NO BREACH OF THE CODE

CASE AUTH/3476/2/21

ANONYMOUS, CONTACTABLE v LEO

Conduct of a representative

A contactable complainant complained about the LinkedIn profile of a named Leo Pharma employee who worked in the medical department.

The complainant alleged that he/she did not believe that the employee in question had ever held the qualification used and thus misrepresented him/herself to the company and health professionals as to his/her professional status.

The complainant noted that on the publicly available LinkedIn profile, with open privacy settings, connected to both health professionals and members of the public, the individual confirmed many activities which he/she had conducted. The complainant alleged breaches of the Code.

In a role as a thrombosis representative at Leo Pharma, the individual's LinkedIn profile stated 'Gained a complete switch to Innohep at [named hospital] after numerous failed attempts over 3 years, business worth £150k'. The complainant submitted that switch services facilitated by a pharmaceutical company using a representative were not allowed under the Code and the individual in question had openly admitted that a switch had occurred and that he/she had taken part in it.

The complainant noted that the individual also stated '...to extend the use of Innohep in treatment in general surgery - upper/lower GI, urology and hepato-biliary' and alleged that naming Innohep and a therapy area (thrombosis mentioned in job title) advertised to the public, breaching the Code.

The complainant further alleged that through the individual's LinkedIn connections to health professionals, he/she had promoted Innohep without prescribing information, a clear link to the location of the prescribing information, the non-proprietary name for Innohep or a date of revision. The complainant alleged breaches of the Code including that the information was disguised promotion.

The complainant alleged that the advertisement had not been certified and that the information about Innohep to the public was not balanced, did not contain any information on adverse events or safety and did not have the adverse event reporting statement required for patients using a medicine.

The complainant further alleged that Innohep was not indicated for 'extended use in treatment in general surgery - upper/lower GI, urology and hepato-biliary' according to the Innohep summary of product characteristics (SPC) and therefore the promotion was not in accordance with the SPC.

The complainant noted that the individual stated that he/she had 'Initiated a project with haematologist and clinics lead for Obs&Gynae ... on benefits of Innohep with positive outcome with guideline development' and alleged that the 'benefits of Innohep' in obstetrics and gynaecology was unreferenced, unqualified and a hanging claim and that the individual had promoted Innohep in a manner not in accordance with its SPC.

The LinkedIn profile stated 'Fully supported the launch of Picato ingenol mebuate for actinic keratosis' and the complainant alleged that this advertised to the public.

The complainant alleged that through the individual's LinkedIn connections to health professionals, he/she had promoted Picato to health professionals without prescribing information, a clear link to the location of the prescribing information, a black triangle or a date of revision. The complainant alleged that the advertisement was disguised promotion and that the promotion was not in accordance with the SPC.

The complainant alleged that the advertisement had not been certified and that the information about Picato to the public was not balanced, did not contain any information on adverse events or safety and did not contain the adverse event reporting statement required for patients taking a medicine.

The complainant noted that the LinkedIn profile included 'Educate and train health professionals in response to unsolicited requests, in the safe and appropriate use of company products particularly in off licence situations where the clinician had already decided to use the product either in a face to face or meeting situation'. The complainant alleged that use of the word 'safe' was never appropriate in the discussion of any prescription only medicine and that the individual had a promotional role and had admitted to promoting in off-licence situations and training health professionals in off-licence use.

The complainant stated that many of these points were also repeated under 'Achievements' which also stated 'Supported the launch of its new product for Actin Keratosis' which the complainant alleged was made to elicit interest in a new product from Leo for actinic keratosis and teased both the public and health professionals on that development.

The complainant noted that 'new' could only be used 12 months from launch and Picato was on the market for many years.

The detailed response from Leo is given below.

The Panel noted the complainant's submission that the employee in question's LinkedIn account was publicly available, with open privacy settings, and that the employee's connections included both health professionals and members of the public. The Panel noted that Leo made no submission in that regard and considered, on the balance of probabilities, that both health professionals and members of the public could view the employee's LinkedIn profile.

The Panel noted Leo's submission that personal LinkedIn profiles were generally used as a form of online curriculum vitae (CV) for the benefit of recruiters and as such, details of specific successes in current and previous roles would be expected. In the Panel's view, regardless of how an individual chose to use a social media platform, the content, if

within the scope of the Code, had to comply with it; the audience was an important consideration in that regard.

The Panel noted Leo's submission that the employee had provided evidence of his/her qualification to Leo at the commencement of his/her employment and the authenticity of the certificate had been confirmed. The Panel considered that the complainant had not established that the employee had wrongly referred to a particular qualification and no breach of the Code was ruled.

Innohep

With regard to the allegation about the switch to Innohep, the Panel noted Leo's submission that the employee in question was approached by a pharmacist at the named hospital who wanted to place Innohep on the hospital formulary and following discussions with relevant health professionals, the formulary positioning was changed by the hospital, effectively 'switching' the current anti-thrombotic that was on the formulary to Innohep.

The Panel was concerned about the impression given by the statement with regard to Leo's role in relation to the switch and queried Leo's submission that the employee was approached by the hospital given that the employee stated that he/she had managed to gain a complete switch to Innohep 'after numerous failed attempts over 3 years'. Nonetheless, the Panel considered that the complainant had not discharged his/her burden of proof that Leo had facilitated a switch service as alleged and the Panel, therefore, ruled no breaches of the Code in that regard.

In relation to the allegation that information within the profile advertised Innohep to the public, the Panel noted Leo's submission that to view this information within a user's profile, someone would need to look at the user's work experience, presumably for the purposes of recruitment. In the Panel's view, LinkedIn was not solely a platform for recruitment; it was a social media platform with a varied audience.

On the evidence before it, the Panel noted that the employee's profile was publicly available and furthermore the employee's connections likely included members of the public who were not associated with recruitment. The Panel considered that the information within the employee's profile, which included reference to Innohep, thrombosis and surgery, was such that Innohep, a prescription only medicine, had been advertised to the public and a breach of the Code was ruled. The Panel considered that high standards had not been maintained in that regard and a breach of the Code was ruled. These rulings were appealed by Leo.

The Panel did not consider that the specific circumstances warranted a breach of Clause 2.

With regard to the allegation that the information about Innohep to the public was not balanced and that it did not contain any information on adverse events or safety, the Panel did not consider that the complainant had established that the lack of safety information about Innohep in the employee's LinkedIn profile meant that the information about Innohep was misleading with regard to the safety of the product and therefore no breach of the Code was ruled. Further the Panel did not consider that the information was intended for patients taking Innohep and therefore the reporting of side effects

statement was not required nor did the information require certification and no breaches of the Code were ruled.

The Panel noted the statements on the employee's profile in relation to Innohep, including references to thrombosis, surgery and a statement regarding a project that he/she had initiated '...on benefits of Innohep...'. In the Panel's view, such information about prescription only medicines on a user profile, which would likely be read by health professionals that the employee had interacted with in his/her role at Leo, was promotional. In the Panel's view, Innohep had been promoted to health professionals without the provision of prescribing information, the non-proprietary name or the date which the material was drawn up or last revised and breaches of the Code were ruled. A further breach was ruled as the material had not been certified. These rulings were appealed by Leo.

The Panel noted that the LinkedIn profile in question was clearly labelled as that of a Leo employee and included positive statements about Leo's medicines. In the Panel's view, the content within the user's profile was clearly promotional. The Panel did not consider that the complainant had established that the promotion of Innohep was disguised and no breach of the Code was ruled.

With regard to the employee's statement, '...to extend the use of Innohep in treatment in general surgery ...', the Panel noted Leo's submission that it would be very difficult to confuse 'extended use', which related to duration of treatment with 'extend the use', which clearly indicated a desire to increase usage of a medicine in a given therapy area/account; there was no implied claim that Innohep could, or should, be used 'for extended use in treatment in general surgery'. The Panel did not consider that the complainant had established that the employee's statement had promoted Innohep in a manner that was inconsistent with its SPC. The Panel therefore ruled no breaches of the Code in that regard.

In relation to the statement, 'Initiated a project with haematologist and clinics lead for Obs&Gynae at [two named hospitals] on benefits of Innohep with positive outcome with guideline development', the Panel noted Leo's submission that the project in question was initiated by the haematologist and the obstetrics and gynaecology clinic lead who had specifically requested more information on Innohep usage in the obstetrics and gynaecology setting. The Panel further noted Leo's submission that it was appropriate for the employee who was in the medical department at the time to respond to the reactive request and act as a medical information service, however, Leo accepted that the inaccuracy of the LinkedIn profile with regards to that point, and the wording used, was misleading and implied that an activity had taken place that was not in accordance with the Code. The Panel noted Leo's submission that it would ask the employee to ensure the LinkedIn profile was amended to more accurately reflect what had taken place.

Whilst the Panel was extremely concerned about the inaccuracy of the statement in terms of who had initiated the project, the Panel considered that the complainant had not established that the claim 'benefits of Innohep' in the context of the statement in question was unqualified or a hanging comparison; nor had the complainant established that the employee had promoted Innohep in a manner inconsistent with its SPC. The Panel therefore ruled no breaches of the Code in that regard.

Picato

In relation to the allegations about the statements about Picato, the Panel noted Leo's submission that the EU marketing authorisation for Picato was withdrawn on 11 February 2020 and it was therefore not available for prescription anywhere in the EU.

The Panel had no information before it as to if Picato was a prescription only medicine when the information was first published on the employee's profile. Picato was not a prescription only medicine at the time of the complaint and therefore on that narrow technical point, the Panel ruled no breaches of the Code in that regard.

The Panel did not consider that the information required certification, nor had an allegation been made about briefing material and it ruled no breaches of the Code. Noting its rulings above, the Panel consequently ruled no breaches of the Code including Clause 2.

Description of employee's role

The Panel considered that reference to the safe and appropriate use of Leo medicines might be seen as a claim that such medicines were safe. Although there might be a difference between the medicine being safe and the safe use of that medicine, the Code stated that the word 'safe' must not be used without qualification and this was not limited to promotional material. The Panel was further concerned that the term 'safe' was used in reference to off licence use. The Panel considered that, on balance, the reference to the safe use of Leo's medicines did not meet the requirements of the Code and a breach was ruled including that high standards had not been maintained. These rulings were appealed by Leo.

The Panel did not consider that the complainant had established that the employee's statement amounted to an admission to promoting off-licence as alleged. No breaches of the Code were ruled in that regard.

The Panel did not consider that the specific circumstances warranted a breach of Clause

New product

The Panel noted Leo's submission that in the 'Achievements' section of the employee's profile, the name of the specific medicine was not mentioned and as noted above the marketing authorisation for Picato was withdrawn in February 2020. Furthermore, the Panel considered that the statement was written in the past tense. The Panel considered that the complainant had not established that the use of the word new in this context was in breach of the Code and ruled accordingly.

The Appeal Board noted that LinkedIn was originally primarily used as a resource for recruitment, however, this social media platform had evolved over time, and this might not be how it was currently predominantly used. The Appeal Board noted that the 'Experience' section on an individual's LinkedIn profile was essentially a summary of previous job roles and appeared below the 'Activity' section where individuals could be posting, sharing, commenting and liking etc. To fully see the 'Experience' section text might require additional clicks and/or scrolling by the reader. The Appeal Board

considered that the information within the 'Experience' section, which would require an individual to actively search for it, was distinct from user activity on LinkedIn such as posts, comments, 'likes' and shares etc which would proactively disseminate information to the user's LinkedIn connections.

The Appeal Board queried if there was ever a need for a medicine to be named within a LinkedIn profile. Leo submitted that it now trained its staff that medicines should not be mentioned in an online profile and instead suggested the use of therapy area.

On the evidence before it, the Appeal Board noted that although the employee's profile was publicly available, to reach the 'Experience' section at issue would require an interest in the individual's work experience and several clicks to fully view the information. Such an interest in an individual would likely be by a potential employer or a recruitment company. Based on the nature of the 'Experience' section the Appeal Board did not consider that the information within the employee's profile, which included reference to Innohep, thrombosis and surgery, was such that Innohep, a prescription only medicine, had been advertised to the public and no breach of the Code was ruled. The complainant had not established that high standards had not been maintained in this regard and the Appeal Board therefore ruled no breach of the Code. The appeal on both points was successful.

The Appeal Board did not consider that the information in question within the 'Experience' section of the LinkedIn profile constituted promotion to health professionals and it therefore ruled no breaches of the Code including that the material did not need to be certified. The appeal on all points was successful.

With regard to the use of the word safe within the employee's profile, the Appeal Board considered that there was a difference between the safe use of medicines and describing a medicine as safe, and in this case the reference to the safe and appropriate use of Leo medicines did not describe a particular medicine as safe. The reference would likely be read as relating to training and medicines in general rather than a specific medicine and no breaches of the Code were ruled including that the complainant had not established that high standards had not been maintained in this regard. The appeal on both points was successful.

A contactable complainant, who stated that he/she had previously worked as a representative for companies other than Leo Pharma, complained about the conduct of a named Leo employee who worked in the medical department.

The case preparation manager determined that in relation to some of the complainant's comments, no *prima facie* case had been established and those comments should not be referred to the Panel for consideration; the parties were so informed and the decision was accepted by the complainant. The remainder of the complainant's comments were referred to the Panel.

COMPLAINT

The complainant noted that the public facing LinkedIn profile of the individual in question described him/her as a '[employee in the medical department]' at Leo Pharma.

The complainant stated that he/she had worked with the individual but did not believe that he/she had ever held the qualification he/she had used online and thus misrepresented him/herself to the company and he/she was also misleading health professionals as to his/her professional status. The complainant asked whether the individual's claim of this qualification was ever proven to any of his/her employers.

The complainant noted that whilst the Code required complainants to provide the evidence of breaches, in this particular situation, that evidence had already been provided by the subject of the complaint on his/her LinkedIn profile and was in the public domain. On the publicly available LinkedIn profile, with open privacy settings, connected to both health professionals and members of the public, the individual confirmed many activities which he/she had conducted. The complainant alleged that these were open admissions of breaching the Code.

In a role as a thrombosis representative at Leo Pharma, the individual's LinkedIn profile stated 'Gained a complete switch to Innohep at [named hospital] after numerous failed attempts over 3 years, business worth £150k'. The complainant submitted that switch services facilitated by a pharmaceutical company using a representative were not allowed under the Code and the individual in question had openly admitted that a switch had occurred and that he/she had taken part in it.

The complainant noted that the individual also stated 'Collaborated with pharmacist at [named hospital] to extend the use of Innohep in treatment in general surgery - upper/lower GI, urology and hepato-biliary'. The complainant noted that that section of the individual's LinkedIn profile named Innohep and a therapy area (thrombosis mentioned in job title - area in which this product was indicated) and so advertised to the public, breaching the Code and was illegal.

The complainant further alleged that through the individual's LinkedIn connections to health professionals, he/she had promoted Innohep to health professionals but that the advertisement to health professionals did not contain a clear link to the location of the prescribing information, the non-proprietary name for Innohep, a date of revision or prescribing information. The complainant alleged multiple breaches of the Code.

The complainant noted that there was no information for health professionals that the LinkedIn profile in question contained promotional information before they read it, and therefore they only realised it was promotional when they read it. The complainant alleged that the information was disguised promotion.

The complainant stated that it could not be excluded that the individual had not provided the information on the product to patients using Innohep and therefore the minimum adverse events wording for patients using a medicine needed to be included.

The complainant alleged that the advertisement had not been certified as it did not meet the Code requirements. Promotional material about prescription only medicines on the internet must comply with all aspects of the Code which the advertisement did not. The complainant alleged that the information about Innohep was not balanced to the public, it did not contain any information on adverse events or safety.

The complainant further noted that Innohep was not indicated for 'extended use in treatment in general surgery - upper/lower GI, urology and hepato-biliary' according to the Innohep summary of product characteristics (SPC) and therefore the individual had admitted to promoting a medicine in a manner not in accordance with the SPC.

The complainant noted that the individual had also stated that while in that role, he/she had 'Initiated a project with haematologist and clinics lead for Obs&Gynae at [two named hospitals] on benefits of Innohep with positive outcome with guideline development'. The only information in the SPC that the complainant could find that might be relevant to that group was Section 4.6 but what had been claimed in the LinkedIn profile ('benefits of Innohep') required comparator studies or supportive evidence beyond the SPC and the 'benefits of Innohep' in obstetrics and gynaecology was unreferenced, unqualified and was a hanging claim. The complainant alleged that the individual in question had promoted Innohep in a manner not in accordance with its SPC.

The complainant stated that the individual was currently listed as an employee in the medical department at Leo according to LinkedIn. In that role the individual stated he/she 'Fully supported the launch of Picato ingenol mebuate for actinic keratosis'. The complainant thus noted that that section of the profile named Picato as a brand, stated its non-proprietary name and therapeutic area (actinic keratosis) and so advertised to the public. The complainant alleged a breach of the Code and of the law.

Through the individual's LinkedIn connections to health professionals, he/she had also promoted Picato, a prescription only medicine, to health professionals. The advertisement to health professionals did not contain a clear link to the location of the prescribing information, a black triangle, a date of revision or prescribing information. The complainant alleged multiple breaches of the Code.

The complainant stated that there was no information for health professionals that the profile contained promotional information before they read it, and therefore they would only realise that it was promotional when they read it, therefore the information was disguised promotion.

The complainant stated that it could not be excluded that the individual had not provided the information on Picato to patients using this medicine and therefore the minimum adverse events wording for patients using a medicine needed to be included. The complainant stated that he/she was a patient who had used Picato.

The complainant alleged that the advertisement had not been certified as it did not meet the requirements of the Code and noted that promotional material about prescription only medicines on the internet must comply with all aspects of the Code which the advertisement in question did not. The information about Picato was not balanced to the public, it did not contain any information on adverse events or safety. Picato was not indicated for actinic keratosis - the SPC said 'non hyperkeratotic, non hypertrophic' actinic keratosis, therefore the complainant alleged that the individual had admitted to promoting a medicine in a manner not in accordance with the SPC.

The complainant noted that at the start of the individual's profile within his/her role, he/she established that his/her responsibility included thrombosis and dermatology. The complainant stated that during the individual's tenure in that role, Leo promoted Dovobet ointment, Picato, Innohep, Kyntheum, Protopic, Dovobet Gel, Dovonex Ointment and Enstilar. The complainant noted that the individual had stated in his/her LinkedIn profile that as part of his/her role he/she would 'Educate and train health professionals in response to unsolicited requests, in the safe and appropriate use of company products particularly in off licence situations where the clinician had already decided to use the product either in a face to face or meeting situation'. The complainant stated that that raised a number of concerns:

- Leo Pharma was a pharmaceutical company and the 'company products' included prescription only medicines as listed above. The use of the word 'safe' was never appropriate in the discussion of any prescription only medicine
- The individual had a promotional role and had here admitted to promoting in off-licence situations and training health professionals in off-licence use.

The complainant stated that many of these points were also repeated under 'Achievements' in the profile and the individual additionally stated 'Supported the launch of its new product for Actin Keratosis'. The complainant alleged that that statement was made to elicit interest in a new product from Leo for actinic keratosis and teased both the public and health professionals on that development.

The complainant noted that 'new' could only be used 12 months from launch and Picato was on the market for many years.

The complainant stated that it was sustained behaviour like this which tarred other pharmaceutical employees when interacting with health professionals and customers.

When writing to Leo, the Authority asked it to consider the requirements of Clauses 2, 3.2, 4.1, 4.3, 4.4, 4.8, 4.10, 7.2, 7.3, 7.9, 7.11, 9.1, 12.1, 14.1, 14.3, 15.2, 15.9, 18.1, 19.1, 26.1, 26.2 and 26.3 of the Code.

RESPONSE

Leo noted that the complainant focused on the LinkedIn profile of one of its employees. The employee had held promotional and non-promotional roles at Leo. The allegations covered a wide range of comments made on the employees LinkedIn profile, including questioning his/her qualifications, allegations of promotion to the public, disguised and inappropriate promotion to health professionals and specific allegations regarding the suitability and compliance of certain activities and projects throughout his/her career at Leo.

Leo noted that the screengrab of the LinkedIn profile provided to it was dated from 23 February 2021. Leo confirmed that the profile wording had not changed as of the date of writing this response.

Although the Authority had not disclosed the complainant's identity, and of course Leo acknowledged his/her right to anonymity, the employee in question was very clear in his/her belief that he/she knew who had made the complaint. It was interesting to note that if Leo's suspicions were correct, the [named] complainant had worked at Leo and was still working in the pharmaceutical industry [company and role stated]. If he/she was the complainant, he/she had clearly misled the PMCPA in the course of his/her complaint and follow-up correspondence, in which he/she claimed to be a retired representative. More concerningly, there had been no attempt to achieve resolution through inter-company dialogue, and at no point had the complaint been voiced directly to Leo. This complaint appeared to have resulted from a difficult working relationship. Leo stated that it was disappointing that some individuals chose to use complaints to the PMCPA as a method of venting their anger. However, the complainant had raised some valid concerns that warranted a full and transparent response.

Leo noted that the first allegation was that the Leo employee had never held the qualification listed. That was incorrect. The employee in question provided evidence to Leo at the commencement of his/her employment (copy provided). The authenticity had been confirmed with the educational institution. Leo considered that this was an unusual, unexpected and malicious allegation in the context of a complaint to the PMCPA and was entirely without foundation. Therefore, there had clearly been no breach of Clause 15.2.

The remainder of the complaint addressed the content of the Leo employee's LinkedIn profile. Leo noted that personal LinkedIn profiles were generally used as a form of online curriculum vitae (CV) for the benefit of recruiters and as such, details of specific successes in current and previous roles would be expected in most cases. The LinkedIn profile in question contained the sort of information someone would expect to see in a CV and was clearly intended with that purpose in mind, rather than to promote a specific company, product or indication. In support of that, Leo provided a copy of the employee's CV (at a date which reflected the timing most closely related to the majority of the allegations) which clearly demonstrated that the wording was 'copy-pasted' from the document to the LinkedIn profile.

Additionally, Leo noted that there was case precedent with regards to the use of product names on non-promotional material, including business cards (Case AUTH/2777/7/15) and websites (Case AUTH/3270/10/19). It was clear in this particular case that the wording used in the LinkedIn profile mirrored that on the employee's CV and therefore the intent was entirely non-promotional, as it was essentially used to highlight the employee's historical career successes.

Leo also noted that as LinkedIn profiles were personal, employees had an expectation of being able to include relevant information in their CV, which provided potential recruiters with enough information about a candidate's relevant experience to be considered for another role. In the highly technical world of the pharmaceutical industry, experience with a relevant medicine or in a particular disease area might well be the facts which triggered an approach from a recruiter. Leo asked the Panel to keep that in mind in its consideration of the case.

Innohep – switch services

Leo stated that in its view, the wording in the LinkedIn profile of 'Gained a complete switch to Innohep...' did not imply that a switch service had been supported, facilitated or utilised. The Leo employee was approached by a clinical pharmacist at [a named hospital] who wanted to place Innohep (tinzaparin sodium), an anti-thrombotic, on the hospital formulary. At that particular hospital, there was only one anti-thrombotic on formulary at any one time and so there was, in effect, an 'all-or-nothing' situation regarding positioning of medicines. Having been approached by the clinical pharmacist and engaged in discussions with relevant health professionals, the formulary positioning was changed by the hospital, effectively 'switching' the current anti-thrombotic to Innohep. Since activity to drive formulary change was entirely appropriate under the Code, in Leo's view this was clearly not a breach of the Code. Although the use of the word 'switch' might be misjudged, the activity itself and the implication in the LinkedIn profile was within the spirit of the Code. Therefore, Leo denied breaches of Clauses 9.1, 15.2, 18.1, 19.1 or 2.

Innohep – use of the medicine

Leo reiterated that there was case precedent that using the name of a medicine alone was not necessarily promotional. In addition, the use of 'Thrombosis' in the job title clearly related to a therapeutic area and not a medicine indication, as demonstrated by other similar job titles used

within Leo and elsewhere. With that in mind, it was difficult to see how the use of 'Thrombosis' in the job title could be interpreted as a specific product indication for any particular medicine. Leo submitted that it was clear that the intent was entirely non-promotional, mirroring the wording used in the individual's CV, and with no product claims. Furthermore, the information appeared in the 'Experience' section of the individual's LinkedIn profile. As such, someone would need to be actively looking for his/her work experience, presumably for the purposes of recruitment or associated activities. As such Leo did not consider that the LinkedIn profile constituted advertising to the public or to health professionals. Therefore, the requirements for prescribing information, non-proprietary name, date of preparation, safety information and certification did not apply. Leo denied breaches of Clauses 9.1, 26.1, 2, 4.1, 4.3, 4.4, 4.8, 12.1, 26.3, 14.1, 14.3 or 26.2.

Leo considered that the allegation that Innohep was not indicated for extended use in treatment in general surgery was based on a statement in the individual's LinkedIn profile, ie '...to extend the use of Innohep in treatment in General Surgery'. Leo considered that it was very clear that these were entirely different, and it would be very difficult to confuse 'extended use', which related to duration of treatment with 'extend the use', which clearly indicated a desire to increase usage of a medicine in a given therapy area/account. There was no implied claim that Innohep could, or should, be used 'for extended use in treatment in general surgery'. Leo denied breaches of Clauses 3.2, 9.1, 15.9 and 2.

Leo submitted that the allegation regarding discussing Innohep in an obstetrics and gynaecology setting actually took place whilst in a role within the medical department rather than as a representative, as erroneously indicated in his/her LinkedIn profile. The project in question was initiated by the haematologist and the obstetrics and gynaecology clinic lead at [two named hospitals], and he/she specifically requested more information on Innohep usage in obstetrics and gynaecology setting. Since that was a reactive request, and the employee was at that time employed within the medical department, it was entirely appropriate for him/her to respond to the request and act as a medical information service. However, Leo accepted that the inaccuracy of the LinkedIn profile with regards to that point, and the wording used was misleading and implied that an activity took place that was not in accordance with the Code; the company would ask the employee to ensure the LinkedIn profile was amended to more accurately reflect what took place. Leo denied breaches of Clauses 3.2, 7.2, 7.3, 9.1, 15.9 and 2.

Picato – use of the medicine

Leo submitted that this allegation stemmed from the fact that the Leo employee had referred to a product he/she had worked on (Picato) alongside an indication (actinic keratosis). However, it was clear that the wording used regarding the employee's historical work on Picato was taken directly from his/her CV. As previously stated, that implied that the intention was not to promote, but to provide an online CV for the purposes of gaining future employment. In addition, the section was not provided 'on the front page' of the profile – readers would need to look through the profile to access that information, which further substantiated the purpose not being to promote a product in a given therapy area, but to highlight areas of employment success.

In addition, Leo noted that the EU marketing authorisation for Picato was withdrawn on 11 February 2020. It was therefore not available for prescription anywhere in the EU, and there were no plans to re-licence the product. With that in mind, the allegation that the Leo employee 'was advertising to the public' was incorrect – the product was unavailable and therefore could

not be promoted. Taking those facts into account, this was clearly not promoting to the public or to health professionals and Leo refuted the complainant's allegations and denied breaches of Clauses 9.1, 26.1, 2, 12.1, 26.3, 14.1, 14.3, 26.2, 3.2 or 15.9.

Employee role

Leo noted that the first allegation regarding the role description centred around the use of the word 'safe'. The Code was very clear that 'safe' must not be used without clarification. Leo fully agreed that 'safe' should never be used when discussing the safety profile of medicines. However, Leo argued that 'safe and effective use' when describing the broad responsibilities of a role was not the same as implying a specific product or class of products was, in itself, inherently 'safe'. In essence, 'safe and effective use' implied selecting the right patient, understanding the indications, contraindications, safety profile and weighing up the risk/benefit profile for a medicine for a specific patient, whereas 'safe', used in the context of a claim about a medicine, was clearly misleading and related directly to the safety profile of that medicine.

Leo stated that it found the allegation regarding the individual having a promotional role rather confusing, as the Leo employee had never conducted a hybrid promotional/non-promotional role. Nevertheless, even if the role had been promotional, Leo understood that that would not preclude the employee from acting in an appropriate, reactive, non-promotional manner through the provision of information relating to off-licence usage, provided that was unsolicited and otherwise compliant with the Code in terms of responding to specific requests for information. It was important and appropriate for pharmaceutical companies to respond to questions about the use of their medicines, and so responses to enquiries were exempt from the Code, provided the answer was factual and limited to answering the original question, and Leo's employees in the medical department were instructed accordingly. Leo denied breaches of Clauses 3.2, 7.9, 9.1, 15.2 and 2.

New product

Leo stated that whilst it accepted and agreed that 'new' could only be used for the first 12 months after the launch of a product, it refuted the allegation that the use of the word in the individual's LinkedIn profile was a breach of the Code. Leo submitted that given the use of 'supported' in 'Supported the launch of Leo's new product for Actin Keratosis', the sentence in the LinkedIn profile was clearly set in the past tense. As such, that put 'new' in an historical context. It was entirely appropriate in the context of listing prior experience, to highlight work on a product that was 'new' at the time, and Leo did not consider that this statement misleadingly implied that the product was still new. In addition, Leo noted that in that section of the profile (Achievements), the name of the specific medicine was not mentioned. Finally, Leo reiterated that the EMA withdrew the marketing authorisation for Picato in February 2020, and, as such, the product was no longer available to be prescribed. Leo denied breaches of Clauses 7.11, 9.1 and 15.2.

In conclusion, Leo considered that an individual's LinkedIn profile most often reflected the content of their CV, as demonstrated clearly in this case. As such, it was not unexpected that individuals would highlight their prior career successes and would disclose relevant information to put those successes in context. Leo considered that naming individual medicines in that context did not necessarily constitute promotion, although accepted that care should be taken to avoid making any claims or comparisons which could in themselves make the material promotional. However, in this particular case, Leo did not see anything that could be deemed promotional. In addition, although some of the wording used in the profile might have been

poorly chosen in hindsight, Leo considered that it was very clear throughout, that the activities underlying the statements were entirely aligned with the letter and spirit of the Code.

Leo submitted that the individual in question had been an exemplar employee throughout his/her career in the medical department and had never before received any allegations of Code breaches.

PANEL RULING

The Panel noted that the complainant's allegations were in relation to information on the personal LinkedIn account of a Leo employee.

The Panel noted that LinkedIn was different to some other social media platforms in that it was a business and employment-orientated network and was primarily, although not exclusively, associated with an individual's professional heritage and current employment and interests; its application was not limited to the pharmaceutical industry or to health care. In the Panel's view, it was of course not unacceptable for company employees to use personal LinkedIn accounts; the Code would not automatically apply to all activity on a personal account. The Panel noted that compliance challenges arose when the personal use of social media by pharmaceutical company employees overlapped with their professional responsibilities or the interests of the company.

The Panel considered that an individual's LinkedIn profile page was visible to his/her connections and potentially to others outside his/her network depending on the individual's security settings. Company employees should assume that information on their LinkedIn profiles would therefore, potentially, be visible to both those who were health professionals or other relevant decision makers and those who were members of the public. In that regard, it was imperative that they acted with extreme caution when using all social media platforms, including LinkedIn, to discuss or highlight issues which impinged on their professional role or the commercial/research interests of their company. Whether the Code applied would be determined on a case-by-case basis, taking into account all of the circumstances including, among other things, content and distribution of the material. If an employee's personal use of social media was found to be in scope of the Code, the company would be held responsible. The Panel considered that companies should assume that the Code would apply to all work-related, personal LinkedIn posts/activity by their employees unless, for very clear reasons, it could be shown otherwise.

The Panel noted the complainant's submission that the employee in question's LinkedIn account was publicly available, with open privacy settings, and that the employee's connections included both health professionals and members of the public. The Panel noted that Leo made no submission in that regard and considered, on the balance of probabilities, that both health professionals and members of the public could view the employee's LinkedIn profile.

The Panel noted Leo's submission that personal LinkedIn profiles were generally used as a form of online curriculum vitae (CV) for the benefit of recruiters and as such, details of specific successes in current and previous roles would be expected in most cases. In the Panel's view, regardless of how an individual chose to use a social media platform, the content, if within the scope of the Code, had to comply with it; the audience was an important consideration in that regard.

Qualification

The Panel noted Leo's submission that the employee had provided evidence of his/her qualification to Leo at the commencement of his/her employment and the authenticity of the certificate had been confirmed with the educational institution. The Panel considered that the complainant had not established that the employee had wrongly referred to having the qualification and no breach of Clause 15.2 was ruled.

Innohep

The Panel noted the complainant's allegation that the statement 'Gained a complete switch to Innohep at [named hospital] after numerous failed attempts over 3 years, business worth £150k', under the heading of thrombosis representative, which was the employee's previously held role at Leo, meant that the individual had facilitated a switch service which was prohibited by the Code.

The Panel noted that the supplementary information to Clause 19.1 Switch and Therapy Review Programmes of the 2019 Code stated:

'Clauses 18.1 and 19.1 prohibit switch services paid for or facilitated directly or indirectly by a pharmaceutical company whereby a patient's medicine is simply changed to another. For example it would be unacceptable if patients on medicine A were changed to medicine B, without any clinical assessment, at the expense of a pharmaceutical company promoting either or both medicines. It would be acceptable for a company to promote a simple switch from one product to another but not to assist a health professional in implementing that switch even if assistance was by means of a third party such as a sponsored nurse or similar. Such arrangements are seen as companies in effect paying for prescriptions and are unacceptable.'

The Panel noted Leo's submission that the employee in question was approached by a clinical pharmacist at the named hospital who wanted to place Innohep on the hospital formulary and following discussions with relevant health professionals, the formulary positioning was changed by the hospital, effectively 'switching' the current anti-thrombotic that was on the formulary to Innohep.

The Panel was concerned about the impression given by the statement with regard to Leo's role in relation to the switch and queried Leo's submission that the employee was approached by the hospital given that the employee stated that he/she had managed to gain a complete switch to Innohep 'after numerous failed attempts over 3 years'. Nonetheless, the Panel considered that the complainant had not discharged his/her burden of proof that Leo had facilitated a switch service as alleged and the Panel, therefore, ruled no breach of Clauses 9.1, 15.2, 18.1, 19.1 and 2 in that regard.

In relation to the allegation that information within the profile advertised Innohep to the public, the Panel noted that within the 'Experience' section of the employee's profile, under the heading of thrombosis representative, and in relation to an activity at a named hospital, he/she had referred to Innohep and '…treatment in general surgery - upper/lower GI, urology and hepatobiliary'. The Panel further noted Leo's submission that to view this information within a user's profile, someone would need to look at the user's work experience, presumably for the purposes of recruitment. In the Panel's view, LinkedIn was not solely a platform for recruitment; it was a social media platform with a varied audience.

The Panel noted Leo's submission that thrombosis in the job title related to a therapeutic area and not a medicine indication. The Panel further noted that Innohep 10,000 IU/ml was indicated for prophylaxis of venous thromboembolism in adult patients undergoing surgery, particularly orthopaedic, general or oncological surgery; prophylaxis of venous thromboembolism in non-surgical adult patients immobilised due to acute medical illness including: acute heart failure, acute respiratory failure, severe infections, active cancer, as well as exacerbation of rheumatic diseases; and prevention of clotting in extracorporeal circuits during haemodialysis and haemofiltration in adults. Innohep 20,000 IU/ml was indicated for treatment of venous thrombosis and thromboembolic disease including deep vein thrombosis and pulmonary embolus in adults and extended treatment of venous thromboembolism and prevention of recurrences in adult patients with active cancer.

On the evidence before it, the Panel noted that the employee's profile was publicly available and furthermore the employee's connections likely included members of the public who were not associated with recruitment. The Panel considered that the information within the employee's profile, which included reference to Innohep, thrombosis and surgery, was such that Innohep, a prescription only medicine, had been advertised to the public and a breach of Clause 26.1 was ruled. The Panel considered that high standards had not been maintained in that regard and a breach of Clause 9.1 was ruled.

The Panel did not consider that the specific circumstances warranted a breach of Clause 2 which was a sign of particular censure and was reserved for such use and no breach was ruled in that regard.

The Panel further noted the complainant's allegation that the information about Innohep to the public was not balanced and that it did not contain any information on adverse events or safety. The Panel noted that Clause 26.2 stated, *inter alia*, that information about prescription only medicines which is made available to the public either directly or indirectly must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product. The Panel noted that it was not necessarily a breach of the Code for material for the public to not include information about adverse events or safety provided that it was not misleading in that regard. The Panel did not consider that the complainant had established that the lack of safety information about Innohep in the employee's LinkedIn profile meant that the information about Innohep was misleading with regard to the safety of the product and therefore no breach of Clause 26.2 was ruled.

The Panel did not consider that the information was intended for patients taking Innohep and therefore the reporting of side effects statement was not required; the Panel ruled no breach of Clause 26.3 in that regard.

The Panel did not consider that the information in question was covered by material that required certification under Clause 14.3 and therefore no breach of Clause 14.3 was ruled.

In relation to the allegation that Innohep was promoted to health professionals, without the obligatory information as required by the Code, the Panel considered that, given the employee's current and previous roles at Leo, his/her connections likely included health professionals, some of which would have, on the balance of probabilities, viewed the employee's profile. The Panel noted the statements on the employee's profile in relation to Innohep, including references to thrombosis, surgery and a statement regarding a project that he/she had initiated '...on benefits of Innohep...'. In the Panel's view, such information about prescription only medicines on a user profile, which would likely be read by health professionals that the employee had interacted

with in his/her role at Leo, was promotional. In the Panel's view, Innohep had been promoted to health professionals without the provision of prescribing information, the non-proprietary name or the date which the material was drawn up or last revised and a breach of Clauses 4.1, 4.3, 4.4 and 4.8 were ruled. Further, the material had not been certified and a breach of Clause 14.1 was therefore ruled.

The Panel noted the complainant's allegation that there was no information for health professionals that the LinkedIn profile in question contained promotional information prior to reading it. The Panel considered that promotional material did not need to be labelled as such, however, it must not be disguised. The Panel noted that the LinkedIn profile in question was clearly labelled as that of a Leo employee and included positive statements about Leo's medicines. In the Panel's view, the content within the user's profile was clearly promotional. The Panel did not consider that the complainant had established that the promotion of Innohep was disguised and no breach of Clause 12.1 was ruled.

With regard to the employee's statement, 'Collaborated with pharmacist at [named hospital] to extend the use of Innohep in treatment in general surgery – upper/lower GI, urology and hepatobiliary', the complainant noted that according to its SPC, Innohep was not indicated for 'extended use in treatment in general surgery - upper/lower GI, urology and hepato-biliary' and alleged therefore the individual had admitted to promoting Innohep in a manner not in accordance with its SPC. The Panel noted Leo's submission that it would be very difficult to confuse 'extended use', which related to duration of treatment with 'extend the use', which clearly indicated a desire to increase usage of a medicine in a given therapy area/account; there was no implied claim that Innohep could, or should, be used 'for extended use in treatment in general surgery'. The Panel did not consider that the complainant had established that the employee's statement had promoted Innohep in a manner that was inconsistent with its SPC. The Panel therefore ruled no breach of Clauses 3.2, 9.1, 15.9 and 2 in that regard.

In relation to the statement, 'Initiated a project with haematologist and clinics lead for Obs&Gynae at [two named hospitals] on benefits of Innohep with positive outcome with guideline development', the Panel noted Leo's submission that the project in question was initiated by the haematologist and the obstetrics and gynaecology clinic lead who had specifically requested more information on Innohep usage in the obstetrics and gynaecology setting. The Panel further noted Leo's submission that it was appropriate for the employee who was an employee in the medical department at the time to respond to the reactive request and act as a medical information service, however, Leo accepted that the inaccuracy of the LinkedIn profile with regards to that point, and the wording used, was misleading and implied that an activity had taken place that was not in accordance with the Code. The Panel noted Leo's submission that it would ask the employee to ensure the LinkedIn profile was amended to more accurately reflect what had taken place.

Whilst the Panel was extremely concerned about the inaccuracy of the statement in terms of who had initiated the project, the Panel considered that the complainant had not established that the claim 'benefits of Innohep' in the context of the statement in question was unqualified or a hanging comparison; nor had the complainant established that the employee had promoted Innohep in a manner inconsistent with its SPC. The Panel therefore ruled no breach of Clauses 3.2, 7.2, 7.3, 9.1, 15.9 and 2 in that regard.

Picato

In relation to the statements about Picato on the employee in question's LinkedIn profile page, the Panel noted Leo's submission that the EU marketing authorisation for Picato was withdrawn on 11 February 2020 and it was therefore currently not available for prescription anywhere in the EU, and there were no plans to re-licence the product.

The Panel had no information before it as to when the information about Picato was first published on the employee's profile and therefore if Picato was classified as a prescription only medicine at that time. However, the Panel noted that Picato was not a prescription only medicine at the time the complainant made his/her complaint and therefore on that narrow technical point, the Panel ruled no breach of Clauses 2, 9.1, 3.2, 26.1, 26.2 and 26.3 in that regard. As Picato was not licensed or available to prescribe at the time the complainant made his/her complaint, on that narrow technical point, the Panel further ruled no breach of Clauses 4.1, 4.3, 4.4, 4.8, 4.10, 12.1 and 14.1.

The Panel did not consider that the information in question was covered by material that required certification under Clause 14.3 and therefore no breach of Clause 14.3 was ruled.

Clause 15.9 referred to briefing material; the Panel did not consider that there had been an allegation made in relation to briefing material and therefore no breach of Clause 15.9 was ruled.

The Panel noted its rulings above and consequently ruled no breach of Clauses 9.1 and 2.

Description of employee's role

The Panel noted the allegation about the use of the word safe in the following statement within the employee's profile:

'Educate and train healthcare professionals in response to unsolicited requests, in the safe and appropriate use of company products particularly in off licence situations where the clinician has already decided to use the product either in a face to face or meeting situation.'

The Panel noted that a very similar statement appeared in the job description provided by Leo and it appeared that the employee in question had taken this statement from his/her job description and added it to LinkedIn. The Panel considered that reference to the safe and appropriate use of Leo medicines might be seen as a claim that such medicines were safe. Although there might be a difference between the medicine being safe and the safe use of that medicine, Clause 7.9 stated that the word 'safe' must not be used without qualification. Clause 7 was not limited to promotional material. The Panel was further concerned that the term 'safe' was used in reference to off licence use. The Panel considered that, on balance, the reference to the safe use of Leo's medicines did not meet the requirements of Clause 7.9 and a breach was ruled.

The Panel considered that high standards had not been maintained in that regard and a breach of Clause 9.1 was ruled.

The Panel noted Leo's submission that its employee had never conducted a hybrid promotional/non-promotional role and even if the role had been promotional, Leo understood that that would not preclude the employee from acting in an appropriate, reactive, non-promotional manner through the provision of information relating to off-licence usage, provided

that was unsolicited and otherwise compliant with the Code in terms of responding to specific requests for information and provided the answer was factual and limited to answering the original question. The Panel did not consider that the complainant had established that the employee's statement amounted to an admission to promoting off-licence as alleged. No breach of Clauses 3.2 and 15.2 were ruled in that regard.

The Panel did not consider that the specific circumstances warranted a breach of Clause 2 which was a sign of particular censure and was reserved for such use and no breach was ruled in that regard.

New product

The Panel noted the complainant's allegation that the statement 'Supported the launch of its new product for Actin Keratosis', under 'Achievements' on the employee's profile, was made to elicit interest in a new product and teased both the public and health professionals; the complainant also alleged that 'new' could only be used 12 months from launch and Picato was on the market for many years.

The Panel noted that Clause 7.11 stated that the word 'new' must not be used to describe any product or presentation which has been generally available, or any therapeutic indication which has been promoted, for more than twelve months in the UK.

The Panel noted Leo's submission that in the 'Achievements' section of the employee's profile, the name of the specific drug was not mentioned and as noted above the marketing authorisation for Picato was withdrawn on 11 February 2020. Furthermore, the Panel considered that the statement was written in the past tense. The Panel considered that the complainant had not established that the use of the word new in this context was in breach of Clause 7.11 and no breach was ruled. Consequently, no breach of Clauses 9.1 and 15.2 were ruled in that regard.

APPEAL FROM LEO

Leo appealed the Panel's rulings of breaches of Clauses 4.1, 4.3, 4.4, 4.8, 7.9, 9.1(x2), 14.1 and 26.1 of the Code.

Leo submitted that, firstly however, it wished to point out that this was one of 13 complaints received in a 12-month period, most of which it believed to be from the same complainant. Leo did not know if this was the case in this instance, though the depth of the complaint, as with most others received in this time period, would suggest this. Leo reminded the Appeal Board that the complainant in this case, targeted a specific Leo employee, and made a wholly spurious and false allegation regarding his/her qualifications. Specifically, the complainant alleged that the employee had falsified their qualification. This allegation was easily proven to be untrue, but Leo mentioned it here to highlight the motivations, as well as the lack of common decency or integrity on the part of the complainant.

Background to LinkedIn

Leo submitted that LinkedIn was a well-established, online professional networking site, which had been in operation for nearly 20 years, since 2002. Signed-up users created a personal profile, essentially an online CV, which contained reverse chronological details of work experience and education. The main purpose and function of this approach, and of LinkedIn as

a whole, was recruitment by allowing employers and potential employees to connect. Such connections were made when one party approved the request to connect from another party. Many human resources departments sourcing candidates increasingly relied on LinkedIn, and the employee profiles created by users, to search for, and shortlist, candidates. Some large professional recruitment companies now relied on LinkedIn completely to find candidates for clients. A full screenshot of the landing page of LinkedIn.com, which showed that the emphasis was quite clearly on finding a job, was provided. Leo provided a screenshot of LinkedIn's company profile on LinkedIn, which, in the Overview 'About us' section, stated:

'With millions of jobs on LinkedIn, find one meant for you. #InItTogether

Founded in 2003, LinkedIn connects the world's professionals to make them more productive and successful. With more than 756 million members worldwide, including executives from every Fortune 500 company, LinkedIn is the world's largest professional network. The company has a diversified business model with revenue coming from Talent Solutions, Marketing Solutions, Sales Solutions and Premium Subscriptions products. Headquartered in Silicon Valley, LinkedIn has offices across the globe.

Website

https://careers.linkedin.com.'

Leo submitted that this demonstrated that the raison d'être of LinkedIn was recruitment. Leo asked the Appeal Board to consider this fact in its assessment of this case. Leo agreed that the fact that LinkedIn, with its growth in user base, now also fulfilled a function as a professional network was of relevance. However, the role of LinkedIn as a recruitment tool must be separated out from its growing role as a professional network in terms of how it was used, and what aspects of a user's profile were seen, and by whom. While 'posts' made by individuals and companies on LinkedIn might, in some circumstances, be treated with similar criterion, one would apply to a social network such as Facebook or Twitter, this categorisation should be kept distinct from the information, the CV, a user had as part of their LinkedIn profile, and which served an entirely different purpose, namely, that of recruitment. Leo referred to Case AUTH/3287/12/19 where a UCB employee had stated their job title, which included an investigational compound along with proposed indication. Leo's understanding of that case was that this information was in the main job title, and therefore, instantly visible to anyone viewing that employee's name alone, regardless of intent, and regardless of whether a LinkedIn user chose to actually visit the UCB employee's LinkedIn page. Leo asked the Appeal Board to bear in mind the important distinction between that case and this one. When it came, however, to the specifics of the detailed CV information contained within a LinkedIn user profile, the intended primary audience for this, recruiters and company human resources departments, was, in Leo's opinion, fundamental to the ruling on this case. Leo referred to the recent outcome of Case AUTH/3397/10/20 where the Panel ruled that whilst one of the interviews in that case referred to use of medicines in the UK, the publication of the interview on a website for senior pharmaceutical executives globally meant that the interview was not advertising a prescription only medicine to UK health professionals, other relevant decision makers or members of the public. The Panel therefore ruled no breaches of the Code. Leo considered a similar principle to apply here – the information contained in a LinkedIn user profile was intended for a specific subset of the public, ie recruiters, and, moreover, as LinkedIn required users to sign up for the service, the additional reach of content on LinkedIn was even more narrow than content simply available on an open-access website.

Candidate search on LinkedIn

Leo referred to a typical recruiter view on LinkedIn. The left-hand side of the screenshot showed the search criteria, a recruiter, including those in company human resources departments, used to search for candidates on LinkedIn. In the 'Skills and Assessments' field (red box, below), a recruiter could type in key words to look for candidates. These key words would typically be contained in the users 'Experience' (the content of which was the subject of the complaint here) and 'Education'. If a company was looking for a particular profile, which might include having worked in a particular therapy area, or with a particular medicine, or both, a recruiter could type in any of these key words in the 'Skills and Assessments' field on the left and identify suitable candidates. It was very common for pharmaceutical companies to source candidates based on their prior experience working in a particular therapy area and/or on a particular medicine, which might well include competitor companies or medicines. Therefore, the more information a candidate included in the 'Experience' section of their LinkedIn profile, the greater the likelihood of a positive search result, depending on the search terms being used by a recruiter.

Leo submitted that, therefore, an unreasonable restriction placed on the profile/CV an individual could upload to LinkedIn, which was of interest only to recruiters rather than the general public or health professionals, would represent a situation unique to UK pharmaceutical company candidates, and have the potential to reduce their visibility to recruiters. The Panel ruling had the potential to be an important case precedent resulting in disadvantaging job candidates, which should be given due consideration and thought by the Appeal Board. Whilst Leo was not proposing an 'anything goes' situation simply because it was contained in a CV, it did not remotely consider that the specifics of this case represented an irresponsible use of LinkedIn, the reasons for which it set out, below.

Innohep – allegations regarding promotional wording in Thrombosis Account Manager role

Leo submitted that the licensed indication of Innohep (tinzaparin sodium) 10000iu/ml was:

'Prophylaxis of venous thromboembolism in adult patients undergoing surgery, particularly orthopaedic, general or oncological surgery.

Prophylaxis of venous thromboembolism in non-surgical adult patients immobilised due to acute medical illness including: acute heart failure, acute respiratory failure, severe infections, active cancer, as well as exacerbation of rheumatic diseases.

Prevention of clotting in extracorporeal circuits during haemodialysis and haemofiltration in adults.

The licensed indication of Innohep (tinzaparin sodium) 20000 iu/ml was:

'Treatment of venous thrombosis and thromboembolic disease including deep vein thrombosis and pulmonary embolus in adults.

Extended treatment of venous thromboembolism and prevention of recurrences in adult patients with active cancer.

For some patients with pulmonary embolism (e.g. those with severe haemodynamic instability) alternative treatment, such as surgery or thrombolysis, may be indicated.'

Leo described the first extract from the employee's CV, which was placed on LinkedIn in the 'Experience' section, and which was ruled in breach of the Code.

Leo submitted that in its original response, it argued that there was existing case precedent that using the name of a medicine alone was not necessarily promotional. In this context, it was clear that the intent was entirely non-promotional, mirroring the wording used in the individual's CV, and with no product claims. Again, this information appeared in the 'Experience' section of the individual's LinkedIn profile. As such, someone would need to be actively looking for their work experience, presumably for the purposes of recruitment or associated activities. This information was not immediately visible when casually browsing user profile – a user had to actively select the user profile to see this information, as well as 'expand' a collapsed experience list.

Leo also argued that the use of the word 'Thrombosis' in the job title clearly related to a therapeutic area and not a medicine indication, as demonstrated by other similar job titles used within Leo and elsewhere.

Leo noted the Panel's view that the information within the employee's profile, which included reference to Innohep, thrombosis and surgery, was such that Innohep, a prescription only medicine, had been advertised to the public and a breach of Clause 26.1 was ruled, as well as associated breaches of Clauses 9.1, 14.1, 4.3, 4.4 and 4.8.

Leo strongly disagreed with the Panel's ruling that the references in this employee's CV to Innohep, thrombosis and surgery constituted advertising to the public, whether in intent, or execution. Leo had clearly stated the licensed indications for Innohep, above. Nowhere in the job experience were Innohep and thrombosis directly juxtaposed. Nor did the licensed indication for Innohep refer to treatment in surgery. It was true to say that Innohep was licensed for prophylaxis of venous thromboembolism in adult patients undergoing surgery, including General Surgery. With regard to treatment doses of Innohep for venous thrombosis or thromboembolic disease, there was no reference to surgery in the wording of the licensed indication, though of course, venous thromboembolism could occur after prolonged immobilisation, including after a surgical procedure. In any case, Innohep was a medicine used for either prophylaxis, ie prevention of, or treatment of, established, venous thromboembolism. It was not a medicine indicated for surgery, general or otherwise, per se. The term 'thrombosis' itself was a general term, referring to a blood clot that could occur in any part of the body, due to a multitude of causes. Thrombosis (blood clots which block blood vessels) could be arterial or venous, examples of which included a deep vein thrombosis, a pulmonary embolism, an ischaemic stroke, a myocardial infarction and acute limb ischaemia, to name but a few. Therefore, Leo failed to understand how the use of this general term, not even juxtaposed with Innohep, constituted promotion to the public, whether surgery was mentioned or not. Leo accordingly appealed a breach of Clause 26.1, and associated breaches.

Leo submitted that the associated beaches of Clauses 14.1, 4.1, 4.3, 4.4 and 4.8 were wholly inappropriate in this instance. This matter was regarding an employee profile on LinkedIn, again, an online CV for the purposes of recruitment. It would be wholly inappropriate, indeed perverse, for such an item to be certified or to include prescribing information or other mandatory information on it, and Leo could not conceive of any scenario where this would be appropriate.

Employee's role and use of the word 'safe'

Leo submitted that the wording in question, again, in the 'Experience' section of the employees profile, was directly cut and pasted from the employees CV.

The wording in Clause 7.9 of the 2019 Code stated:

"...The word 'safe' must not be used without qualification."

Leo submitted that, therefore, this clause did not appear to prohibit the use of the word 'safe', or associated grammatical derivatives of the word, rather that, if used, then it must be qualified. The Panel considered that reference to the safe and appropriate use of Leo medicines might be seen as a claim that such medicines were safe. Leo, again, disagreed with this assessment. The qualifier in this situation regarding the use of the word 'safe' was clearly with regard to the role of the employee in education and training. It was making the point that with regard to answering unsolicited enquiries on company products, whether within licence or off-licence, there would be safety considerations which health professionals needed to be educated and trained on. The wording referred to 'safe use of' - it was not referring to a 'safe drug'. In this context, the education provided by the employee included training on injection technique -Innohep (tinzaparin sodium) was designed to be administered via subcutaneous injection. however, in some instances, this was known to be erroneously administered intramuscularly. There was definitely a 'safe' methodology when it came to injection of any medicine, and it was largely this to which 'safe use of' referred to. This was no way, intentionally or unintentionally, conveyed that the Leo portfolio of products was safe. Leo found it inconceivable that anyone reading this would be drawn to that conclusion, other than for the purposes of making a complaint. Indeed, Leo considered for a moment the scenario where the text had read the following, without the use of the word 'safe':

'Educate and train healthcare professionals in response to unsolicited requests, in the appropriate use of company products, particularly in off licence situations where the clinician has already decided to use the product, either in a face to face or meeting situation.'

Leo submitted that in this scenario, one interpretation of this revised text might be that there was *always* an appropriate use of company products, particularly in off-licence situations. Though this clearly would not be the intent of the text, it could be interpreted as such. Use of the word 'safe' in this instance was a grammatically clear way of conveying a responsible approach to education and training on company products in response to unsolicited requests.

On a technical point, Clause 7.9 referred to safety as it related to 'a product'. It did not extend to generalisations about a whole company portfolio. The only product mentioned in this part of the employee's job role within the medical department was Picato, which, at the time of the complaint, had not had a marketing authorisation in the UK for some time.

Conclusion

Leo decided to appeal this ruling for two reasons. Firstly, it was appealing on technical grounds, namely that the LinkedIn online CV of the Leo employee, did not, from a content perspective, fulfil the definition of promotional material. Nor did it somehow imply that the entire Leo portfolio of medicines was 'safe'.

Secondly, however, and more importantly, Leo submitted that a worrying case precedent was being set with regard to the right of individuals within the pharmaceutical industry to represent themselves and their work experience to recruiters effectively on Linkedln. If the ruling in this case was allowed to stand, then the rights of candidates to seek employment in the UK pharmaceutical industry would be compromised in favour of a ruling on Linkedln content which, though it might fulfil the expanded and theoretical definition of promotion, did not, to any meaningful or practical extent, advertise a prescription only medicine to UK health professionals, other relevant decision makers or members of the public.

RESPONSE FROM COMPLAINANT

There was no response from the complainant on the appeal.

APPEAL BOARD RULING

The Appeal Board noted that LinkedIn was originally primarily used as a resource for recruitment, however, this social media platform had evolved over time, and this might not be how it was currently predominantly used. The Appeal Board noted that the 'Experience' section on an individual's LinkedIn profile was essentially a summary of previous job roles and appeared below the 'Activity' section where individuals could be posting, sharing, commenting and liking etc. To fully see the 'Experience' section text might require additional clicks and/or scrolling by the reader. The Appeal Board considered that the information within the 'Experience' section, which would require an individual to actively search for it, was distinct from user activity on LinkedIn such as posts, comments, 'likes' and shares etc which would proactively disseminate information to the user's LinkedIn connections.

In relation to the allegation that information within the profile advertised Innohep to the public, the Appeal Board noted that within the 'Experience' section of the employee's profile, under the heading of thrombosis representative, and in relation to an activity at a named hospital, he/she had referred to Innohep and '…treatment in general surgery - upper/lower GI, urology and hepato-biliary'.

The Appeal Board queried if there was ever a need for a medicine to be named within a LinkedIn profile. The representatives from Leo submitted that it now trained its staff that medicines should not be mentioned in an online profile and instead suggested the use of therapy area.

On the evidence before it, the Appeal Board noted that although the employee's profile was publicly available, to reach the 'Experience' section at issue would require an interest in the individual's work experience and several clicks to fully view the information. Such an interest in an individual would likely be by a potential employer or a recruitment company. Based on the nature of the 'Experience' section the Appeal Board did not consider that the information within the employee's profile, which included reference to Innohep, thrombosis and surgery, was such that Innohep, a prescription only medicine, had been advertised to the public and no breach of Clause 26.1 was ruled. The Appeal Board decided on the narrow grounds of its ruling of no breach of Clause 26.1 that the complainant had not established that high standards had not been maintained in this regard and it therefore ruled no breach of Clause 9.1. The appeal on both points was successful.

In relation to the allegation that Innohep was promoted to health professionals, without the obligatory information as required by the Code, the Appeal Board considered that, given its comments and ruling above, it did not consider that the information in question within the 'Experience' section of the LinkedIn profile constituted promotion to health professionals and it therefore ruled no breach of Clauses 4.1, 4.3, 4.4 and 4.8. Consequently, the material did not need to be certified and it ruled no breach of Clause 14.1. The appeal on all points was successful.

The Appeal Board noted the allegation about the use of the word safe in the following statement within the employee's profile:

'Educate and train healthcare professionals in response to unsolicited requests, in the safe and appropriate use of company products particularly in off licence situations where the clinician has already decided to use the product either in a face to face or meeting situation.'

The Appeal Board considered that there was a difference between the safe use of medicines and describing a medicine as safe, and in this case the reference to the safe and appropriate use of Leo medicines did not describe a particular medicine as safe. The Appeal Board considered that the reference would likely be read as relating to training and medicines in general rather than a specific medicine and no breach of Clause 7.9 was ruled. The Appeal Board considered that the complainant had not established that high standards had not been maintained in this regard and ruled no breach of Clause 9.1. The appeal on both points was successful.

During its consideration of this case, the Appeal Board noted that a CV was a personal matter but when it was in the public domain, such as within a LinkedIn profile, there was an additional responsibility on pharmaceutical company employees to ensure that the language used and the impression given was appropriate and that the content did not breach any codes, laws or regulations. Employees should be extremely cautious about any reference to a medicine and about how the pharmaceutical industry might be perceived by the public and health professionals. The Appeal Board was uncomfortable with some of the language in the employee in question's LinkedIn profile and requested that Leo be advised of its concerns in this regard.

Complaint received 9 February 2021

Case completed 18 November 2021