

ANONYMOUS, NON-CONTACTABLE REPRESENTATIVE v CIPLA

Conduct of a senior manager

An anonymous non-contactable individual who described him/herself as being employed by a third party sales organisation which had a contract with Cipla, complained about the conduct of a named senior manager at Cipla who had been in post for some time but had little or no knowledge of the Code and little regard for it. Despite this, he/she controlled the day-to-day workings of representatives.

The complainant stated that representatives were asked to put pressure on surgeries to switch patients to Cipla products. The senior manager went to visit customers with representatives and put direct pressure on customers to switch patients. The complainant alleged that at a recent meeting with a named asthma nurse specialist the senior manager was asked if Cipla would sponsor some educational meetings; he/she replied that Cipla would, once it saw an increase in sales in the local area.

The complainant alleged that one of his/her colleagues was asked to drive a long distance to see a practice nurse who had a question about the use of an inhaler with a spacer device. The medicine, however, was not licensed for this.

The complainant stated that the senior manager regularly played a part at stands in exhibitions, yet had no ABPI qualification.

The complainant submitted that the senior manager regularly emailed customers following up on queries that should go to medical information.

The detailed response from Cipla is given below.

The Panel noted the company's submission that the senior manager was not a representative and there was no need for him/her to take and pass the representative's examination. Cipla decided that the individual would take the examination. On the information provided it appeared that if the senior manager was working as a representative, he/she appeared to be within the timeframe for taking and passing the examination. The Panel did not consider that the complainant had provided evidence to demonstrate on the balance of probabilities that the senior manager was working as a representative and if so that he/she had not met the requirements in the Code for taking and passing the representatives' examination. Thus the Panel ruled no breach of the Code.

The Panel noted that there were differences between the complainant's view of the senior manager's activities and Cipla's. The sales strategy to promote cost savings by switching to Cipla's product meant that encouraging switches for existing patients

would be part of the representatives' discussions with those upon whom they called. This was not necessarily unacceptable. No evidence had been provided regarding the alleged pressure on representatives to arrange for surgeries to switch nor about the senior manager putting pressure on surgeries to switch. No information was provided about Cipla's involvement in any switch. In relation to the meeting with the asthma nurse specialist, Cipla submitted that the representative had not attended and the senior manager had discussed the company and continuity of supply. There was no mention of a discussion about educational support being linked to increased sales and the complainant had provided no evidence in this regard. The Panel did not consider that the complainant had provided evidence to show that there was a breach of the Code in relation to this aspect of the complaint. No breaches of the Code were ruled.

The company submitted that a representative had telephoned the practice nurse who had a question about the use of a spacer device. The complainant had not identified the relevant medicine. Cipla had not provided evidence to show how the representatives were trained on the products. It appeared that some of Cipla's medicines were indicated for use with a spacer and according to Cipla its representatives were fully trained and aware of the licensed indications of its products. The Panel noted that the complainant had provided no evidence that medicines had been promoted in a manner inconsistent with their summaries of product characteristics at the meeting in question and thus ruled no breach of the Code in this regard.

The Panel noted that again no evidence had been provided regarding the allegation that the senior manager followed up queries that should be answered by medical information. Cipla had not provided any information about the current arrangement submitting that it was in the process of reviewing and strengthening its process in this regard. The Panel was concerned about the response in relation to this allegation. The company should have a robust process for medical information. However the complainant had not provided any evidence and thus not shown on the balance of probabilities that a breach had occurred. The Panel therefore ruled no breach of the Code in this regard.

The Panel did not consider that the complainant had provided evidence to show that the senior manager had promoted medicines at a stand meeting or that any such activity was in breach of the Code. The Panel therefore ruled no breach of the Code. In considering the matters overall, the Panel did not consider that the complainant had shown on the

balance of probabilities that there was a breach of Clause 2 of the Code. This clause was used as a sign of particular censure and reserved for such use.

An anonymous non-contactable individual who described him/herself as being employed by a third party sales organisation which had a contract with Cipla, complained about the conduct of a named senior named manager at Cipla.

COMPLAINT

The complainant explained that Cipla employed two sales teams through two named contract sales organisations and that colleagues from both organisations shared his/her concerns. The complainant alleged that the named senior manager at Cipla had little or no knowledge of the Code and little regard for it. Despite this, he/she continued to control the day-to-day workings of representatives.

The complainant stated that representatives were continually being asked to put pressure on surgeries to switch patients to Cipla products. The senior manager went to visit customers with representatives and put direct pressure on customers to switch patients. The complainant alleged that at a recent meeting with an asthma nurse specialist (named) the senior manager was asked if Cipla would sponsor some educational meetings; he/she replied that Cipla would, once it saw an increase in sales in the local area.

The complainant alleged that one of his/her colleagues was asked to drive a long distance to see a practice nurse who had a question about the use of an inhaler with a spacer device. The medicine, however, was not licensed for this and so the representative should not have been asked to do that.

The complainant stated that the senior manager regularly played a part at stands in exhibitions, yet had no ABPI qualification. Once introduced to customers he/she would often then take on a relationship with that customer and cut the representative out.

The complainant submitted that the senior manager regularly emailed customers following up on queries that should go to medical information. The complainant stated that he/she and his/her colleagues had complained to management at the third-party contract sales organisations but they did not do anything because they might lose the business.

When writing to Cipla, the Authority asked it to consider the requirements of Clauses 2, 3.2, 9.1, 16.3 and 19.2 of the 2016 Code.

RESPONSE

Cipla submitted that the named senior manager had been employed by Cipla for over five years in various roles. Details were provided.

Cipla submitted that the manager was not a representative as defined in Clause 16, however the

expectation was that he/she would pass the ABPI examination within two years. He/she planned to take the examination shortly (details provided).

Cipla stated that neither third party had received any formal internal complaints about the manager. However, as a precaution the manager had been asked to step back from initiating any direct contact with the contract sales force until he/she had sat the ABPI examination. Details of his/her relationship with the third party organisation were provided.

With regard to the senior manager's knowledge of the Code, Cipla stated that when he/she started work with the company it conducted an 'Overview of the Code' training session led by the medical signatory. Cipla submitted that the manager was not a representative as defined in Clause 16.3 and so he/she knew that he/she should not conduct customer facing activities. Given his/her role he/she took an interest in the sales teams and would accompany sales calls and interact with the representatives from both outsource companies.

With regard to the alleged pressure on representatives to get surgeries to switch to Cipla medicines, Cipla explained that the contract sales organisations promoted Sereflo (salmeterol/ fluticasone propionate) and Kelhale (beclomethasone dipropionate). Both had a value-based message and details of the strategy was provided. Training materials, promotional materials and briefing documents were all certified and in place.

Cipla submitted that the senior manager had accompanied calls, as an observer, to understand how the sales strategy was received. He/she did not have the relevant training to be a sales representative for Cipla.

The meeting with the asthma nurse specialist was set up by a representative and the senior manager was due to accompany this call to ensure that Cipla as a company was introduced. The representative could not attend and the manager ended up in the meeting alone, which could have been avoided. The conversation, however focused on the company and its capability for continuity of supply.

Cipla acknowledged that the manager had contacted a representative in one area about an issue in another, and the representative agreed to call the practice to resolve the issue, rather than drive. The sales team was fully trained and knew the licensed indications for Cipla brands and which could be used with spacers and which could not. Cipla submitted that this was covered in their training and summary of products characteristics (SPC) validations and that the contract sales organisation's inputs corroborated this.

With regard to exhibition stands, Cipla submitted that since November 2018, a formal process had been in place for stand meetings to be approved centrally, so it had visibility on all of those activities. Cipla ensured that it always had ABPI qualified representatives to man the stand. The manager could attend relevant meetings, but not as a representative of the company as detailed above.

The manager was aware that he/she could not act as a representative of Cipla as defined by Clause 16. He/she did accompany calls and took an active interest in the sales strategy.

With regard to the allegation that the manager followed up queries, Cipla stated that the medical information process would be reviewed including the execution done to date. Irrespective of the review outcome, the company would work to strengthen the implementation of the process for all employees in the course of the next four months.

Cipla submitted that the contract sales organisations had confirmed that no employee had raised any of the comments made by the complainant.

Cipla denied that it had breached Clause 2 as the intention of its senior management team was to abide by the Code in all interactions with health professionals.

Cipla noted that Clause 3.2 required that the promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its SPC. Cipla submitted that the contract sales team had been appropriately trained and validated on the SPCs for the products promoted.

With regard to the maintenance of high standards, Cipla submitted that it had a strong internal code of conduct, similar to the principles in the Code.

Cipla reiterated that the senior manager was not employed as a representative; he/she was a senior manager in the UK business, and so Clause 16.3 did not apply to him/her.

With regard to the conversation with the asthma nurse specialist and the alleged conditional offer to sponsor educational meetings, Cipla refuted that any conversations about medical and educational goods and services (MEGS) took place; Cipla did not have any MEGS activities in place.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure for the PMCPA stated that anonymous complaints would be accepted but that like all other complaints, 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 and could not be contacted for more information.

The Panel noted Cipla's submission that the senior manager was not a representative. The definition of a representative was given in Clause 1.7 of the Code as a representative calling upon members of the health professions and other relevant decision makers in relation to the promotion of medicines. Given the company's submission about the senior manager's role, it was difficult to see

why the senior manager needed to accompany representatives on calls. The company submitted that this was to observe the representative whereas the complainant took a different view. The senior manager had conducted a meeting with a health professional which was said to focus on discussions about the company and the continuity of supply. The Panel considered that this was likely to be a discussion within the definition of promotion given in Clause 1.2 of the Code as any activity which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.

The Panel noted the company's submission that the senior manager was not a representative and there was no need for him/her to take and pass the representative's examination. Cipla decided that the individual would take the examination and in the interim would not have direct contact with the sales force until he/she had taken the examination. The Panel noted the company's submission about when the senior manager's role commenced and when he/she was planning to take the examination. The Panel had no information before it as to the senior manager's activities in his/her previous role at Cipla UK. On the information provided it appeared that if the senior manager was working as a representative, he/she appeared to be within the timeframe for taking and passing the examination. The Panel did not consider that the complainant had provided evidence to demonstrate on the balance of probabilities that the senior manager was working as a representative and if so that he/she had not met the requirements in the Code for taking and passing the representatives' examination. Thus the Panel ruled no breach of Clause 16.3.

The Panel noted that there were differences between the complainant's view of the senior manager's activities and Cipla's. The sales strategy to promote cost savings by switching to Cipla's product meant that encouraging switches for existing patients would be part of the representatives' discussions with those upon whom they called. This was not necessarily unacceptable. No evidence had been provided regarding the alleged pressure on representatives to arrange for surgeries to switch nor about the senior manager putting pressure on surgeries to switch. No information was provided about Cipla's involvement in any switch. In relation to the meeting with the asthma nurse specialist, Cipla submitted that the representative had not attended. The senior manager had according to Cipla discussed the company and continuity of supply. There was no mention of a discussion about educational support being linked to increased sales and the complainant had provided no evidence in this regard. The Panel did not consider that the complainant had provided evidence to show that there was a breach of the Code in relation to this aspect of the complaint. No breach of Clauses 9.1 and 19.2 of the Code was ruled.

The company submitted that a representative had telephoned the practice nurse who had a question about the use of a spacer device and not driven as alleged. The complainant had not identified the

relevant medicine. Cipla had not provided evidence to show how the representatives were trained on the products. It appeared that some of Cipla's medicines were indicated for use with a spacer and according to Cipla its representatives were fully trained and aware of the licensed indications of its products. The Panel noted that the complainant had provided no evidence that medicines had been promoted in a manner inconsistent with their SPCs at the meeting in question and thus ruled no breach of Clause 3.2 of the Code in this regard.

The Panel noted that again no evidence had been provided regarding the allegation that the senior manager followed up queries that should be answered by medical information. Cipla had not provided any information about the current arrangement submitting that it was in the process of reviewing and strengthening its process in this regard. The Panel was concerned about the response in relation to this allegation. The company should have a robust process for medical information. However the complainant had not provided any evidence and thus not shown on the balance of probabilities that a breach had occurred. The Panel

therefore ruled no breach of Clause 9.1 of the Code in this regard.

The Panel noted that the senior manager attended meetings where exhibition stands were used and Cipla's submission that the senior manager was not attending as a representative. It was not clear exactly what role the senior manager would have at such meetings. The Panel did not consider that the complainant had provided evidence to show that the senior manager had promoted medicines at a stand meeting or that any such activity was in breach of the Code. The Panel therefore ruled no breach of Clause 9.1 of the Code.

In considering the matters overall, the Panel did not consider that the complainant had shown on the balance of probabilities that there was a breach of Clause 2 of the Code. This clause was used as a sign of particular censure and reserved for such use.

Complaint received **9 May 2019**

Case completed **20 August 2019**
