director agreeing to their continued employment subject to their passing the examination within a reasonable time. The Panel considered that the company should ensure that the

relevant employees contacted the Director forthwith and that they should not carry out the medical representative's role unless the appropriate extension had been granted.

The Panel noted that five Rosemont representatives had not passed an appropriate Medical Representatives Examination as required by the Code. A breach of Clause 16.3 was ruled. The Panel was concerned that the matter was only identified during a compliance audit some seven years after the exemption was removed. High standards had not been maintained. A breach of Clause 9.1 was ruled.

On balance the Panel did not consider that the circumstances warranted a breach of Clause 2 which was used as a sign of particular censure and was reserved for such circumstances. No breach of Clause 2 was ruled.

Voluntary admission received **29 October 2013**

Case completed **28 November 2013**