CASE AUTH/3161/2/19

EMPLOYEE v LEO PHARMA

Alleged promotional practices

A named, non-contactable, current employee of Leo Pharma complained about some of the company's promotional practices.

The complainant was concerned that the company was breaching the Code because it:

- **encouraged representatives to visit doctors five times a year ie more often than the allowed 3 unsolicited visits;**
- **did audits only for customers that used the company's products;**
- **did not put speaker slides through the medial legal approval process;**
- **encouraged representatives not to report adverse reactions for the company's medicines;**
- **encouraged representatives to email customers without their permission.**

The detailed response from Leo is given below.

The Panel noted that the complainant only provided brief details about his/her complaint. There were no attachments provided to support the allegations. A complainant had the burden of proving their complaint on the balance of probabilities. It considered each allegation as follows:

1 Visits to doctors

The Panel considered that there was no evidence before it that the actual number of calls made on a doctor or other prescriber by a representative had breached the requirements of the Code. However, the Panel was concerned about the representative briefing material.

The Panel noted that the topical dermatology customer segmentation plan slides which referred to call frequency did not differentiate between an unsolicited call and a 'contact' as defined by Leo and made no reference to the Code requirements. The Panel considered that the slides should have clearly set out the position. Although it was helpful to remind representatives of the Code requirements verbally, in a follow-up email and in the SOP, in the Panel's view, each representative briefing that related to call frequency needed to stand alone and should have reiterated the Code requirements and definitions of a call versus a 'contact' as defined by Leo.

The Panel considered that the reference to call frequencies of 4 and 5 for health professionals in the topical dermatology customer segmentation slides, without any definition of a call or reiteration of the Code requirements, meant that, on the balance of probabilities, the briefing material advocated a course of action likely to lead to a breach of the Code and the Panel ruled a breach of the Code.

On balance, the Panel did not consider that Leo had failed to maintain high standards and ruled no breach.

2 Audits

The Panel considered that the allegation was unclear. It was not for the Panel to infer detailed reasons to support allegations. Complainants needed to provide sufficient detail so that the respondent company and the Panel could clearly understand the concerns. Further it was for the complainant to establish his/her case on the balance of probabilities. It was not necessarily a breach of the Code for audits to be linked to the use of a medicine; all the relevant circumstances would need to be considered. The Panel considered that the very general nature of the allegation and the lack of evidence was such that the complainant had not discharged his/her burden of proof. The Panel therefore ruled no breach of the Code including Clause 2 in this regard.

3 Speaker slides

The Panel noted that the complainant had not referred to any specific speaker slides. The Panel noted Leo's submission that its processes require promotional speaker slides to be certified. The Panel noted relevant details from Leo's standard operating procedure (SOP). The Panel considered that, based on the evidence before it, the complainant had not proved, on the balance of probabilities, that speaker slides had not been appropriately approved as required by the Code. The Panel thus ruled no breach in this regard.

4 Adverse event reporting

The Panel noted Leo's submission that all field force staff undertook pharmacovigilance training prior to commencing promotional activities and annual pharmacovigilance training was conducted for all staff including the field force. The Panel further noted Leo's submission that the training clearly laid out the expectation to report all adverse events, other experiences and product complaints for all Leo medicines, even if it was an expected event documented in the summary of product characteristics (SPC).

The Panel noted that the complainant had provided no evidence in support of his/her allegation that the field force was encouraged not to report adverse reactions. The Panel considered that, based on the evidence before it, the complainant had not proved, on the balance of probabilities, that there had been a breach of the Code in this regard and therefore ruled no breach.

5 Emails to customers

The Panel noted that the complainant had not referred to any specific instances or provided any evidence in support of his/her allegation that representatives were encouraged to email customers without their permission. The Panel noted relevant details in Leo's SOP. Further that it was not possible for a representative to send a Leo approved promotional email outside of the customer relationship management system and that the system itself would not issue an email without documented prior consent for the receipt of promotional information. The Panel considered that, based on the evidence before it, the complainant had not proved, on the balance of probabilities, that representatives were encouraged to email customers without their permission and therefore ruled no breach in this regard.

A named, non-contactable, current employee of Leo Pharma complained about some of the company's promotional practices.

COMPLAINT

The complainant was concerned that the company was breaching the Code because it:

- encouraged representatives to visit doctors five times a year ie more often than the allowed 3 unsolicited visits;
- did audits only for customers that used the company's products;
- did not put speaker slides through the medial legal approval process;
- encouraged representatives not to report adverse reactions for the company's medicines;
- encouraged representatives to email customers without their permission.

When writing to Leo, the Authority asked it to bear in mind the requirements of Clauses 2, 9.1, 9.9, 14.1, 15.6, 15.9, 19.1 and 19.2 of the 2016 Code.

RESPONSE

Leo Pharma submitted that it took the Code extremely seriously and had a range of detailed procedures and training in place to ensure compliance with it, including for activities undertaken by representatives.

The company noted that the complainant had the burden of proving his/her complaint and that he/she had raised general points about procedures without referring to any one particular or specific instance/activity/material of concern, nor to any brand or therapy area and had not provided any evidence in support of the allegations.

Leo Pharma stated it had considered all therapy area business units in the UK and its investigations had covered all field force activities within those business units ie bio-dermatology, topical dermatology, thrombosis and market access. The investigations into each area included, but were not limited to; interviews with individuals (eg business unit head, head of sales etc), current standard operating procedures (SOPs) and work instructions (WIs), internal systems (eg PromoMats) and internal governance.

1 Visits by representatives

Leo stated that it had three therapy area teams in the UK; topical dermatology, bio-dermatology and thrombosis. The company had reviewed relevant briefings in these teams that were applicable at the time of the complaint and there were no briefings which directly or indirectly required representatives to make more than 3 unsolicited calls per year or 5 unsolicited calls per year as alleged.

Leo stated that its standard operating procedure (SOP) Interactions by Sales with HCPs set out expectations and requirements for interactions between representatives and health professionals. Within a section about face-to-face interactions, a bullet point referred specifically to the frequency, timings and duration of calls. The SOP explicitly specified that the representative should not exceed 3 calls on average and outlined what constituted a solicited call and therefore not in the scope of the 3 unsolicited calls. In addition, all representatives had to undertake annual, online refresher training on the Code which covered the requirements of the Code with respect to frequency and manner of calls and were required to pass the associated evaluation test.

Topical dermatology department briefing

Leo submitted that the 'customer segmentation plan' was presented to the dermatology representatives at a meeting in January 2019. The representatives were asked to aim for an annual contact (frequency) rate of 3-5 on health professionals in certain segments. A contact was any interaction with a customer, whether in the course of a solicited or unsolicited one-to-one call, or in the course of undertaking other routine activities such as attendance at an educational meeting which were attended by multiple health professionals. Such group meetings might have been organised by Leo or they might have been third party meetings (at which other companies might have been present). Interactions (contacts) at such meetings occurred by virtue of the fact that health professionals and representatives were both present at the same meeting to participate in that event and not because the representative had arranged a one-to-one solicited or unsolicited call. The maximum annual contact rate of 5 (in one health professional segment) that had been asked of the representatives was a modest target that could be comfortably achieved without exceeding 3 unsolicited calls per year.

Leo stated that the representatives were incentivised to achieve these annual contact rates, as set out in a follow-up email to them. This email set out the requirements of the Code regarding the frequency of unsolicited calls at the bottom (this requirement of the Code had also been verbally emphasised at the preceding meeting). The incentives applied to achievement of coverage (percentage of target health professionals who had received a contact) and

contact frequencies with those health professionals in each cycle (a 4-month period) were pro-rated from the annual target of contacts as set out in the earlier briefing. The amounts of incentive were modest and the maximum could be earned by achieving the specified annual contact rate (up to 5 in one of the health professional segments). Going above this rate did not qualify for additional incentive, rather the incentives were designed to effectively dis-incentivise a higher contact rate per health professional than that specified because over-calling on some health professionals would reduce the time they had to deliver the right frequency and coverage on the target health professionals. The scheme had been so designed to ensure the quality of the planned calls as much as their quantity.

No briefings were presented that required more than 3 unsolicited calls per year. Given that even the maximum annual target of 5 contacts was modest and realistic and that the associated incentives were modest (and designed to limit contact frequency to that specified), and given that the representatives had been instructed on the requirements of the Code in relation to call frequency, Leo rejected the allegation that representatives had been encouraged (whether directly or indirectly) to undertake more than 3 unsolicited calls per year. Therefore, Leo submitted that there had been no breach of the Code. Leo stated that the complainant referred specifically to 5 [unsolicited] calls and the topical dermatology briefing was the only one which had any specific reference to the number 5. Therefore, as far as it was possible to reasonably discern, the above was the only briefing that was of concern and in scope. However, it provided overview of the relevant field force briefings in the other business units:

Bio-dermatology briefing

Leo submitted that no briefings required representatives to undertake more than 3 unsolicited calls per year or 5 unsolicited calls per year as alleged. In fact, no formal contacts/coverage/ frequency rates had been finalised, agreed or instructed to the representatives.

Thrombosis Briefing

Leo submitted that the target rates had been consistent in the thrombosis business for at least 4 years. The operational metrics included the contact rate of 7 and 3.5 on target was a daily rate which sets an expectation of contacts with 7 individual health professionals, with an average of 3.5 of these being on target.

Under the customer segmentation plan which had been in place for 4 years the representatives were asked to aim for an annual contact (frequency) rate of 6 on health professionals in certain segments.

Within all representatives' annual objective setting documents, the following operational metrics for 2019 were included:

> 'Coverage of targets >90%
> Contact rate 7 and 3.5 on target
> In line with the ABPI Code of Practice Clause 15.4 on frequency of calls, no more than 3 unsolicited calls'

No briefings were presented that required more than 3 unsolicited calls per year. Leo noted that the wording 'In line with the ABPI Code of Practice Clause 15.4 on frequency of calls, no more than 3 unsolicited calls' was included in individual objective setting documentation, which showed that representatives were reminded of Code requirements about calls and were not incentivised to breach the Code.

Leo stated that the targets set, as described above, were realistic, achievable and would not require representatives to undertake more than 3 unsolicited calls per year. Therefore, Leo rejected the allegation that representatives were being encouraged to undertake more than 3 unsolicited calls per year.

For all three teams, to accurately monitor this out in the field, the CRM system included the mandatory completion of 'call classification' when inputting data into the system. This field required the representative to select 'solicited' or 'unsolicited' before the call could be submitted and finalised in the system. Across all three business units in 2018, details of the number of the representatives' records for unsolicited calls on unique health professionals were provided. Each health professional received on average 1.85 unsolicited calls from representatives. Leo submitted that this was well within the limits prescribed by the Code. In summary, Leo submitted that no business unit had encouraged representatives to exceed the number of permissible unsolicited calls per year and data from the CRM system indicated that the average number of such calls in 2018 was within the limits. Therefore, Leo denied that there had been a breach of the Code.

2 Audits

Leo noted that the complainant had not referred to any specific audits or related documents/evidence and had not defined what he/she meant by audit. The term audit might apply to a wide range of different activities including, but not limited to, therapy review services and scientific data generation activities. The complainant had not stated which of these he/she intended to be considered. Leo stated that it had not included scientific data generation activities or grants supplied in response to unsolicited requests.

Leo stated that across all of the business units it was not currently undertaking any active audits and it no longer offered any new services. Within the past 12 months, it had two projects which had been active but were discontinued in 2018. Details were provided.

One of the audits was the provision of written instructions and/or importable software searches for patient's identification by GPs within their practice databases for the project which ended in 2018. Leo stated that this project was undertaken as a promotional activity and was not a medical education, goods or service (MEGS) in scope of

Causes 19.1 and 19.2. The content was certified in accordance with the requirements for promotional material and briefed accordingly to representatives. It was routine practice for representatives to ask health professionals to identify patients who might be suitable for their promoted products (but to have no knowledge of, or involvement in, the management of such patients).

Therefore, Leo submitted that this project was not in scope of, nor in breach of, Clauses 19.1 or 19.2 and therefore it was not in breach of Clauses 9.1 or 2.

Leo submitted that the second audit was a third-party vendor which delivered a software programme, the Thrombosis Audit tool, and subsequent software maintenance support to various NHS hospitals.

It was several years since this software had been provided to any hospital, and in recent years support was provided to Leo primarily in the form of software maintenance; the third party could provide technical support to the hospital on the programme, if required.

In 2018, Leo identified that two trusts still used the software; details were provided.

This support was provided as a MEGS, within the scope of Clause 19.1 and 19.2. The support was provided to the NHS (and not an individual), the software tool was unbranded, and the provision was not linked to prescription, supply, administration, recommendation or purchase of a Leo medicine.

Support for the Thrombosis Audit tool stopped in 2018.

In summary, Leo submitted that neither of the identified projects were in breach of 19.1 and 19.2 and therefore were not in breach of 9.1 or 2.

3 Speaker slides

Leo stated that the Code required the certification of promotional speaker slides, and the applicable processes at Leo were designed to ensure that this was undertaken.

Leo submitted that the complainant had not made it clear as to which speaker slides or types of meetings were at issue. Given the breadth of this complaint and the sparse information, Leo provided a copy of its SOPs about meetings and the certification process. The SOP gave detailed definitions of meetings and the required process for their approval. The meeting approval process was completed in the CRM system. The SOP clearly outlined that if the meeting was promotional, all relevant content had to be approved through the internal approval process.

Since September 2018, in addition to this SOP, control had been implemented (which had not yet been incorporated into the SOP but had been trained to the representatives) with the inclusion of a 'HCP compliance' approval step ('HCP compliance' consisted of a senior compliance executive or medical manager). This requirement was described in a guidance document and the associated approval flow was embedded in the CRM system which the representatives must use.

Leo stated that the electronic review process was outlined in a working instruction. Within this was stated the process review, approval and certification of material and a clear description of the internal process to be followed including individual roles and responsibilities and the system used was given.

Veeva PromoMats acted as internal monitoring to show whether promotional speaker slides had been certified/approved to the originator of the job bag and as part of his/her responsibilities the process required him/her to communicate this to the job bag owner and approve the document for distribution, as outlined in the SOP. Leo maintained a list of nominated medical signatories and non-medical/ other signatories as required by Clause 14.1.

Furthermore, in Leo's speaker agreement and briefing letter, the section 'Presentation Requirements' specifically instructed the speaker to ensure that his/her slides were submitted to the meeting organiser at least 10 days before the event. This additional control measure was intended to prevent unapproved/uncertified promotional slides from potentially being used.

In summary, Leo stated that the processes as described required promotional speaker slides to be certified. Therefore, Leo denied a breach of Clause 14.1 and 9.1.

4 Adverse event reporting

Leo submitted that it took compliance with pharmacovigilance (PV) requirements very seriously. This included compliance with reporting adverse events (AEs), other experiences (OEs) and product complaints (PCs) and training all employees including representatives. The Leo Code of Conduct was mandated by the Global Safety department and stipulated that all Leo employees were trained when they started employment with the company and annually thereafter.

Leo submitted that in the UK, all new employees (and those returning from long term sick or maternity leave) were trained and instructed in detail on PV knowledge and reporting requirements as part of core induction training, as set out in a working instruction. All field force members undertook PV training which included PV training presentations, as well as scenario testing pertinent to the relevant therapeutic area, before they were allowed to promote Leo products. Examples of field based initial training were provided. This training covered all elements of PV including its history, why it was needed, how it was regulated, the role of the Qualified Person in Pharmacovigilance (QPPV) and UK Safety Contact person (SCP) who were available 24/7, classification of AE/OE/PCs, social media usage, out of office requirements and the Leo reporting requirements, timeframes and method of reporting via email or telephone to Leo medical information. The PV training clearly set out the expectations

to report all AEs, OEs and PCs even if it was an expected event documented in the SPC for any Leo product.

Attendance sheets were completed for each training and signed by the PV trainer. Copies of the slides used together with the attendance sheets and quizzes were maintained electronically and in hard copy. PV training was tracked on a PV tracker maintained electronically in a secure folder. In addition, staff kept a note of PV training in their own training records. All staff were issued with a pocket-sized card which contained reminder instructions on AE reporting that covered all the details for reporting and important definitions.

Annual PV training was conducted face-to-face or via skype to all staff including the field force; the training was adapted to reflect new information and was tailor-made each year to maintain engagement, it contained all core elements of PV together with reporting requirements and scenario testing quizzes. Attendance sheets were completed. All annual training was tracked and filed appropriately. Assessment of the quality of training was conducted.

Leo firmly rejected the allegation that it encouraged representatives not to report adverse reactions. On the contrary, Leo undertook mandatory induction and annual training for all staff and therefore Leo submitted that there had been no breach of Clauses 15.6, 15.9, 9.1 or 2.

5 Emails to customers

Leo noted that the complainant had not referred to a specific email sent without prior consent from a recipient health professional nor of any associated briefings and nor had he/she provided any relevant evidence. Leo stated that it would focus on describing its processes for the issuing of promotional emails by the field force that required prior consent from the recipient health professional. The company stated that its process prevented any promotional emails from being distributed without explicit and documented prior opt-in consent for receipt of promotional information.

Within the SOP Interactions by Sales with HCPs there were several points outlined about emailing customers. This SOP clearly stated that email might not be used for promotional purposes without the explicit and documented consent of the recipient.

Details for each of the three therapy teams were provided.

Leo stated that in summary, it was not possible for a representative in any of the business units to send an approved promotional email outside of the CRM system. The system itself would not send an email without a documented and signed opt-in prior consent from the intended recipient.

Leo submitted that there were no briefings and instructions from the company which encouraged representatives to email customers without their permission. On the contrary, representatives had been briefed on the compliant manner for securing consent before sending promotional emails and had made such approved promotional emails available only in the electronic CRM system within which it was impossible to send such emails without documented prior consent. Leo thus denied a breach of Clauses 9.1 and 9.9.

Conclusion

Leo stated that, as demonstrated, it had a range of detailed procedures and training to ensure compliance with the Code. This included procedures and training for the activities referred to by the complainant. The company's investigation did not find any instances of briefings that encouraged representatives to breach the Code in relation to unsolicited call rates, audits, promotional speaker slides, email consents or adverse event reporting. On the contrary Leo noted that it had provided procedural documents and briefings which demonstrated compliance.

Leo stated that it took compliance to the Code very seriously and that it rejected any breach of Clauses 2, 9.1, 9.9, 14.1, 15.6, 15.9, 19.1 and 19.2.

PANEL RULING

The Panel noted that the complainant only provided brief details about his/her complaint. There were no attachments provided to support the allegations. A complainant had the burden of proving his/her complaint on the balance of probabilities. The Panel noted the detailed response from Leo. It considered each allegation as follows:

1 Visits to doctors

The Panel noted that the supplementary information to Clause 15.4 stated, *inter alia*, that the number of calls made on a doctor or other prescriber by a representative each year should not normally exceed three on average. This did not include attendance at group meetings and such like, a visit requested by the doctor or other prescriber or a visit to follow up a report of an adverse reaction, all of which could be additional to the three visits allowed.

The supplementary information also included that when briefing representatives, companies should distinguish clearly between expected call rates and expected contact rates. Contacts include those at group 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.

The Panel noted Leo's submission that a customer segmentation plan for the topical dermatology business unit presented at an internal meeting in January 2019 asked representatives to aim for an annual contact rate of 3-5 for health professionals in certain segments. The Panel further noted Leo's submission that the maximum annual contact rate of 5 could be comfortably achieved without exceeding 3 unsolicited calls per year as it defined a 'contact' as any interaction with a customer and

included, *inter alia*, attendance at group meetings. The Panel noted that the slides from the customer segmentation plan in question referred to 'calls' not 'contacts' and made no reference to the Code or the supplementary information. The Panel noted Leo's submission that the Code requirements were verbally noted at the meeting in question. A follow-up email to the representatives described the financial incentives available if targets were achieved and included the statement: 'Please be aware that in line with the ABPI code of practice you cannot conduct more than 3 unsolicited calls on a customer in a 12 month period. If the calls are solicited there is no limit'. There was no definition for what constituted a solicited call. The Panel noted that Leo's SOP on interactions by sales with health professionals stated that the number of calls made upon a doctor or other prescriber by a representative each year should not exceed three on average and it outlined examples of activities which could be in addition to those three calls.

With regard to another business unit, bio-dermatology, the Panel noted Leo's submission that no formal contacts/coverage/frequency rates had been finalised, agreed or instructed to the representatives and targets for 2019 were to be determined in individual plans of action.

With regard to the thrombosis business unit, the Panel noted Leo's submission that representatives were asked to aim for an annual contact rate of 6 for health professionals in certain customer segments. The Panel noted that the thrombosis customer segmentation plan slides submitted by Leo made no reference to target annual call or contact rates and the company had provided the Authority with no material that referred to this annual contact rate of 6.

The Panel noted Leo's submission that across all three business units in 2018, analysis of the customer relationship manager system indicated that each individual health professional received on average 1.85 unsolicited calls from Leo.

The Panel considered that there was no evidence before it that the actual number of calls made on a doctor or other prescriber by a representative had breached the requirements of the Code. However, the Panel was concerned about the representative briefing material. The Panel noted that Clause 15.9 stated that briefing material for representatives must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code. The detailed briefing material referred to in this clause consisted of both the training material used to instruct representatives about a medicine and the instructions given to them as to how the product should be promoted.

The Panel noted that the topical dermatology customer segmentation plan slides which referred to call frequency did not differentiate between an unsolicited call and a 'contact' as defined by Leo and made no reference to the Code requirements. The Panel considered that the slides should have clearly set out the position. Although it was helpful to remind representatives of the Code requirements verbally, in a follow-up email and in the SOP, in the Panel's view, each representative briefing that related to call frequency needed to stand alone and should have reiterated the Code requirements and definitions of a call versus a 'contact' as defined by Leo. It was important to be clear particularly as representatives were rewarded for certain call/contact related activities.
Noting its comments above, the Panel considered that the reference to call frequencies of 4 and 5 for health professionals in the topical dermatology customer segmentation slides, without any definition of a call or reiteration of the Code requirements, meant that, on the balance of probabilities, the briefing material advocated a course of action likely to lead to a breach of the Code and the Panel ruled a breach of Clause 15.9. On balance, the Panel did not consider, given the particular circumstances of this case, that Leo had failed to maintain high standards in this regard and ruled no breach of Clause 9.1.

2 Audits

The Panel noted Leo's submission that it was not currently undertaking any audits but had two projects in the past 12 months which had now been discontinued. The first project was a set of written search instructions and/or importable software searches, developed by a third party, which were intended to help GPs identify patients suitable for Enstilar within the practice database; Leo submitted that this was not a medical and educational goods or services (MEGS) arrangement but a promotional activity. The second project Leo submitted was a MEGS and support was provided to NHS trusts in the form of a software tool to capture cases of venous thromboembolism and to run reports on such cases in order to identify trends within the hospital; the data was not shared with nor utilised by Leo and the provision of the MEGS was not linked to the prescription, supply, administration, recommendation or purchase of a Leo medicine.

The Panel considered that the complainant's allegation was unclear with regard to which audit(s) he/she was referring to. It was not for the Panel to infer detailed reasons to support allegations. Complainants needed to provide sufficient detail so that the respondent company and the Panel could clearly understand the concerns. Further it was for the complainant to establish his/her case on the balance of probabilities. It was not necessarily a breach of the Code for audits to be linked to the use of a medicine; all the relevant circumstances would need to be considered. The Panel considered that the very general nature of the allegation and the lack of evidence was such that the complainant had not discharged his/her burden of proof. The Panel therefore ruled no breach of Clauses 19.1 and 19.2 and thus no breach of Clauses 9.1 and 2 in this regard.

3 Speaker slides

The Panel noted that the complainant had not referred to any specific speaker slides. The Panel noted Leo's submission that its processes require

promotional speaker slides to be certified. The Panel noted that the LEO SOP 'Medical Events – Meetings, LEO organised and LEO sponsored UK/IE' included in relation to certification requirements:

> 'All meetings in the scope of this SOP require the following documentation to have been approved within ERACs [electronic review approval and certification system]…If pre-approved templates are not used, the following materials used for promotional materials, will be subject to certification: Speaker slides – for promotional meetings only.'

The Panel further noted Leo's submission that its speaker agreement and briefing letter instructed speakers to submit their slides to the meeting organiser at least 10 days before the event and that this was to prevent uncertified slides from being used.

The Panel considered that, based on the evidence before it, the complainant had not proved, on the balance of probabilities, that speaker slides had not been appropriately approved as required by the Code. The Panel thus ruled no breach of Clauses 14.1 and 9.1 in this regard.

4 Adverse event reporting

The Panel noted Leo's submission that all field force staff undertook pharmacovigilance training, which included presentations and relevant therapy area scenario testing, prior to commencing promotional activities and annual pharmacovigilance training was conducted for all staff including the field force. The Panel further noted Leo's submission that the training clearly laid out the expectation to report all adverse events, other experiences and product complaints for all Leo medicines, even if it was an expected event documented in the summary of product characteristics (SPC).

The Panel noted that Clause 15.6 of the Code stated that representatives must transmit forthwith to the scientific service referred to in Clause 25.1 any information which they receive in relation to the use of the medicines which they promote, particularly reports of adverse reactions. The Panel noted that it was of the utmost importance that information about adverse reactions and such like was processed by the company in accordance with, *inter alia*, the Code.

The Panel noted that the complainant had provided no evidence in support of his/her allegation that the field force was encouraged not to report adverse reactions. The Panel considered that, based on the evidence before it, the complainant had not proved, on the balance of probabilities, that there had been a breach of the Code in this regard. The Panel therefore ruled no breach of Clauses 15.6, 15.9, 9.1 and 2.

5 Emails to customers

The Panel noted that the complainant had not referred to any specific instances or provided any evidence in support of his/her allegation that representatives were encouraged to email customers without their permission. The Panel noted that Leo's SOP 'Interactions by Sales with HCPs [healthcare professionals] UK/IE' stated: '… telephone, text messages and email must not be used for promotional purposes except with the prior permission of the recipient'. The Panel further noted Leo's submission that it was not possible for a representative in any of the business units to send a Leo approved promotional email outside of the customer relationship management system and that the system itself would not issue an email without documented prior consent for the receipt of promotional information.

The Panel considered that, based on the evidence before it, the complainant had not proved, on the balance of probabilities, that representatives were encouraged to email customers without their permission. The Panel therefore ruled no breach of Clause 9.9 and no breach of Clause 9.1 in this regard.

Complaint received	**19 February 2019**
Case completed	**18 June 2019**