CASE AUTH/3735/2/23 ***NO BREACH OF THE CODE***

HEALTH PROFESSIONAL v ELI LILLY

Allegations about the conduct of a Lilly representative

CASE SUMMARY

This case was in relation to the activities of a named Lilly sales representative at a Dermatology department.

The outcome under the 2021 Code was:

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.1	**Requirement to maintain high standards at all times**
No Breach of Clause 17.2	**Requirement that representatives must maintain high standards of ethical conduct in the discharge of their duties and comply with all relevant requirements of the Code**
No Breach of Clause 17.4(x2)	**Requirement that representatives must ensure that the frequency, timing and duration of calls, together with the manner in which they are made, does not cause inconvenience and that the wishes of individuals on whom representatives call and the arrangements in force at any particular establishment must be observed**
No Breach of Clause 21.2	**Requirement that no more than four samples of a particular medicine be provided to an individual health professional during the course of a year**
No Breach of Clause 21.3	**Requirement that samples may only be supplied in response to written requests which have been signed and dated.**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

A complaint was received from a health professional about Eli Lilly and Company Limited ("Lilly").

COMPLAINT

The complainant alleged that a named Lilly medical representative had been told on numerous occasions not to attend the complainant's busy dermatology department without prior authorisation. The department had a sign visible (which the complainant alleged the representative admitted to knowing about) which stated clearly that no representatives were to attend the department without prior agreement.

The named representative had allegedly repeatedly attended the department and even used personal appointments at the hospital to coincide with contact time in the department and had come in during clinical sessions such as light therapy, day treatment and outpatient clinic. This was allegedly despite being asked not to.

The complainant stated they had now told the representative that they were not to attend the named Dermatology department under any circumstances without prior consent from the clinical lead and not to drop off any letters, cards or samples. The complainant alleged that the fact they had to tell the representative this several times constituted a breach of professional practice which needed to be taken further.

When writing to Lilly, the case preparation manager cited Clauses 5.1 and 2 of the 2021 Code as well as a number of other clauses. Lilly responded to the allegations (see response from Lilly below). The case preparation manager wrote again to Lilly following receipt of its response to inform them that an error had been made and asked the company to consider the requirements of Clauses 17.2, 17.4, 21.2 and 21.3 of the 2021 Code in addition to Clause 5.1 and 2 cited previously (see section 'further information from Lilly' below).

LILLY'S RESPONSE

Lilly stated that it took such complaints very seriously. Lilly had received an email message from a named doctor on 10 February 2023 with similar content to this complaint. As soon as Lilly received that doctor's email it began an investigation into the matter and took immediate action to deliver on the doctor's expectations. Lilly provided an email from the representative's supervisor to the named doctor to further *'clarify [named doctor's] expectations on how [named representative] engages with [them] and with the dermatology staff members in [named hospital]'*, and that the representative had also obtained pre-approval from the named doctor for their next visit upon agreeing with the relevant Department staff their availability.

Chronology:

The named Lilly sales representative had been making visits (for calls or contacts) to the Department since October 2021.

Lilly submitted that before such visits, the representative would enquire verbally or via email if physicians and/or nurses were available and arranged the visit accordingly. The representative was aware of a sign displayed in the Department stating that no sales representatives should attend without prior agreement. However, because the sign did not provide clear directions on with whom such prior agreement was to be made, in view of the consistent facilitation of the representative's visits by physicians and nurses in the Department upon email correspondence or verbal agreement, the representative assumed in good faith that verbal/email alignment with the relevant physician or nurse was sufficient and this was the Department's *de facto* practice.

On 10 February 2023, during a visit, the named doctor informed the representative that they must first email ahead and obtain pre-approval from them for visits. Lilly submitted that this was the first time that the representative was told directly about the requirement for pre-approval by the named doctor before making visits. On the same day this doctor sent a complaint to Lilly, and as Lilly understood, also submitted a complaint to the PMCPA. After receiving this instruction from the doctor, for all subsequent visits, upon agreeing with the relevant Department staff their availability for a visit, the representative in question had also obtained pre-approval from the named doctor via email.

Allegations and responses:

Lilly understood that the allegations were as follows:

- The representative in question was told on numerous occasions not to attend the Department without pre-approval, but did so anyway;
- They entered clinical sessions including light therapy, day treatment and outpatient clinic, despite being asked not to;
- They took advantage of personal hospital appointments to coincide with contact time in the Department;
- They dropped off letters, cards and samples.

Lilly submitted that the representative in question denied that they were told on numerous occasions not to attend the Department without pre-approval. As detailed above, on all prior occasions, Department staff were content to facilitate their visits upon email or verbal alignment, subject to staff availability. After receiving the instruction from the named doctor on February 10, for all subsequent visits, the representative had obtained pre-approval from the complainant via email in addition to the agreement from the Department staff to be visited.

The representative denied that they ever entered clinical sessions including light therapy, day treatment and outpatient clinic, or otherwise. Lilly submitted that it was the most basic and established requirement for its representatives not to interact with health professionals in the presence of patients.

The representative denied that they took advantage of personal hospital appointments to coincide with contact time in the Department. They did not have any appointment at [named hospital] as a patient in 2022 or 2023.

The representative denied that they dropped off promotional letters, cards, and samples. Lilly stated that it did not provide samples and was not aware of promotional letters or cards being distributed at the Department.

As a consequence of the above, Lilly did not accept the complaint met the threshold for unprofessional practice, as alleged by the complainant, and did not believe it constituted breaches of Clause 2 (Upholding Confidence in the Industry) and Clause 5.1 (High Standards).

Steps taken by Lilly upon receipt of the complaint:

Lilly stated that it immediately began an investigation into the complaint upon receiving the named doctor's email message on February 10.

During the investigation, the representative in question informed Lilly that there was a sign displayed in the Department stating that no sales representatives should attend without prior agreement.

The Code 2021 (the 'Code') stipulated that the frequency, timing and duration of calls/visits must not cause inconvenience, and arrangements in force at any particular establishment must be observed (Clause 17.4). Although there might have been some confusion as to which arrangements were in force, because the representative's visits were facilitated by physicians and nurses without pre-approval from the named doctor, Lilly had made it clear to the representative that in light of this confusion, they should have clarified with the Department the exact process they needed to follow for visits. Lilly reminded the representative of the Lilly briefing which stated that 'all incentive goals should be achieved following the highest standards of Integrity; any compliance violation/failure would lead to potential disciplinary action with consequences to participation in the incentive program. In the UK and Ireland, all promotion must be within the requirements provided within the ABPI and IPHA Codes of Practice, respectively'. Lilly made it clear to the representative in question that failure to do so in future would incur disciplinary measures.

Supplementary information:

Lilly's commitment to high standards:

Lilly submitted that the UK company had a comprehensive Ethics and Compliance training programme completed by all its employees (including the representative in question) with regular updates to ensure Lilly engaged externally with its health care professionals with the utmost professionalism and integrity. These included:

- Training on the Lilly Red Book: Lilly values Integrity, Excellence, and Respect for People and the Red Book sets the expectation for this behaviour.
- An Ethics and Compliance live course covering Lilly's key procedures and policies (in addition to their training plan on its SOP's) that must be completed by all new employees and subsequently every two years.
- Certified briefings (redacting company confidential data) to sales representatives detailing when/if representatives were able to call in person on health professionals. Please note the:
    - Repeated mention of the importance Lilly placed on following the Code regarding frequency of calls and the high standards Lilly expected in those interactions.
    - Upfront disclosure that 'All incentive goals should be achieved following the highest standards of Integrity. Any compliance violation/failure would lead to potential disciplinary action with consequences to participation in the incentive program. In the UK and Ireland, all promotion must be within the requirements provided within the ABPI and IPHA Codes of Practice, respectively'.

Further information:

- CRM records related to [named hospital] Dermatology Department: encompassing both calls and contacts with HCPs in 2023
- The named representative's Medical Representatives Examination Certificate
- Email communication to the named doctor
- Lilly submitted that the representative in question did not drop off any promotional letters, cards or samples at the Department, so these have not been included.

Lilly stated that it would continue to ensure its sales representatives were fully compliant with the Code, and in particular continue to ensure that they complied with the requirements set forth in Clause 17.4 of the Code regarding visits.

Lilly stated that it recognised the challenging environment its healthcare professionals operated within and always wished to engage them in a professional manner at a convenient time. Lilly endeavoured to develop a valued long term collaboration with the named doctor and their team for the benefit of their patients and remained open to a direct dialogue to resolve any misunderstanding that might have occurred.

Further response from Lilly

Lilly stated that it was clear in the complaint that the core of the claim was about a Lilly sales representative visiting a clinic without the prior consent of a named doctor. The complainant also stated in their complaint that they had told the representative not to drop any letters, cards, or samples. Lilly felt that this was interpreted as a general warning from the complainant as they did not cite any specific circumstances regarding samples that would result in a potential Code violation. Lilly believed that referring to Clauses 21.1 [sic] and 21.2 without asking for further clarity or detail or evidence from the complainant, whether they had any allegation in relation to product sampling, shifted the burden of proof on to the respondent and harmed the procedural fairness.

Lilly wanted to seek clarity therefore on whether unsubstantiated claims should be referred to the Panel. Lilly believed it would have made sense given the general nature of the complaint for the complainant to be asked whether they had a specific allegation around sampling and, if so, to provide the details/proof before referring to the relevant Code clauses or raising these claims before the Panel. This approach may increase the efficiency of the case preparation process and reduce the case completion timelines.

Lilly submitted that even though there was no specific situation raised in the complaint regarding samples, Lilly had already highlighted in its original response that they do not supply samples in the UK and, as such, these would not have been available to the representative in question.

Lilly stated that in relation to Clauses 17.2 and 17.4, it had provided its response in detail above.

PANEL RULING

The Panel noted the complainant's allegation that a named representative had been told on numerous occasions not to attend the dermatology department without prior authorisation. The complainant referred to a sign in the department which allegedly stated that no representatives were to attend the department without prior agreement.

Clause 17.4 stated, among other things, that representatives must ensure that the frequency, timing and duration of calls on health professionals together with the manner in which they are made do not cause inconvenience and that the wishes of individuals on whom representatives want to call and the arrangements in force at any particular establishment must be observed.

Clause 17.2 stated that representatives must maintain a high standard of ethical conduct in the discharge of their duties and comply with all relevant requirements of the Code.

The Panel understood from Lilly's submission that before visits to the department, the representative would enquire verbally or via email if physicians and/or nurses were available and arranged the visit accordingly. The Panel took account of Lilly's submission that the representative in question was aware of the sign displayed in the department, however, as the sign did not provide clear directions of with whom exactly such prior agreement was to be made, and there had been consistent facilitation of the representative's visits by physicians and nurses in the department following email correspondence or verbal agreement, that the representative assumed that such agreement with the relevant physician or nurse being visited was the department's *de facto* practice and sufficient.

The Panel took account of Lilly's submission that the first time the representative in question was told about the requirement for email pre-approval from a specific named doctor ahead of all visits to the department was on the same day the PMCPA received a complaint. Lilly submitted that after receiving this instruction from the named doctor, the representative, for all subsequent visits, following agreement with the relevant department staff for a visit, also obtained email pre-approval from the named doctor.

The Panel took account of Lilly's submission that the representative denied that they were told on numerous occasions not to attend the department without pre-approval and denied that they ever entered clinical sessions including light therapy, day treatment and outpatient clinic, or otherwise. Lilly further submitted that the representative denied that they took advantage of personal hospital appointments to coincide with contact time in the department.

The Constitution and Procedure stated that the complainant had the burden of proving their complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties.

The Panel noted that the parties' accounts differed; it was difficult in such cases to know exactly what had transpired. A judgement had to be made on the available evidence bearing in mind the extreme dissatisfaction usually necessary on the part of a health professional before they were moved to submit a complaint.

The Panel did not have before it the exact wording of the department sign. It appeared that both parties agreed that the sign stated that no representatives were to attend the department without prior agreement. The Panel took account of Lilly's submission that the sign did not name who exactly in the department prior agreement had to be made and therefore the representative assumed their current practice of obtaining agreement with the relevant staff member visited would meet the department's requirements.

Bearing in mind that the department sign in question did not appear to make specific reference to the named doctor, and there was no evidence that the representative in question had visited without the requisite prior email consent from the named doctor after being informed by them of this requirement, the Panel considered that the complainant had not established, on the balance of probabilities, that the representative had failed to observe the arrangements in force at the department nor failed to maintain a high standard of ethical conduct in this regard and the Panel ruled **no breach of Clauses 17.2 and 17.4**.

Regarding the allegation that the representative had 'repeatedly attended the department' the Panel noted that Lilly had provided an extract from the representative's customer relations

management (CRM) records in relation to the department between January and mid-February 2023. Lilly submitted that the record encompassed both calls and contacts.

The supplementary information to Clause 17.4 stated that companies should arrange that the frequency of visits does not cause inconvenience. The number of calls made on a doctor or other prescriber by a representative each year should not normally exceed three on average. This does not include 'Contacts' which may be additional to the three calls such as: those at group events/meetings, visits requested by doctors or other prescribers, visits in response to specific enquiries and visits to follow up adverse reaction reports. Targets must be realistic and not such that representatives breach the Code in order to meet them. When briefing representatives companies should distinguish clearly between expected call rates and expected contact rates.

The Panel noted that the representative briefing document titled 'UK and ROI 2023 Incentive Scheme' (INT-DG-GB-0323), certified in January 2023, referred to the relevant ABPI Code requirements. The briefing stated, '… if a doctor/other prescriber reaches this limit (3 unsolicited promotional calls) with no offer of request to re-visit or attendance at a group meeting, this customer can no longer receive an unsolicited call by a representative for the remainder of the year.'

The Panel took account of the briefing material and the CRM records. The CRM extract provided did not appear to differentiate between 'calls' and 'contacts' as defined in the Code. The extract made no differentiation between solicited and unsolicited calls. The extract referred to 'interactions' and it was unclear what the purpose of each interaction was. It appeared that during the first 6 weeks of the year, the representative had thirteen interactions with nine different staff at the department, including phone interactions.

The Panel was concerned that the CRM records were unclear with regard to the reason for the interaction and therefore it was unclear whether the interaction was a 'call' or a 'contact' as defined in the Code; one individual in the department had been interacted with by phone three times in 6 weeks. Nonetheless, bearing in mind the allegation was specifically in relation to repeated attendance at the department, the Panel considered, on the evidence before it, that the complainant had not established that the frequency of visits by the representative to the department had breached the requirements of the Code and the Panel ruled **no breach of Clause 17.4** in that regard.

The Panel noted that the complainant referred to having now instructed the representative in question to not drop off 'any letters, cards or samples'. The Panel took account of Lilly's submission that the representative denied that they dropped off promotional letters, cards or samples. Lilly submitted that it did not provide samples and that it was not aware of promotional letters or cards being distributed at the department. Bearing in mind the lack of evidence and that Lilly had submitted that it did not provide samples in the UK, the Panel ruled **no breach of Clauses 21.2 and 21.3** with regard to the complainant's reference to samples.

With regard to 'letters and cards', bearing in mind the lack of evidence and that there was no clear allegation in this regard, the Panel considered that the complainant had not established that Lilly had failed to maintain high standards and therefore the Panel ruled **no breach of Clause 5.1.**

Noting its rulings of no breach of the Code above, the Panel subsequently ruled **no breach of Clause 2.**

Complaint received **10 February 2023**

Case completed **8 May 2024**