ANONYMOUS, NON-CONTACTABLE EMPLOYEE v LEO

In-house communications material and reporting line of a medical science liaison team

An anonymous, non-contactable employee complained about in-house material produced by Leo Pharma to engage staff in the forthcoming launch of Enstilar (calcipotriol/betamethasone) cutaneous foam. The complainant provided copies of two emails and photographs of cut-out aerosol cans of Enstilar placed around the office. The complainant stated that the product had no marketing authorization and the material at issue could potentially be viewed by visitors.

The detailed response from Leo is given below.

The Panel noted that the complainant could not be contacted for any more information; he/she had provided no evidence that visitors had seen any of the material at issue.

The Panel considered that it was not necessarily unacceptable for a company to display product material within its own offices, but displays of such material in areas routinely accessed by visitors, or even viewed by passers-by, needed to be appropriate. The Panel did not agree with Leo's submission that no-one who visited the offices for a legitimate business purpose could be considered a member of the public. In the Panel's view the status of the visitor, his/her reason for visiting and the arrangements for the visit would be relevant. Each example would have to be considered on its own merits. Companies should be aware of the impact and impression such material could have on visitors and the messages that might be conveyed. The Panel noted that Leo's offices were on the second floor; visitors would generally be taken to one of the meeting rooms, away from the staff areas where the cut-outs were displayed.

In the circumstances, the Panel considered that there was no evidence to support the complainant's allegation that Leo had promoted Enstilar to the public as alleged. No breach of the Code was ruled including no breach of Clause 2.

The complainant further alleged that the reporting line for the company's medical scientific liaison officers (MSLs) did not seem correct. The complainant provided a copy of an internal email announcing that a commercial manager in one therapy area would take on the additional responsibility as head of MSLs in another therapy area.

The Panel initially considered the case on the assumption that there were two separate MSL teams and considered that there was no evidence to support the complainant's allegation that the line management of the dermatology MSLs was necessarily unacceptable. Leo had provided draft material to show that it had recognised the inherent conflicts of interest in its interim management arrangements but had taken steps to mitigate and manage these. The Panel noted Leo's submission that the product areas, thrombosis and dermatology were distinct and separate. The complainant had cited no examples of inappropriate conduct by either the interim manager or the MSLs.

Following notification of the outcome, Leo clarified the arrangements. The Panel's impression that there were two distinct MSL teams was wrong; there was only one MSL team carrying out activities in both therapy areas (dermatology and thrombosis).

The Panel noted that MSLs carrying out activities in thrombosis would report to the head of sales (thrombosis), albeit only in relation to their activities in dermatology, as did the thrombosis sales force. The interim dual role of the head of sales of (thrombosis) and the dual responsibilities and reporting lines of the MSLs needed to be very carefully managed. It did not appear that Leo had finalised the work instruction covering the new arrangement. It was important to consider whether the activities were compatible with each other if they were undertaken by one individual, and how the activities were perceived. The more functions combined into one role the more difficult it was to ensure compliance with the Code and generally promotional and non-promotional activities should be performed by separate staff. The Panel noted Leo's submission that the governance of the MSL function would remain the medical director's responsibility.

The Panel noted its concerns above but considered that there was still no evidence to support the complainant's allegation that the line management of the MSLs in relation to dermatology by the head of sales (thrombosis) was necessarily unacceptable. Leo had provided draft material to show that it had recognised the inherent conflicts of interest in its interim management arrangements but had taken steps to mitigate and manage these. The interim head of MSLs was required to ensure that all of his/her interactions with MSLs were related to dermatology activities only and to refer MSLs to the medical director if any matters were raised in relation to thrombosis activities. The complainant had cited no examples of inappropriate conduct by either the interim manager or the MSLs. The Panel therefore ruled no breach of the Code including Clause 2.

An anonymous, non-contactable, 'concerned' employee complained about the conduct of Leo Pharma.

1 Alleged promotion of an unlicensed medicine

COMPLAINT

The complainant provided copies of internal communications about Enstilar (calcipotriol/ betamethasone) cutaneous spray foam for the treatment of psoriasis, due to be launched in May. Photographs of a large cut-out aerosol can of Enstilar were provided as well as a screen image promoting the product. All of the material appeared to be displayed in an office setting. The complainant also provided copies of two emails briefing staff about the upcoming product launch. The complainant stated that the product had no marketing authorization and the material was on view in the offices and potentially to visitors.

When writing to Leo, the Authority asked it to respond in relation to the requirements of Clauses 2, 9.1 and 26.1 of the Code.

RESPONSE

Leo strongly refuted the suggestion that it had promoted a prescription only medicine to members of the public as all of the material at issue was displayed within the company's private, secure office (in the open-plan and staff kitchen areas) and was directed at head office staff for the legitimate business purpose of internal engagement and familiarisation with a product launch campaign. Members of the public never had access to these secure offices and it would be physically impossible for them to see the materials in the offices.

Leo explained that its offices were on the second floor of a building in an isolated part of Berkshire which had no public use or access. The building housed 5 companies (including Leo) with a common reception area on the ground floor. Post, packages and the like were left at reception and visitors reported to the reception staff at this initial entry point into the building. Any visitor with a legitimate, pre-arranged business purpose within the Leo offices was announced by telephone to their Leo contact. Visitors were then collected from reception by Leo staff and accompanied to a specific area within the Leo offices for their meeting. Everyone else present within the areas shown on the complainant's photographs were employed or otherwise contracted by Leo.

Leo noted that entry to its offices was only possible through one of two entrance doors, both of which required staff security passes.

Leo submitted that the photographs provided by the complainant were of three cut-out can stands and one screen image. A number of the photographs were duplicates either as close-ups or different angles. Leo provided a table to show the location of the materials at issue and when they were first displayed in the building. All of the material at issue had been displayed in the staff lunch/kitchen area, in the open-plan work area or in an internal meeting room for Leo staff only.

Leo noted that its formal meeting rooms were grouped together at one end of the floor with their own coffee/refreshment area. Most visitors would be shown to a room in the meetings area, away from the open-plan office and staff lunch/kitchen area.

Although visitors were not physically barred from the Leo open-plan and staff kitchen area, those areas were not designed or intended primarily for the use of visitors. They were designed for and were used by Leo staff rather than business visitors and all those present in the offices at any given moment were highly likely to be all Leo employees only.

The stands displayed in the offices were to remind staff that Enstilar would be available in a can which was a new and innovative way to apply a psoriasis product. The purpose of the internal communications campaign was for employees to understand the work being undertaken by a cross-functional launch team in preparation for the product launch and to ensure that all employees were part of the company commitment to have a successful launch. Such internal communication was a common and routine means in the pharmaceutical and other industries to help communicate to employees what their priorities should be in an otherwise busy work schedule; in this case, support for a new product launch. This theme was reiterated in the TV screenshot which noted a new method of delivery. The TV was normally set to a news channel and would have been temporarily set to the image display.

Leo noted that none of the internal imagery stated a licensed indication for Enstilar (or even a therapy area) and was also marked for internal use. Leo therefore denied a breach of Clause 26.1 that prescription only medicines must not be advertised to the public. No members of the public would have had access to these materials and although the complainant referred to 'visitors', all visitors to the Leo offices were there for a legitimate business purpose and so could not be considered to be members of the general public for the purposes of Clause 26.1.

Leo further noted that the complainant had also provided a number of internal emails announcing progress in the licensing and launch plans for Enstilar. It was clear that these internal emails were not available to visitors or the public.

Leo submitted that in its view, it was legitimate to provide business information to current employees which might relate to both existing medicines and those not yet marketed.

As could be expected, there were a number of activities and projects within the company that would be undertaken to get a product to market. The internal Enstilar awareness campaign was to facilitate an environment of employee engagement and a collective means of working together towards a common goal – the forthcoming UK licence and subsequent launch of the product. This ensured that all company staff, regardless of function, recognised the need to prioritise support for the launch.

Furthermore, Leo noted that in all the emails, employees were consistently reminded that the product did not have an external licence and that they should not discuss this with external stakeholders unless specifically briefed to do so.

Leo submitted that its standards had been sufficiently high to prevent promotion of a prescription only medicine to the public. In this regard, the company thus denied breaches of Clauses 9.1 and 2.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints would be accepted, but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant could not be contacted for more information.

The Panel noted Leo's submission that the material provided by the complainant showed different components of an internal communications campaign designed to engage staff throughout the organisation in the forthcoming launch of a new medicine. The two emails provided had been distributed internally and reminded readers not to discuss Enstilar with external stakeholders unless briefed to do so. Leo had submitted that the large cut-out cans of Enstilar and the television screen were all displayed in the staff lunch/kitchen area, in the open-plan work area or in an internal meeting room for Leo staff only. Access to the offices was controlled. The Panel noted Leo's submission that visitors to the offices would generally be taken to one of the meeting rooms, away from the staff areas where the cut-outs were displayed.

The Panel considered that it was not necessarily unacceptable for a company to display product material within the confines of its own offices, but displays of such material in areas routinely accessed by visitors, or even viewed by passers-by, needed to be appropriate. The Panel did not agree with Leo's submission that no-one who visited the offices for a legitimate business purpose could be considered a member of the public. In the Panel's view the status of the visitor, his/her reason for visiting and the arrangements for the visit would be relevant. Each example would have to be considered on its own merits. In the Panel's view, companies had to be aware of the impact and impression such material could have on visitors and the messages that might be conveyed. The Panel noted that Leo's offices were on the second floor. The only people who had access to the offices were Leo staff and visitors.

The Panel considered that although most visitors to Leo's offices would be shown to a room in the meetings area away from the open plan office and staff lunch/kitchen area, some might, nonetheless, see the cut-outs and screen. The Panel considered that if a visitor had seen the hard copy material at issue they would be very aware that the company was shortly to launch a new product. The cut-outs of the can included a green traffic light and the brand name; other material which included the brand name and the generic name, made it clear that the product was ready for launch. One piece referred to the global launch. Although the screen image showed the brand name and generic name, it did not refer to the forthcoming launch. The Panel noted that the complainant had provided no evidence that visitors had seen any of the material placed around the office or that the internal company emails had been provided to anyone other than Leo staff.

In the circumstances, the Panel considered that there was no evidence to support the complainant's allegation that Leo had promoted Enstilar to the public as alleged. No breach of Clauses 2, 9.1 and 26.1 were ruled.

2 Reporting line of medical scientific liaison officers (MSLs)

COMPLAINT

The complainant provided a copy of an internal email which announced that the head of sales (thrombosis) would take on the additional responsibility as head of MSLs dealing specifically with the dermatology side of the business. The head of sales (thrombosis) would continue to report to the business unit director of thrombosis and would have a dotted line responsibility to the medical director who would directly manage the thrombosis activities of the MSLs.

The complainant alleged that the report line of MSLs to a sales manager did not seem to be correct.

When writing to Leo, the Authority asked it to respond in relation to the requirements of Clauses 2 and 9.1.

RESPONSE

Leo stated that its MSL function currently reported to the medical director (as indicated in the email submitted by the complainant) and would continue to report to the medical director even after the new interim head of MSLs was in position as of 1 May 2016. Moreover, the governance of the MSL function had been, and would remain, the medical director's responsibility.

Leo believed that this was in line with the PMCPA document 'Guidance about Clause 3' which stated 'the overall governance of the medical and scientific liaison executives and the like should be the responsibility of the medical director or similar, irrespective of reporting lines, rather than the commercial side of the company'.

Leo explained that dermatology MSLs would report into the medical director via the new, interim head of MSLs as of 1 May and thrombosis MSLs would report directly to the medical director. During the temporary period (of up to one year), the interim head of MSLs would continue to line manage the thrombosis regional business managers (RBMs) and report into the business unit director of thrombosis

for that purpose. Leo stated that its thrombosis and dermatology business units were so distinct and separate that such an arrangement was possible whilst retaining an acceptable level of governance over the MSL function. They were served by two distinct sales forces that did not promote products in both therapy areas and furthermore they did not have any routine local/regional interaction such as combined sales team meetings.

Furthermore, the head of sales (thrombosis) would look after the dermatology MSL team, a part of the business for which he had no sales targets delivery responsibility or incentives. This safeguard was already considered to ensure appropriate management structure for the MSLs reporting to the head of sales (thrombosis) and was communicated in the email announcement.

Leo was confident, given his/her length of time and seniority within the pharmaceutical industry, that the manager understood the important compliance requirements for managing an MSL team before this decision was taken and that this need could be appropriately managed by a senior member of Leo staff recognising the need to clearly separate non-promotional and promotional approaches.

To reiterate, the temporary reporting structure for the head of MSL role reflected the fact that the individual in the role would undertake two different roles for two completely different business units. This was a pragmatic and caretaking measure to meet business needs in a relatively small company such as Leo. For an interim period the head of MSL role would effectively be shared between the head of sales (thrombosis) and the medical director.

The complainant appeared to be concerned that such a reporting line arrangement, involving national level managers was, in and of itself, in breach of the Code. Leo did not consider this was so and such a reporting line arrangement, as long as the medical director retained overall responsibility for governance, was not in breach of the Code.

Leo noted that the complainant had not alleged that the MSLs had undertaken any activity that was in breach of the Code nor that they had been directed to undertake such activity in future.

Leo confirmed that it considered the MSL role was non-promotional and it had a strict internal policy on the activities of MSLs and a standard operating procedure (SOP) for the Medical Science Liaison functions (SOP 006445) made the non-promotional requirements of this function very clear. This was further supported by job descriptions for the two relevant roles within this medical function – the head of medical science liaisons and the medical scientific liaison officer. Copies of all these documents were provided.

Leo was confident that it had a strong culture of compliance which was supported by the Leo Code of Conduct which, together with the company's guidelines, procedures and policies, underpinned the ways of working within Leo. The Leo Code of Conduct provided guidance to translate the values into consistent actions by resolving ethics and compliance issues arising in employees' daily work. Compliance with the Leo Code of Conduct was mandatory for all employees who had a shared responsibility to ensure compliance at Leo and this was also even more important for Leo managers who must ensure that Leo standards were followed at all times.

Leo stated that the MSLs' role and responsibilities centred around reactive responses to requests for information at either an individual level, presentations for senior health professionals with their team or medical presentations representing Leo at third party events. They would also engage with health professionals in relation to research projects. They might also be involved in advisory boards meetings as part of the medical function or provide internal disease/therapy area training to Leo employees including sales representatives. These activities might be in any disease or therapy area for Leo including dermatology and thrombosis.

Leo stated that MSLs were incentivised on individual performance and on company performance. They were not incentivised on local or regional sales performance or activity input metrics such as the number of visits to health professionals. For the interim head of MSLs/head of sales (thrombosis) a proportion of his/her bonus would be based on sales targets in the thrombosis division and the rest would be related to people management goals to include the management of the dermatology MSLs.

Leo stated that further safeguards had been developed as the change in reporting lines would not take effect until 1 May 2016 and a work instructions document had been prepared which was currently in draft awaiting approval to support this new internal caretaking position. A copy of the draft work instruction was provided.

Leo considered that it had taken adequate steps to safeguard and support both the head of sales (thrombosis) and the MSLs reporting to this manager for the short period. For these reasons Leo denied breaches of Clause 9.1 and Clause 2.

PANEL RULING (initial)

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure for the Prescription Medicines Code of Practice Authority stated that anonymous complaints would be accepted, but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant could not be contacted for more information.

The Panel noted that the email provided by the complainant stated that following an internal move by the then current head of MSLs, the dermatology MSLs would, for an interim period of one year, be line managed by the head of sales from a completely separate side of the Leo business. However,

given the inherent possible conflict of interest in a commercial manager line managing an MSL team, the Leo draft work instruction to cover this arrangement stated that to ensure compliance with Leo policies and with the Code, the overall governance of these MSLs, would remain the responsibility of the medical director. The draft work instruction set out in detail the relationships between the parties and, *inter alia*, required the interim head of MSLs (dermatology) to promptly raise any possible conflict of interest situations with the managers/medical director to ensure that these could be properly mitigated. Further, the interim head of MSLs (dermatology) was to meet twice monthly with the medical director to ensure appropriate governance and guidance was given to the interim manager.

The Panel considered that there was no evidence to support the complainant's allegation that the line management of the dermatology MSLs was necessarily unacceptable. Leo had provided draft material to show that it had recognised the inherent conflicts of interest in its interim management arrangements but had taken steps to mitigate and manage these. The Panel noted Leo's submission that the product areas, thrombosis and dermatology were distinct and separate. The complainant had cited no examples of inappropriate conduct by either the interim manager or the MSLs. The Panel therefore ruled no breach of Clauses 2 and 9.1.

FURTHER COMMENTS FROM LEO

Upon receiving details of the outcome of the Panel's consideration, Leo was concerned to note that the Panel referred to 'dermatology MSLs' and 'thrombosis MSLs' and 'dermatology MSL team' which were not terms used by Leo. There was one MSL team and not two distinct and separate MSL teams, one for dermatology and one for thrombosis.

Leo submitted that it was explicit in its response that its MSLs undertook activities in both dermatology and thrombosis. Leo had described the MSL role and stated '…the MSL officer role centres around…. These activities may be in any disease or therapy area for Leo including dermatology and thrombosis'. Leo submitted that it had a small MSL function (comprised of 4 positions) that worked as a single team supporting all therapy areas and who would all have shared reporting structure to both the new interim head of MSLs and the medical director.

Leo submitted that MSLs would report directly to the medical director for activities which involved thrombosis as a therapy area and to the interim head of MSLs (who was also national sales head (thrombosis) looking after the thrombosis sales team) for the dermatology areas of their activities. Leo submitted that this was made clear when it stated 'For an interim period the head of MSL role would effectively be shared between the head of sales (thrombosis) and the medical director'. Leo submitted that overall governance of the MSLs remained with the medical director who would also have governance over the interim head of MSLs for those specific medical affairs area related parts of the appointee's role.

Leo submitted that this additional clarification would not impact the Panel's ruling and furthermore that it demonstrated that the single MSL team would always be directly managed by a medical, non-commercial role.

Leo was confident that the information previously provided was accurate but apologized if it was not sufficiently explicit to avoid possible misunderstandings.

The Authority decided that the original Panel should reconvene to consider this matter in light of the clarification from Leo. Leo was so informed and asked to respond including in relation to the requirements of Clauses 2 and 9.1 of the Code.

COMMENTS FROM LEO

Leo submitted no additional information but highlighted the following points:

- the single MSL team would always be directly managed by a medical, non-commercial role. As there was a single MSL team all the MSLs would have both a direct reporting line and also direct access to the medical director. The governance of the activities of the MSLs would remain the responsibility of the medical director and consequently this should not impact the original Panel rulings.
- appropriate governance arrangements were covered by the work instruction previously provided. Leo was confident that the work instruction met the appropriate governance needs and correct support for the MSLs as well as the MSLs interim head/head of sales (thrombosis) to operate compliantly during this period.
- the interim reporting line decision was only taken after careful consideration of the compliance requirements to ensure the whole team (both MSLs and the interim head of MSLs) was adequately supported and that consideration was evidenced by the details within the email announcement, sent before the anonymous complaint was made.

Leo submitted that this clearly demonstrated its commitment to the requirements of the Code and it denied breaches of Clauses 9.1 and 2.

PANEL RULING

The Panel noted its previous rulings of no breaches of Clauses 9.1 and 2. The Panel had considered that there was no evidence to support the complainant's allegation that the line management of the dermatology MSLs was necessarily unacceptable. Leo had provided draft material to show that it had recognised the inherent conflicts of interest in its interim management arrangements but had taken steps to mitigate and manage these. The Panel noted Leo's submission that the product areas, thrombosis and dermatology were distinct and separate. The complainant had cited no examples of inappropriate conduct by either the interim manager or the MSLs.

The Panel noted Leo's subsequent clarification that there was a single MSL team that would carry

out activities in both dermatology and thrombosis therapy areas. Previously the Panel was under the impression that there were two distinct MSL teams. The Panel considered that although Leo had not actually stated in its original response that there were two separate MSLs teams, it did not clearly state that a single MSL team was responsible for activities in both the thrombosis and dermatology therapy areas. The Panel noted Leo's submission that '….its thrombosis and dermatology business units were so distinct and separate…' and that 'They were served by two distinct sales forces that did not promote products in both therapy areas' and considered that it was not explicitly clear that there was only one MSL team carrying out activities in both therapy areas. The Panel considered that the confusion was due to a misunderstanding and lack of clarity.

The Panel noted that MSLs carrying out activities in thrombosis would report to the head of sales (thrombosis), albeit only in relation to their activities in dermatology, as did the thrombosis sales force. The interim dual role of the head of sales (thrombosis) and the dual responsibilities and reporting lines of the MSLs needed to be very carefully managed. It did not appear that Leo had finalised the work instruction. It was important to consider whether the activities were compatible with each other if they were undertaken by one individual, and how the activities were perceived. The more functions combined into one role the more difficult it was to ensure compliance with the Code and generally promotional and non-promotional activities should be performed by separate staff. The Panel noted Leo's submission that the governance of the MSL function would remain the medical director's responsibility.

The Panel noted its concerns above but considered that there was still no evidence to support the complainant's allegation that the line management of the MSLs in relation to dermatology by the head of sales (thrombosis) was necessarily unacceptable. Leo had provided draft material to show that it had recognised the inherent conflicts of interest in its interim management arrangements but had taken steps to mitigate and manage these. The interim head of MSLs was required to ensure that all of his/her interactions with MSLs were related to dermatology activities only and to refer MSLs to the medical director if any matters were raised in relation to thrombosis activities. When accompanying MSLs as a manager to visit a health professional in relation to dermatology, he/she would forego attendance in the unlikely event that the health professional was known to him/her in a sales capacity. The complainant had cited no examples of inappropriate conduct by either the interim manager or the MSLs. The Panel therefore ruled no breach of Clauses 2 and 9.1.

Complaint received **11 April 2016**

Case completed **3 June 2016**