

CASE AUTH/3244/9/19

EMPLOYEE V LEO

Conduct of the Medical Scientific Liaison (MSL) Team

An anonymous and non-contactable complainant who stated that they were an employee of Leo Pharma complained about the company's dermatology medical scientific liaison (MSL) team.

The complainant alleged that the MSL team ran promotional meetings but that they did not have to do the ABPI examination within 2 years of starting.

The complainant stated that he/she had seen some of the emails sent by the MSLs to customers alleging that they provided a lot more off-label or pre-licence information on products than was asked for and, in that regard, the MSLs provided unsolicited information. The same was true for the medical information team. The complainant stated that he/she was referring to the launch of Kyntheum in this regard and suggested that Leo should provide copies of its medical information responses sent to customers since launch.

One of the MSLs won an award at the annual conference – a prize which was always given to representatives and which was awarded to representatives in other divisions in 2019. The complainant did not know what metric or criteria was used but giving the award to an MSL blurred the line between sales and medical.

The complainant stated that as a group the MSLs did not really know the difference between their role and that of a representative and that was demonstrated daily in their approach and willingness to run promotional meetings. The complainant queried whether the MSLs had had much compliance training or direction. Leo was taking advantage of the MSLs' lack of knowledge and using them to promote off-label and pre-licence.

The detailed response from Leo is given below.

The Panel noted that the complainant was anonymous and non-contactable and had provided little information and no documentation to support his/her complaint. As with any complaint, the complainant had the burden of proving his/her complaint on the balance of probabilities; the matter would be judged on the evidence provided by the parties.

The Panel noted that the Code included that all relevant personnel, including representatives and members of staff, and others concerned in any way with the preparation or approval of material or activities covered by the Code, must be fully conversant with the Code and the relevant laws and regulations. The Panel noted from the specimen MSL job description that the MSL role would include the preparation of

materials. The Panel noted Leo's submission that it had a range of detailed procedures and training to ensure compliance with the Code. According to Leo, the MSL team had been briefed and trained on its role which included training on the Code. The Panel did not consider that the complainant had established that the MSL or medical information team had not been trained in line with the requirements of the Code and no breach was ruled.

The Panel noted that a representative was defined as calling on members of the health professions and other relevant decision makers in relation to the promotion of medicines. This was a wide definition and could cover the activities of those employees that companies might not call representatives.

Promotion was defined broadly as any activity undertaken by a pharmaceutical company or with its authority which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.

The Panel noted that given the MSLs' role as described by Leo and the broad definition of promotion in the Code, some of their interactions with health professionals etc, especially those initiated by the company, might be considered promotional. The Panel noted that the status of each such interaction should be considered on its individual merits.

The Panel noted that whilst the Code did not prohibit MSLs and the like from promoting medicines as such, companies must take care to ensure that it was done within the requirements of the Code. Companies would need to be extremely careful to ensure that such promotional activity was very clearly separated from the non-promotional role of an MSL and the like and that the distinction must be clear to health professionals.

The Panel noted Leo's submission that MSLs were not allowed to run promotional meetings; their role was strictly non-promotional and so they did not promote the prescription, supply, sale or administration of any medicine. The Panel noted that whilst there was no evidence of MSLs running promotional meetings as alleged, according to the MSL SOP and Leo's submission, MSLs could proactively present predominantly educational information at a speaker meeting which could be organised by Leo (including the sales team), provided the content was not off label. The Panel noted Leo's submission that any information presented would need to be on-label and within the licensed indication of the product being discussed at the wider meeting and if there was content related to the company's product, prescribing information was supplied in line with the requirements of the Code. The Panel did not consider such proactive presentations by Leo staff, including MSLs, could be anything other than promotional. That such MSL presentations contained predominantly educational material did not mean that they did not satisfy the broad definition of promotion. The Code required all meetings to have a clear educational content. In any event, context was important and presentation of otherwise non-promotional material in a promotional context could render such non-promotional material promotional. In this regard, the MSL presentations appeared, on occasion, to be an integral part of what were described as sales meetings. The Panel also noted that it was important to bear in mind the impression about the status of the MSL that might be given to the audience at such meetings.

The Panel noted that PMCPA Guidance about Clause 3 included that if, as part of their role, the medical and scientific liaison executives (MSL) and the like promoted licensed products and indications then they were covered by the Code including the specific requirements for representatives. The Panel further noted that non-promotional activities by MSLs were also potentially covered by the Code. In the Panel's view, noting its comments above, part of the MSL's role at Leo was promotional and therefore the Panel disagreed with Leo's submission that its MSLs were not required to take an appropriate examination. It appeared from Leo's response that its MSLs had not taken such an examination and the Panel therefore ruled a breach of the Code.

The Panel noted its comments and ruling above and considered that failure of the MSLs to take an appropriate examination meant that high standards had not been maintained. A breach of the Code was ruled.

The complainant had provided no specific details and no evidence to support his/her allegations that emails sent by MSLs or medical information to customers provided more off-label or pre-licence information on products than what was asked for.

The Panel noted that the complainant had not established that Leo's MSLs or medical information department had responded to unsolicited queries such that they were promoting unlicensed medicines or indications and therefore no breaches of the Code were ruled.

With regard to the award being given to an MSL, the Panel noted Leo's submission that in 2019, each business unit consistently awarded in three categories and details were provided. One category was limited to sales and the other two categories were open to all areas of business including, but not limited to, medical. For each category the business unit head submitted nominations to the senior leadership team. There were winners of these awards in other business units which extended to other non-sales departments. For the two categories not limited to sales, there were no metrics identified. These awards were decided on an informal basis to recognise those attributes not related to sales metrics. The Panel did not consider that the complainant had provided evidence to show that this blurred the lines between sales and medical as alleged and no breach of the Code was ruled.

The Panel noted that a ruling of a breach of Clause 2 of the Code was a sign of particular censure and reserved for such. The Panel noted its rulings of breaches of the Code above. In that regard, the Panel did not consider that the particular circumstances of this case warranted additional censure and therefore no breach of Clause 2 was ruled.

An anonymous and non-contactable complainant who stated that they were an employee of Leo Pharma complained about the company's dermatology medical scientific liaison (MSL) team.

COMPLAINT

The complainant alleged that the MSL team ran promotional meetings but that they did not have to do the ABPI examination within 2 years of starting.

The complainant stated that he/she had seen some of the emails sent by the MSLs to customers alleging that they provided a lot more off-label or pre-license information on products than was asked for and, in that regard, the MSLs provided unsolicited information. The same was true for the medical information team. The complainant stated that he/she was referring to the launch of Kyntheum in this regard and suggested that Leo should provide copies of its medical information responses sent to customers since launch.

One of the MSLs won an award at the annual conference – a prize which was always given to representatives and which was awarded to representatives in other divisions in 2019. The complainant did not know what metric or criteria was used but considered that giving the award to an MSL blurred the line between sales and medical.

The complainant considered that as a group the MSLs did not really know the difference between their role and that of a representative and that was demonstrated daily in their approach and willingness to run promotional meetings. The complainant queried whether the MSLs had had much compliance training or direction.

Leo was, in the complainant's view, taking advantage of the MSLs' lack of knowledge and using them to promote off-label and pre-licence.

When writing to Leo, the Authority asked it to consider the requirements of Clauses 2, 3.1, 3.2, 9.1, 16.1 and 16.3 of the Code.

RESPONSE

Leo explained that its dermatology MSL team members were trained to work across all aspects of dermatology, however, they were aligned to one of two teams. It was a collaborative team with cross-over when appropriate for any product that was in development (pipeline) and/or that Leo supplied to market. Leo provided an organogram which showed reporting lines into the medical affairs function.

Leo stated that the MSLs were required to act in accordance with their defined roles and responsibilities as outlined by both the MSL job description and the MSL SOP (copies provided). Both documents outlined a list of activities that MSLs might undertake, which could include reactive and proactive activities such as a speaker within the capacity of a medical expert on the data. The MSLs were not allowed to run promotional meetings; their role was strictly non-promotional and so they did not promote the prescription, supply, sale or administration of any medicine. The team had been clearly briefed and trained in this role with clear roles and responsibilities. This specificity included training on the Code undertaken through an external online vendor. As the role was not that of a representative, the MSLs were not required to take the ABPI Sales Representative Examination, and therefore there had been no breach of Clauses 16.1 and 16.3.

The MSLs were not incentivised on regional or local product sales and no targets were set for the number of interactions with health professionals. Personalised objectives were set once a year across the business and consisted of 3 – 4 business goals (ie 'What do I need to deliver my role?') and 1 – 2 behavioural goals (ie 'How do I deliver my business goals?', 'What behaviours are critical?'). The objectives were combined into a 'Development Plan' for the individual to identify areas they needed to develop further for their future potential role. Each goal was divided into aspects to deliver, by a set time frame with a measurable outcome. An

example relating to a study was provided by Leo which also stated that in 2019 no MSL objectives related to the running of or presence at meetings.

A modest percentage of base salary was potentially payable as a bonus for the MSL team, none of which was predicated on the achievement of regional or local sales, although national level company performance and personal objectives were taken into consideration.

Leo noted that the complainant had the burden of proof to provide evidence, however, as he/she had not referred to any one specific activity whether by date, time period, location or product content, the company provided an overview of the dermatology MSL activities for 2019.

The MSL team logged their interactions on the company's customer relations management (CRM) database. The CRM database was not used to track MSL interactions with health professionals against targets, since no such targets had ever been set. This could be used as a database to provide information on activity levels where required for planning purposes or providing an overview of the MSL undertaken.

In line with the MSL SOP, in 2019 the MSLs had undertaken the following types of meetings:

- Use of MSLs as speakers at educational meetings. Within the context of an educational meeting the MSL team, as medical experts, might present complex information. This meeting could be organised by Leo Pharma (including the sales team) or by a third party. However, any information presented would need to be on-label and within the licensed indication of the product being discussed at the wider meeting. As with such a meeting where the external speaker was a health professional, if there was content related to the company's product, prescribing information was supplied in line with the requirements of Clause 4. In this context, the MSL would not discuss anything which might be deemed off-label or pre-licence. Any unsolicited requests for such information would follow the internal medical information procedure or would be followed up by one of the MSLs at another time.
- Reactive meetings: MSLs had undertaken meetings with individual health professionals upon request for specific information.
- Visits for administrative activities in relation to non-interventional studies: These were visits related to procedurally mandated activities eg site closure.
- Visits in relation to real world evidence projects eg collection of educational case studies: These were visits undertaken to health professionals under contract to provide case studies to Leo.

With regard to enquiry handling, Leo noted that the complainant had not referred to any specific medical information response undertaken by the medical information department or the MSLs. Rather he/she had alleged, in very general terms, that the medical information department and/or MSLs provided unsolicited, off-label information.

Medical information services were undertaken on behalf of Leo by a specialist outsourced vendor, Unsolicited requests to the medical information department could be received directly via email or telephone or indirectly via representatives following interactions in the field. The field force

was required to document and forward any requests to medical information. This included the enquirer's title and contact details, details of scientific papers requested, if appropriate, overview of the requested information and confirmation of the unsolicited nature.

The medical information department could only use standard responses to provide information to any requests from health professionals and patients. Medical information only responded to unsolicited requests. In the event that the enquiry could not be answered with a standard response, an alternative set of publicly available sources might be used or, alternatively, the enquiry escalated for further consideration and response by the medical department. Responses were limited to the information requested.

Information might be supplied in response to unsolicited, appropriately documented, enquiries from health professionals related to off-label use or unlicensed medicines. If off-label use was confirmed in the enquiry, then the relevant details were passed to pharmacovigilance for appropriate follow-up. The globally approved standard responses developed for off-label use were objective, factual and contained non-promotional information regarding off-label use of the product. The process required the prescriber to be made fully aware of the label status of the product and that the use of the product would be outside of the licence and was the prescriber's responsibility. The process also required that only information related to the specific off-label use in the enquiry was supplied.

Occasionally a request might be escalated to an MSL to reactively provide information according to medical information processes and this would be logged in the medical information system.

With regards to the award, Leo noted that it held a three-day annual company conference to include activities such as team building events and overall company strategy and presentations. The conference included an evening in which all the UK affiliates were brought together to celebrate the achievements of the company and highlight those people who had made outstanding contributions to their corresponding business unit. In 2019, each of the three business units consistently awarded in three categories, details were provided. Two of the categories were open to all areas of business including, but not limited to, medical. One of the categories was limited to sales.

For each category the business unit head submitted nominations to the senior leadership team. These nominations were discussed and a winner was selected for each category. In 2019, one of the open categories was awarded to an MSL. In addition, there were winners of these awards in other business units which extended to other non-sales departments, for example, human resources. As two of the categories were not limited to sales there were no metrics identified. These awards were decided on an informal basis to recognise those attributes not related to sales metrics.

The sales role at Leo was predominantly focused on calling on health professionals and prescribers to promote medicines to them. In order to undertake this role, Leo required representatives to have passed the ABPI examination within two years. The job description (copy provided) outlined the roles and responsibilities of the account managers, which was substantially different to those described for the MSL role.

In conclusion, Leo stated that it had a range of detailed procedures and training to ensure compliance with the Code. This included procedures and training on the Code. Leo stated that

its investigation did not find any type of MSL activity which was not within the conduct of policies or in breach of the Code. On the contrary, Leo considered that, based on the information above, the MSL role and medical information function were non-promotional and clearly differentiated from that of the representatives.

Leo stated that it took compliance very seriously and that, as above, there had been no breaches of Clauses 3.1, 3.2, 16.1 or 16.3. High standards had been maintained with detailed procedures and training and therefore there was no breach of Clause 9.1 and consequently there had been no breach of Clause 2.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable and had provided little information and no documentation to support his/her complaint. As with any complaint, the complainant had the burden of proving his/her complaint on the balance of probabilities; the matter would be judged on the evidence provided by the parties. The complainant could not be contacted for further information.

The Panel noted that Clause 16.1 stated that all relevant personnel, including representatives and members of staff, and others retained by way of contract, concerned in any way with the preparation or approval of material or activities covered by the Code, must be fully conversant with the Code and the relevant laws and regulations. The Panel noted from the specimen MSL job description provided by Leo that the MSL role would include the preparation of materials. The Panel noted Leo's submission that it had a range of detailed procedures and training to ensure compliance with the Code. According to Leo, the MSL team had been briefed and trained on its role which included training on the Code undertaken through an external online vendor. The Panel did not consider that the complainant had established that the MSL or medical information team had not been trained in line with the requirements of Clause 16.1 and no breach of that Clause was ruled.

The Panel noted that Clause 1.7 defined a representative as calling on members of the health professions and other relevant decision makers in relation to the promotion of medicines. This was a wide definition and could cover the activities of those employees that companies might not call representatives.

The Panel noted that Clause 1.2 of the Code defined promotion broadly as any activity undertaken by a pharmaceutical company or with its authority which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.

The Panel noted that given the MSLs' role as described by Leo and set out in the MSL job description and the broad definition of promotion in the Code, some of their interactions with health professionals etc, especially those initiated by the company, might be considered promotional. The Panel noted that the status of each such interaction should be considered on its individual merits.

The Panel noted that whilst the Code did not prohibit MSLs and the like from promoting medicines as such, companies must take care to ensure that it was done within the requirements of the Code. Companies would need to be extremely careful to ensure that such

promotional activity was very clearly separated from the non-promotional role of an MSL and the like and that the distinction must be clear to health professionals.

The Panel noted Leo's submission that MSLs were not allowed to run promotional meetings; their role was strictly non-promotional and so they did not promote the prescription, supply, sale or administration of any medicine. The Panel noted that whilst there was no evidence of MSLs running promotional meetings as alleged, according to the MSL SOP and Leo's submission, MSLs could proactively present predominantly educational information at a speaker meeting which could be organised by Leo (including the sales team), provided the content was not off label. The Panel noted Leo's submission that any information presented would need to be on-label and within the licensed indication of the product being discussed at the wider meeting and if there was content related to the company's product, prescribing information was supplied in line with the requirements of Clause 4. The Panel did not consider such proactive presentations by Leo staff, including MSLs, could be anything other than promotional. That such MSL presentations contained predominantly educational material did not mean that they did not satisfy the broad definition of promotion. The Code required all meetings to have a clear educational content. In any event, context was important and presentation of otherwise non-promotional material in a promotional context could render such non-promotional material promotional. In this regard, the MSL presentations appeared, on occasion, to be an integral part of what were described as sales meetings. The Panel also noted that it was important to bear in mind the impression about the status of the MSL that might be given to the audience at such meetings.

The Panel noted that PMCPA Guidance about Clause 3 provided helpful informal guidance including that if, as part of their role, the medical and scientific liaison executives (MSL) and the like promoted licensed products and indications then they were covered by the Code including the specific requirements for representatives (Clauses 15 and 16). The Panel further noted that non-promotional activities by MSLs were also potentially covered by the Code. In the Panel's view, noting its comments above, part of the MSL's role at Leo was promotional and therefore the Panel disagreed with Leo's submission that its MSLs were not required to take an appropriate examination as required by Clause 16.3. It appeared from Leo's response that its MSLs had not taken such an examination and the Panel therefore ruled a breach of Clause 16.3.

The Panel noted its comments and ruling above and considered that failure of the MSLs to take an appropriate examination meant that high standards had not been maintained. A breach of Clause 9.1 was ruled.

The complainant had provided no specific details and no evidence to support his/her allegations that emails sent by MSLs or medical information to customers provided more off-label or pre-licence information on products than what was asked for.

The Panel noted that Clause 1.2 provided an exemption to the definition of promotion stating that replies made in response to individual enquiries from members of the health professions or other relevant decision makers or in response to specific communications from them, whether of enquiry or comment, were excluded from the definition of promotion, but only if they related solely to the subject matter of the letter or enquiry, were accurate and did not mislead and were not promotional in nature. The Panel noted that the exemption only applied to unsolicited enquiries, an enquiry made without any prompting from the company. If an enquirer subsequently requested further information this could be provided and would be exempt from

the Code provided the additional information met the requirements of this exemption. The Panel noted that when relying on this very limited exemption, in relation to a meeting about an unlicensed product, documentation was very important. The Panel noted Leo's submission that occasionally unsolicited requests to the medical information department might be escalated to an MSL to reactively provide information according to medical information processes. The process required that only information related to the specific off-label use in the enquiry was supplied. The process also required the prescriber to be made fully aware of the label status of the product and that the use of the product would be outside of the licence and was the prescriber's responsibility.

The Panel noted that the complainant had not established that Leo's MSLs or medical information department had responded to unsolicited queries such that they were promoting unlicensed medicines or indications and therefore no breach of Clauses 3.1 and 3.2 were ruled.

With regard to the award being given to an MSL, the Panel noted Leo's submission that in 2019, each business unit consistently awarded in three categories. Aside from the sales category, the two other categories were open to all areas of business including, but not limited to, medical. For each category the business unit head submitted nominations to the senior leadership team. There were winners of these awards in other business units which extended to other non-sales departments, for example, human resources. As these two categories were not limited to sales, there were no metrics identified. These awards were decided on an informal basis to recognise those attributes not related to sales metrics. The Panel did not consider that the complainant had provided evidence to show that this blurred the lines between sales and medical as alleged and no breach of Clause 9.1 was ruled.

The Panel noted that a ruling of a breach of Clause 2 of the Code was a sign of particular censure and reserved for such. The Panel noted its rulings of a breach of Clauses 16.3 and 9.1 above. In that regard, the Panel did not consider that the particular circumstances of this case warranted additional censure and therefore no breach of Clause 2 was ruled.

Complaint received **13 September 2019**

Case completed **20 July 2020**