**CASE AUTH/3265/10/19**

# COMPLAINANT v BRACCO

## ABPI Medical Representatives Examination

**A named, contactable complainant stated that Bracco had employed representatives, without ABPI qualifications, to sell medicines. The representatives had been with Bracco for at least 3 years. The complainant alleged that Bracco had ignored the Code requirements in this regard. The complainant alleged that a named representative had not sat the ABPI examination within his/her first two years of being a representative.**

**The complainant provided a screenshot of an advertisement for CTExprès syringe-less CT injector which referred to Iomeron (iomeprol) on the display screen of the device and did not include prescribing information.**

**Finally, the complainant alleged that a named member of staff did not appear to understand the Code.**

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

**The Panel noted that the representative worked as a representative prior to joining Bracco in a role where he/she would ultimately be promoting medicines as a well as medical devices. It was concerning that Bracco had not checked the position when employing the representative.**

**The Panel noted Bracco's submission that the representative had not told the company that he/she did not have the examination.**

**The Panel noted Bracco's submission regarding the dates the representative had sat the examination. As the full examination had not been taken within a year the Panel ruled a breach of the Code.**

**The advertisement provided by Bracco was A3 in size and focussed on CTExprès, a syringe-less CT injector. The advertisement claimed 'user friendly', 'faster patient throughput', 'Optimizes patient-tailored dosing to reduce waste' as well as reductions in consumable costs, contrast media usage and clinical waste costs. The illustration included 2 reservoirs labelled 'contrast media'. The display indicated that these were Iomeron 482mL.**

**The Panel considered that the inclusion of a product name on the display meant that the prescribing information was required and the failure to do so was ruled in breach of the Code.**

**With regard to the allegation that a named employee did not appear to understand the Code, the Panel noted that the Constitution and Procedure for the PMCPA stated the**

**complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant had provided no evidence to support his/her allegations. The Panel therefore ruled no breach of the Code.**

**The Panel considered that when taking the rulings together, Bracco had failed to maintain high standards and thus a breach of the Code was ruled.**

A named, contactable complainant alleged that a representative from Bracco UK Limited had not passed the ABPI medical representatives examination, that advertisements did not contain prescribing information and that a senior manager did not understand the Code.

**COMPLAINT**

The complainant stated that Bracco had employed representatives, without ABPI qualifications, to sell medicines. The complainant alleged that Bracco had ignored the Code requirements in this regard. The complainant named a particular representative who had not sat the ABPI examination within his/her first two years of being a representative. The complainant gave details of the representative's attempts at the examination and noted that despite failing it, he/she was still selling pharmaceutical products.

The complainant also alleged that Bracco had placed advertisements for pharmaceutical products without including any prescribing information. The complainant provided a screenshot of an advertisement for CTExprès syringe-less CT injector which referred to Iomeron (iomeprol) on the display screen of the device.

Finally, the complainant alleged that a named member of staff did not appear to understand the Code.

When writing to Bracco, the Authority asked it to consider the requirements of Clause 16.1 in relation to the allegation about the named member of staff, Clause 16.3 in relation to the allegation about the representative, Clause 4.1 in relation to allegation about the lack of prescribing information and Clause 9.1 in relation to all of the matters raised.

**RESPONSE**

Bracco submitted that it was satisfied that the named employee had the required qualifications, technical knowledge, training and experience to carry out the responsibilities of his/her role.

Bracco stated that it had a robust process of validation for both pharmaceutical promotion spend and materials which had a requirement for staged approvals culminating in medical then director level sign-off. All procedures and practices related to the Code had regular internal audits and external inspections.

On the basis of the above, Bracco stated that it was confident that the employee had the requisite understanding and knowledge of the Code and that the company had robust processes in place to ensure marketing materials complied with the Code.

Bracco accepted that it currently had one employee who had not passed a recognised examination within the required timeline. Details were provided. The representative had

worked for other companies and had not told Bracco that he/she did not hold the ABPI qualification as he/she believed it was not required because previous employers stated this when he/she was in similar roles. Bracco provided a statement from the employee attesting to this.

Bracco stated that it assumed at the time that the representative already had the qualification as he/she had been working for pharmaceutical companies prior to joining Bracco.

That the representative did not have the qualification was discovered in early 2018 during a routine inspection. Bracco immediately changed its process to ensure all employees confirmed proof of attainment of the ABPI qualification before starting employment. It was decided, given the unusual circumstances and considering the focus of the role on promoting medical devices versus promoting medicines, that the company would allow the employee to sit and pass the ABPI examination within two years. Details of his/her examination attempts were provided. On receipt of the PMCPA letter informing Bracco of the complaint the company had stopped the employee from engaging in any promotion of pharmaceuticals until a decision was made as to his/her future. Before receipt of the complaint Bracco had intended to support the employee in preparation for an examination then contact the PMCPA with a voluntary admission.

Bracco stated that given the importance of prescribing information to patient safety, it took its inclusion in material promoting its medicines very seriously. However, the material in question was unambiguously promoting a medical device and not a medicine. CTExprès was a syringeless contrast delivery system for use with CT scanners which was regulated as a medical device. As such, Bracco submitted that the material was outside the scope of the Code and was not subject to any requirement to include prescribing information in the material.

The promotional material in question was a journal advertisement which was placed in the June, July and October editions of RAD magazine. The advertisement had not appeared in any other publication and there was no plan to place it again in RAD magazine. Bracco subsequently submitted that the advertisement had also appeared in the November issue of RAD magazine.

In reference to the complaint, Bracco considered that the complainant had referred to the display screen on the device which required selection from a prescribed list of all marketed pharmaceuticals (from all companies) in order to fully populate the screen data and this showed a named pharmaceutical product. The inclusion of a named pharmaceutical product was incidental to the advertisement, as this was required to demonstrate the functionality of the device by showing the on-screen display. In the form the advertisement appeared in RAD magazine, the pharmaceutical name of the medicine would not have had any prominence. The text size of the brand name was extremely small and it was unlikely that readers would have focused on that. The image specifically of the device's display in the complainant's email of 16 October 2019 was an enlarged version and thus did not represent what would have been visible to readers of the advertisement when it appeared in RAD magazine. Bracco provided a copy of the RAD magazine advertisement which it stated was representative of the advertisement which appeared in RAD magazine.

Further, the two bottles of pharmaceutical product situated on either side of the main unit clearly showed mock-up bottles labelled 'Contrast Media' and were not labelled with a proprietary branded agent. Additionally, there were no claims made in the advertisement for the specific medicine. Bracco submitted that the advertisement did not fall within the scope of the Code as it was clearly for a medical device. Bracco denied a breach of Clause 4.1.

In relation to Clause 9.1, Bracco strongly refuted any charge and could show that the company had systemic processes and standards to ensure compliance. The complaint at issue was exceptional. The company did not consider that there was any substance to the allegations of the employee not having appropriate knowledge of the Code and could demonstrate that he/she had a wealth of experience in this area, along with appropriate training and qualifications. Additionally, as noted above, Bracco did not consider that the advertisement for CTExprès included in the complainant's email fell within the scope of the Code as it was an advertisement for a medical device.

Bracco stated that with the exception of one person, all of its relevant employees had either taken and passed the ABPI examination within the prescribed timeline or had joined the company having already gained the qualification. Bracco noted that some members of its sales and marketing team were responsible solely for medical devices. However, given that there was a risk that these employees could become involved in discussions with health professionals about the use of Bracco's branded contrast agents, the company insisted all such employees must achieve the ABPI qualification. As noted above, the representative's role primarily involved the promotion of medical devices. However, the company required him/her to pass the ABPI examination and had suspended his/her promotion of medicinal products unless and until he/she passed the relevant ABPI examination.

Bracco stated that every relevant employee was issued with the latest hard copy version of the Code on publication and had regular updates at team meetings, especially when there were changes to the Code. All relevant employees had access to a digital learning academy. Finally, a comprehensive range of corporate guidelines and local standard operating procedures (SOPs) supported the company's systems and guided its processes to ensure that marketing materials were subject to appropriate review and to ensure compliance with the Code and other applicable requirements.

In response to a request for further information Bracco stated that the representative completed online and classroom training with pharmaceutical products. Initially his/her activity was with medical devices. The representative started promoting pharmaceutical products in February 2018.

It was discovered the representative did not have the ABPI examination in mid-January 2018. Bracco was not sure of the exact date but the representative was immediately informed that he/she had to sit the examination.

In response to a request for further information Bracco provided details of the representative's examination record.

**PANEL RULING**

The Panel noted that the representative started working as a representative with companies prior to joining Bracco in August 2016 in a role where he/she would ultimately be promoting medicines as a well as medical devices. It was concerning that Bracco had not checked the position when employing the representative.

It appeared that the representative had been promoting medicines for many years and therefore potentially needed to take and pass the examination. It appeared that the representative was

misinformed that the examination was not needed. The Panel noted Bracco's submission that the representative had not told the company that he/she did not have the examination.

The PMCPA checked its records for the companies named as previous employers. These companies were not members of the ABPI and it appeared that at the time of the representative's employment they had not agreed to comply with the Code and accept the jurisdiction of the PMCPA.

The Panel noted Bracco's submission that the representative had started promoting medicines in early 2018 and ceased in late 2019.

The Panel noted that according to the Code, the representative should have sat the examination in early 2019 and passed it a year later 2020. The Panel noted that only four papers had been taken within the first year. It appeared that the representatives needed to take the examination for medical representatives and that the attempts in 2019 were for that examination. As the full examination had not been taken within a year the Panel ruled a breach of Clause 16.3.

The advertisement provided by Bracco was A3 in size and focussed on CTExprès, a syringe-less CT injector. The advertisement claimed 'user friendly', 'faster patient throughput', 'Optimizes patient-tailored dosing to reduce waste' as well as reductions in consumable costs, contrast media usage and clinical waste costs. The illustration included 2 reservoirs labelled 'contrast media'. The display indicated that these were Iomeron 482mL.

The supplementary information to Clause 4.1 Advertisements for Devices, stated that when an advertisement related to the merits of a device used for administering medicines, such as an inhaler, which was supplied containing a variety of medicines, the prescribing information for one only needed to be given if the advertisement made no reference to any particular medicine. Full prescribing information must, however, be included in relation to each particular medicine which was referred to.

The Panel considered that the inclusion of a product name on the display meant that the prescribing information was required. The failure to do so was ruled in breach of Clause 4.1.

With regard to the allegation that the named employee did not appear to understand the Code, the Panel noted that the Constitution and Procedure for the PMCPA stated the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant had provided no evidence to support his/her allegations. The Panel therefore ruled no breach of Clause 16.1 of the Code.

The Panel considered that when taking the rulings together, in particular the ruling of a breach of Clause 16.3, Bracco had failed to maintain high standards and thus a breach of Clause 9.1 was ruled.

**Complaint received** **16 October 2019**

**Case completed** **13 February 2020**