

**CASE AUTH/3544/7/21**

## **ANONYMOUS v LUNDBECK**

### **Representative contact and call rates**

**An anonymous contactable complainant complained about representative contact and call rates at Lundbeck Limited.**

**The complainant stated that from July 2020 to June 2021, sales representatives were not briefed on how often health professionals could be called upon. Excessive calls had been made due to no briefing availability (more than three calls were regularly made as noted on the customer recording system, contradictory to guidance in the Code that three calls were the maximum).**

**The complainant alleged that calls and contacts had not been defined within this time as there was no guidance within a standard operating procedure (SOP). Promotional materials and items had not been approved for use in a virtual capacity within the same time period and no guidance was given in an SOP about remote calls. The complainant alleged that Lundbeck knew these activities were inappropriate but had not submitted a voluntary admission.**

**The complainant further alleged that the compliance culture at Lundbeck was not transparent.**

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

**The Panel noted that Lundbeck did not provide the relevant SOP in relation to representatives; however, it provided the training slides, dated March 2021, in relation to the Lundbeck UK Representative Interactions SOP, which appeared to include screen shots from the SOP with further explanation. The Panel noted that these slides referred to calls and contacts, including definitions and the Code's requirements in relation to frequency. The slides also referred to requirements in relation to remote detailing including that employees must only use platforms that had been approved by Lundbeck in this regard. The Panel further noted that training provided by an external consultant in January 2021 referred to the Code requirements in relation to call and contact rates and included Code cases.**

**Whilst the Panel noted that representatives were provided with briefings related to remote detailing and engagement with health professionals, these appeared to focus on logistical and technical matters and did not appear to be in the context of the Code requirements. It would be helpful if all briefings to representatives in relation to interactions with health professionals referred to the Code requirements in relation to frequency of calls and contacts. Nonetheless, the Panel did not consider that the**

**complainant had discharged his/her burden of proof that there were no briefings provided by Lundbeck in relation to remote calls, distinguishing calls versus contacts and the frequency of calls, during the time period July 2020 to June 2021 as alleged, and the Panel ruled no breach of the Code.**

**The Panel noted Lundbeck's submission that it did not identify that the number of calls, as defined by the Code, on any customer, exceeded 3 per year within the time period cited by the complainant (July 2020 – June 2021). The Panel noted that the complainant bore the burden of proof and did not consider that he/she had established that Lundbeck representatives had made excessive calls as alleged and therefore ruled no breach of the Code.**

**The Panel noted the allegation that promotional materials had not been approved for use in a virtual capacity but noted that no evidence had been provided. The Panel noted Lundbeck's submission that the materials and emails available for use through the remote platform, that representatives had been trained to use, were certified for use in the 'virtual capacity'. The Panel considered that the complainant had not provided evidence to demonstrate that promotional materials had not been approved as alleged and thus ruled no breach of the Code.**

**Noting its comments and rulings above, the Panel did not consider that Lundbeck had failed to maintain high standards or had failed to comply with Clause 2 and it consequently ruled no breach of the Code.**

An anonymous contactable complainant complained about representative contact and call rates at Lundbeck Limited.

## **COMPLAINT**

The complainant stated that from the period of July 2020 to June 2021, sales representatives were not briefed on how often health professionals could be called upon. Excessive calls had been made due to no briefing availability (more than three calls were regularly made as noted on the customer recording system, contradictory to guidance in the 2019 ABPI Code that three calls were the maximum).

The complainant alleged that calls and contacts had not been defined within this time for sales representatives as there was no guidance within a standard operating procedure (SOP). Promotional materials and items had not been approved for use in a virtual capacity within the same time period and no guidance was given in an SOP about remote calls. The complainant alleged that Lundbeck knew these activities were inappropriate but had not submitted a voluntary admission and breaches of Clauses 15.4, 15.9, 15.10, 14.1, 9.1 and 2 of the 2019 Code had occurred.

The complainant alleged that the compliance culture at Lundbeck was not transparent.

When writing to Lundbeck, the Authority asked it to consider the requirements of the clauses cited by the complainant.

## **RESPONSE**

Lundbeck stated that the complainant in this case (Case AUTH/3544/7/21) appeared to be the same anonymous complainant as in Case AUTH/3510/5/21, representing themselves as 'whistleblowing' which implied by definition that they were an internal employee, and yet Lundbeck was disappointed he/she had not used internal procedures or been able to provide any specific or substantive evidence to base their allegations on.

Lundbeck assured the Authority that it took this complaint very seriously and it had carried out as thorough an investigation as possible, considering the very broad allegations made and the lack of evidence provided.

### **Response to allegations**

In order to address the allegations made by this anonymous complainant in a clear and concise manner, Lundbeck broke down its response into four different sections:

- A. Background to representative activity.
- B. Allegation about excessive calling by representatives.
- C. Certification of Lundbeck's promotional material.
- D. Allegation about high standards.

#### **• A. Background to representative activity**

Lundbeck submitted that its representatives all received initial and ongoing compliance training to ensure that they conducted their role in a manner which was compliant with the ABPI Code. Lundbeck submitted that its representatives were not bonused on activity (ie interactions with customers) thus ensuring there was no motive or incentive to excessively call on customers.

#### **Face-to-face representative activity**

The onset of the COVID-19 pandemic meant that Lundbeck ceased face-to-face interactions with customers on 16 March 2020 following Government guidance. On 10 September 2020, with the UK 'opening up', Lundbeck issued guidance which allowed the resumption of some face-to-face interactions with customers as long as specific guidance was followed. When another national lockdown was announced on 31 October and imposed from 5 November 2020, Lundbeck made a company decision to continue working from home, with the allowance for some very limited remote interactions with customers. This lasted until July 2021 when the decision was made that face-to-face interactions could resume again.

Therefore, during the whole time period outlined by the complainant there were very limited capabilities for face-to-face interactions with health professionals due to decisions by Lundbeck in light of restrictions posed by COVID-19. Lundbeck submitted that any that were allowed would have only taken place in September and October 2020.

#### **Virtual/Remote representative activity**

The COVID-19 pandemic meant that the industry, including Lundbeck, had to make changes to the way that representatives interacted with customers. Lundbeck rolled out Veeva Engage as a remote platform for representative interactions with health professionals in April 2020 (copies of training materials were provided). Representatives were provided with an accompanying

certified briefing on how to use the platform to interact with their customers and following completion of the training and the provision of this briefing they were allowed to engage with their customers remotely. Additional training sessions were delivered throughout the time period including at the company's September 2020 conference and again in June 2021.

Therefore, during the whole time period outlined by the complainant, Lundbeck representatives had the capabilities to engage remotely with customers, if it was appropriate to, following the roll-out and training of the Veeva Engage platform in April 2020.

Lundbeck submitted that the Authority would be aware that the same Code principles of representative engagement with health professionals and other relevant decision makers would apply whether the interaction was face-to-face or through a remote virtual channel.

- **B. Allegation about excessive calling by representatives**

#### **Calls versus Contacts Guidance**

Lundbeck submitted that it provided substantial guidance and training to its representatives on the Code and their compliance responsibilities, particularly, and frequently, around Clauses 15 and 16 (2019 Code). In relation to the time period outlined by the complainant and therefore the training of most relevance, Lundbeck utilised their representatives time 'off the road' to provide Code training through online Code modules in Q1 2020; which was followed up with external compliance training in Q1 and Q2 2021. These training courses all covered Clause 15.4 and distinguished clearly between calls and contacts thus providing repeated clarity to the company's representatives on what was expected from them with regard this clause. Completion of the trainings was documented by Lundbeck and provided to the PMCPA.

Lundbeck stated that this online modular training was further complemented by dedicated 'Sales Interactions' training conducted in March 2021 to ensure all representatives had absolute clarity, following a number of COVID enforced lockdowns and a long period 'off the road', on how they could interact with their customers compliantly. This training, which was carried out in preparation for the representatives being allowed to fully (ie both face-to-face and remotely) re-engage with their customers again, also focused specifically on the Code requirements around calls versus contacts and what would constitute excessive calling.

This training in the lead up to, and during, the time period outlined by the complainant built upon historical training provided by the company on representative compliance. This included the company's Initial Training Programme (ITP) compliance training provided as part of representative onboarding as well as regular annual refresher training which placed an emphasis on Clause 15.4 as highlighted by the examples of training carried out in both 2018 and 2019 (copies of training materials were provided). Lundbeck also included the requirements of Clause 15.4 in representatives' reward and recognition scheme to remind them of their responsibilities to carry out their role compliantly. This compliance message was then further supported through the representative (KAM) job description which outlined that adherence to the Code was a core element of the role.

In summary, as evidenced above, Lundbeck submitted that it was apparent that its key account managers (KAMs) had received repeated ongoing briefing and training on Clause 15.4 and specifically the definition of calls and contacts. This was particularly apparent in the time period leading up to, and during, that outlined by the complainant.

Therefore, Lundbeck refuted a breach of Clause 15.9 as alleged by the complainant.

### **Excessive Calling**

Lundbeck noted that the complainant then went further by alleging that the lack of definition and briefing provided by Lundbeck during the time period outlined meant that *'Excessive calls (more than 3 calls were regularly made as noted on the customer recording system, contradictory to guidance in ABPI Code 2019 that 3 calls was maximum)'* therefore, alleging a breach of Clauses 15.4 and 15.10.

Lundbeck noted that the complainant did not provide any evidence to support the allegation that representatives were excessively calling on customers, therefore Lundbeck were unable to investigate any specific representative's activities. However, as part of Lundbeck's investigation it reviewed the company's Customer Relationship Management (CRM) system for all representative activity and during the time period outlined by the complainant, the number of *Calls*, as defined in the Code, never exceeded the permitted maximum of 3 per year (copy provided).

Therefore, Lundbeck refuted a breach of Clauses 15.4 and 15.10 as alleged by the complainant.

- **C. Certification of Lundbeck's promotional material for use in a virtual capacity**

Lundbeck noted the complainant had not identified any specific material(s) or provided any evidence to support his/her allegation that *'promotional materials and items had not been approved for use in a virtual capacity'*.

Lundbeck submitted that it certified all promotional material in line with internal approval processes and the Code; therefore, the materials and approved emails available for use by representatives through the remote platform, that they had been trained to use, were certified for use in the *'virtual capacity'*.

Lundbeck therefore refuted any breach of Clause 14.1 and was happy to provide example materials (and accompanying certificates).

- **D. Allegation about high standards**

Lundbeck noted the complainant had not provided any evidence to support their assertion that Lundbeck had not maintained high standards and had brought discredit to the industry, yet they had alleged breaches of Clauses 9.1 and 2.

Considering that Lundbeck had refuted all other breaches in this complaint based on the findings of its internal investigation, it accordingly refuted any breach of Clauses 9.1 and 2.

### **Summary**

Lundbeck was disappointed to receive this complaint from an anonymous complainant who had made baseless allegations without the provision of any supporting evidence. Lundbeck felt that this complaint was another attempt to distract the company from its continued efforts to build on the significant progress that had been made in 2021 with respect to healthcare compliance.

Lundbeck hoped this response clearly reflected that it had conducted repeated healthcare compliance training with its representatives, particularly in the time period referred to by the complainant. Importantly, the whole organisation continued to undertake more compliance training as Lundbeck strove to better understand and comply with the ABPI Code.

Lundbeck submitted that it was apparent that its representatives had been provided with repeated training and clarity around Clause 15.4 of the ABPI Code and their understanding of this was reflected by the fact that there had not been one incident of excessive calling identified through its review of the CRM system during the time period outlined.

Lundbeck kindly asked the Authority to consider that the lack of evidence presented by the complainant confirmed that no *prima facie* case had been established, as per Section 5.5 of the PMCPA Constitution and Procedure.

### **PANEL RULING**

The Panel noted that the Constitution and Procedure stated that 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 Panel noted the complainant's allegations that Lundbeck representatives were not provided with briefing materials on how often health professionals could be called upon and that there was no guidance within an SOP about calls and contacts, nor remote calls. The Panel noted that Lundbeck did not provide the relevant SOP in relation to representatives; however, it provided the training slides, dated March 2021, in relation to the Lundbeck UK Representative Interactions SOP, which appeared to include screen shots from the SOP with further explanation. The Panel noted that these slides referred to calls and contacts, including definitions and the Code's requirements in relation to frequency. The slides also referred to requirements in relation to remote detailing including that employees must only use platforms that had been approved by Lundbeck in this regard. The Panel further noted Lundbeck's submission that external training courses had been delivered during the representatives' time 'off the road' which covered Clause 15.4 and distinguished between calls and contacts. In this regard, the Panel noted that training provided by an external consultant in January 2021 referred to the Code requirements in relation to call and contact rates and included related Code cases.

Whilst the Panel noted that representatives were provided with briefings related to remote detailing and engagement with health professionals, these appeared to focus on logistical and technical matters and did not appear to be in the context of the Code's requirements. The Panel considered that it would be helpful if all briefings to representatives in relation to interactions with health professionals referred to the Code requirements in relation to frequency of calls and contacts. Nonetheless, the Panel did not consider that the complainant had discharged his/her burden of proof that there were no briefings provided by Lundbeck in relation to remote calls, distinguishing calls versus contacts and the frequency of calls, during the time period July 2020 to June 2021 as alleged, and the Panel ruled no breach of Clause 15.9.

The Panel noted the complainant's allegation that Lundbeck's representatives had been excessively calling upon health professionals and that more than three calls were regularly being recorded in its customer recording system. The Panel noted Lundbeck's submission that during its investigation, it reviewed the company Customer Relationship Management (CRM)

system and did not identify that the number of calls, as defined by the Code, on any customer, exceeded 3 per year within the time period cited by the complainant (July 2020 – June 2021). The Panel noted that the complainant bore the burden of proof and did not consider that he/she had established that Lundbeck representatives had made excessive calls as alleged and therefore ruled no breach of Clause 15.4.

The Panel noted that the complainant had alleged a breach of Clause 15.10 but gave no specific details in this regard. Clause 15.10 stated that companies were responsible for the activities of their representatives if these were within the scope of their employment even if they were acting contrary to the instructions which they had been given. In the Panel's view, Clause 15.10 was a statement of principle and could not be breached. The Panel therefore made no ruling on this matter.

The Panel noted the allegation that promotional materials had not been approved for use in a virtual capacity but noted that no evidence had been provided. The Panel noted Lundbeck's submission that the materials and approved emails available for use by representatives through the remote platform, that they had been trained to use, were certified for use in the 'virtual capacity' and that Lundbeck would provide examples if requested. The Panel was not an investigatory body; it made its rulings on the evidence provided by both parties and the complainant had the burden of proof. In that regard, the Panel considered that the complainant had not provided evidence to demonstrate that promotional materials had not been approved for use in a virtual capacity as alleged and thus ruled no breach of Clause 14.1.

Noting its comments and rulings above, the Panel did not consider that the complainant had provided evidence to demonstrate that Lundbeck had failed to maintain high standards and the Panel ruled no breach of Clause 9.1. The Panel consequently ruled no breach of Clause 2.

**Complaint received**      **20 July 2021**

**Case completed**        **25 April 2022**