

ANONYMOUS, CONTACTABLE COMPLAINANT v LEO

Use of LinkedIn

An anonymous, contactable complainant alleged that Leo Pharma's use of LinkedIn did not comply with the Code.

The complainant submitted that the Leo UK corporate website suggested a link to the Leo LinkedIn page, however, the reader was directed to 'Leo Pharmaceuticals Ballerup DK', which appeared to be the global LinkedIn page for Leo Pharma. That page contained a variety of postings but it was clear that Leo UK used that global page.

The complainant alleged that some posts and materials were not suitable for a UK audience and some did not contain all the requirements of the Code. As a result, it appeared that Leo UK was directing an intended UK audience to a site containing uncertified material. Leo UK employees had interacted with those posts through reactions to the posts on LinkedIn such as 'likes'.

The complainant queried whether Leo UK could confirm that all posts on Leo Pharmaceuticals Ballerup DK page had been certified under the UK Code.

The complainant stated that there was no accounting how many times a recipient might have received notice of an inappropriate post if multiple Leo employees had interacted with such a post and a health professional was connected with more than one Leo employee.

The complainant stated that based on their LinkedIn job titles, it would appear that Leo UK employees had engaged with posts through LinkedIn reactions ('likes', support or celebrate engagement). The complainant made multiple allegations about a number of posts, including that in some instances promotion had been disguised and that Leo had not trained its staff on the use of social media.

Post A

The post, which was accompanied by a video of Leo employees, read:

'29th October is #worldpsoriasisday. At Leo Pharma, we're marking this day by launching a series of patient videos that outline everyday challenges of living with psoriasis. Learn more about our commitment to helping people with psoriasis, not just today - but every day - by visiting www.everydaypsoriasis.com #beinformed #WPD2020 #everydaypsoriasis.'

The complainant stated that on clicking the URL link, readers would believe they were being directed to a psoriasis website, when in fact the link brought them to www.leo-pharma.com and to a page which gave information on psoriasis. The complainant

alleged that this was very misleading and on initial presentation disguised the possible source of information as another URL.

Post B

The complainant stated that the post, which was accompanied by a video with a UK patient read:

'Jane's Story.... "What makes me feel bad is when I see other people looking... Because you can see the cogs working like, oh, is she contagious?"

Psoriasis doesn't care what day it is. That's why we at Leo Pharma have chosen to mark #worldpsoriasisday this year with a series of patient stories about everyday challenges of living with psoriasis. Learn more about how we're committed to helping people with psoriasis not just today but every day by visiting www.everydaypsoriasis.com #beinformed #WPD2020 #everydaypsoriasis.'

The complainant noted that the post had been 'liked' and 'supported' by three named Leo UK employees and queried whether the post and video had been certified.

Readers would be led to believe they were being directed to a psoriasis website, when in fact the link brought them to www.leo-Pharma.com and to a page which gave information on psoriasis. The complainant alleged that this was very misleading and on initial presentation disguised the possible source of information as another URL.

Post C

The post, which was accompanied by a video called 'EADV Teaser' featuring a UK health professional, read:

'Are you a healthcare professional planning to attend #EADVVirtual next week?

Then we've got a treat for you - our sponsored Satellite Symposium will take the "virtual" theme to another level. Watch [named health professionals from Germany, UK and Canada] as they use the power of digital visualisation to explore our theme "Long-term topical management of psoriasis: the road ahead" (SAT 3.3 virtual room Alibert).'

The complainant alleged that the post acted as an invitation to a promotional event and was therefore promotional in itself. The complainant queried whether Leo UK had certified the presentations, videos, or content for the EADV symposium.

The complainant alleged that two named Leo UK employees had interacted with the post through 'likes' and 'applause' and promoted a prescription only medicine to the public. The complainant noted that the invitation did not contain prescribing information or any mandatory information which an advertisement should carry. The video aspect of the post featured some very fast-moving preview shots of what the viewer could expect at the symposium and was called an 'EADV Teaser' by Leo which the complainant alleged breached the Code.

The results of the study for Enstilar were included with the wording 'No skin atrophy' on one slide. The complainant alleged that the video advertised a prescription only medicine to the public, did not contain prescribing information nor date of revision.

The complainant pointed out that Section 4.8 of the Enstilar summary of product characteristics (SPC) stated 'Local reactions can occur after topical use, especially during prolonged skin application, including skin atrophy....'. To state 'no skin atrophy' was misleading, not balanced, compromised safety and promoted a medicine outside of its authorisation.

The complainant alleged that the use of LinkedIn represented disguised promotion and by interacting with the post, Leo UK had invited a UK audience to the symposium at which one of the presentations was by a UK health professional; the content of the symposium should have been certified.

Post D

The post read:

'We are proud to welcome our new oral IL-17A protein-protein interaction modulator to our clinical pipeline.

Did you know that it's very challenging to obtain an oral small molecule drug with the efficacy of an antibody?

Through clever design, our R&D team has come up with a drug candidate which has been selected to enter development. Why is this news so ground-breaking? We'll let our [named senior executive] explain the science behind. #PioneeringTogether.'

The post was accompanied by a video in which a senior Leo employee made product claims.

The complainant noted that a senior Leo employee and four other named employees had 'liked' the post and by engaging with the post on PPI-IL-17, the Leo UK employees had shared content in which an unauthorised medicine had been positioned in a positive way, and was advertising to the public and a health professional audience before granting of the authorisation. The posting and video did not contain a black triangle or prescribing information. The information provided to the public on the PPI-IL-17 also raised a lot of hope, potentially unfounded given the stage of development.

Post E

The post read:

'Eczema is not only a skin condition. Atopic dermatitis is a type of eczema that can have a significant, negative impact on quality of life, primarily due to

distressing itch, sleep disturbance and social embarrassment due to visible lesions. On World Atopic Eczema Day, we are proud to support eczema warriors.

Learn more about how we are working to make a difference in the lives of people living with skin diseases at www.leo-Pharma.com
#DermatologyBeyondTheSkin #LeoPharmaCares #AtopicEczemaDay.'

Leo UK employees had 'liked' this post and the complainant queried whether the post and video had been certified.

Post F

The post read:

'Thank you to writer and eczema warrior [name] for sharing your story with Leo Pharma on #AtopicEczemaDay to help us address the greatest needs of people living with eczema. We are inspired by your journey and passion for raising the voices of eczema warriors.

Learn more about how we are working together to make a difference in the lives of people living with skin conditions at www.leoPharma.com
#DermatologyBeyondTheSkin #LeoPharmaCares'.

This was accompanied by a picture asking the reader to 'Add your voice to World Atopic Eczema Day.'

The complainant noted that two named Leo UK employees had 'liked' this post and queried if it had been certified.

Post G

The post read:

'We're proud to stand with people living with eczema on #AtopicEczemaDay and every day. LEARN MORE about how we are working to make a difference in the lives of people living with skin diseases at www.leo-Pharma.com
#DermatologyBeyondTheSkin #LeoPharmaCares.'

The text was accompanied by a picture giving the date of Atopic Eczema Day and:

'How do YOU care for atopic eczema?.'

The complainant noted that eight named Leo UK employees had 'liked' the post and queried if it had been certified and whether the information accessed via the link had been assessed under the Code.

Post H

The post read:

'August is Psoriasis Action Month. Psoriasis is a skin condition that impacts more than 8 million people in the United States and 125 million people worldwide. Raising awareness can be a first step toward changing the perception of psoriasis. Show your support by learning more about the disease and get involved. #PsoriasisActionMonth #ThisIsPsoriasis #PioneeringDermatology #DermatologyBeyondTheSkin.'

The complainant noted that two named Leo UK employees had 'liked' the post and queried whether the post had been certified or if the information accessed via the link had been assessed under the Code.

Post I

The post read:

'We are proud to share this great news regarding Gorlin Syndrome Alliance. On November 9, 2020, our patient organisation partner will conduct a Listening Session with FDA. This ninety-minute virtual meeting is a fantastic opportunity to raise awareness on [sic] Gorlin Syndrome and give a voice to people living with this condition. To learn more about the session please refer to the post below #DermatologyBeyondTheSkin #PioneeringTogether.'

The complainant noted that a named senior Leo UK employee had 'liked' this post and queried whether it had been certified.

Post J

The post read:

'Did you know atopic dermatitis (AD) - also known as atopic eczema - is the most common inflammatory skin disease in the developed world? Learn more at [a link was provided to a website called eczema.com which appeared to be a Leo website].'

A picture accompanied the post with a message:

'Atopic dermatitis affects up to 5% of adults across the United States, Canada, Europe and Japan.'

The complainant noted that two named Leo UK employees had 'liked' the post and queried whether it had been certified and whether the material accessed via the link been assessed under the Code.

Post K

The post stated:

'#PRESS: Today, we announce results from the Phase 3 PSO-LONG study of potential long-term, proactive psoriasis management as ePosters by American Academy of Dermatology. Leo Pharma is committed to building on our 30+ year heritage of pursuing innovative products for patients affected by psoriasis, as well as other chronic skin conditions. You can read more about the results here.'

The post was accompanied by a picture and the following statement attributed to a senior executive:

'Our vision in psoriasis is to provide prescription solutions for patients with all severities of psoriasis. Our diverse pipeline of innovative late stage drug candidates aims to support a range of treatment options for people living with psoriasis and other chronic skin conditions across the globe.'

The complainant noted that two named Leo UK employees had 'liked' the post and queried whether the post text and picture had been certified.

The complainant alleged that the post promoted a link to material which discussed the long-term use study results for Enstilar, therefore advertising a prescription only medicine to the UK public. Neither the post nor the item on the link had prescribing information.

Post L

The post read:

'#PRESS: Today we featured new Phase 3 data for adults with moderate-to-severe atopic dermatitis (AD) at the American Academy of Dermatology virtual meeting experience. We focus on advancing treatments that have the potential to address areas of high unmet need for the millions of people who experience some form of eczema, including AD.'

Leo Pharma has devoted decades of research and development to advance the science of dermatology, setting new standards of care for people with skin conditions. For more: [link provided].'

The post was accompanied by a picture with the following statement:

'Leo Pharma's heritage in medical dermatology and strategic focus on advancing the science of skin inflammation diseases uniquely positions us to address the significant and varied unmet needs of people living with atopic dermatitis.'

The complainant noted that a named Leo UK employee had 'liked' the post which promoted a link to material which discussed the Phase 3 results of a yet to be authorised prescription medicine, tralokinumab, therefore advertising a prescription only medicine to the UK public and promoting a product before authorisation to a health professional.

Neither the post nor the item on the link had prescribing information. The complainant queried whether the post text and picture had been certified.

Post M

The post read:

'Psoriasis is a chronic, systemic #inflammatorydisease that primarily affects the skin. Psoriasis does not just cause physical discomfort; the true burden of psoriasis is much bigger. Learn more at:' – a web address was listed.

A picture accompanied the post with a statement that:

'125 million people worldwide live with psoriasis.'

The complainant noted that seven named Leo UK employees had 'liked' the post and queried whether the post and picture had been certified and whether the material accessed via the link had been assessed under the Code.

Post N

The post read:

'#PRESS: Today we announced top line results from the Phase 3 randomised, double blind, placebo controlled multinational 52 week ECZTRA 1-3 clinical studies evaluating an investigational treatment in adults with moderate-to-severe atopic dermatitis (AD). AD is the most common inflammatory skin disease in the developed world that affects up to 5 percent of adults across the United States, Canada, Europe and Japan. AD can have a significant, negative impact on patients well being, primarily due to distressing itch, sleep deprivation and social stigmatisation due to visible lesions.'

The complainant noted that three named Leo UK employees had 'liked' the post which promoted a link to material which discussed the Phase 3 results of a yet to be authorised prescription medicine, tralokinumab, therefore advertising a prescription only medicine to the UK public and promoting a product before authorisation to a health professional. Neither the post nor the item on the link had prescribing information. The complainant queried whether the post text and link had been certified.

The detailed response from Leo is given below.

The Panel noted Leo's submission that the LinkedIn page at issue was the corporate page for Leo Pharma globally; it was owned by Leo Pharma Ballerup Denmark which Leo submitted was stated at the top of the page and managed by the global corporate communications team in Denmark. The Panel did not have a copy of this LinkedIn page before it. The Panel further noted Leo's submission that the content posted was directed globally, with contributions from Leo affiliates around the world; Leo's global team

posted content for all users, whereas Leo affiliates only posted content directed towards their local audiences.

The Panel considered that information or promotional material about medicines placed on the Leo Pharma global LinkedIn page outside of the UK would be within the scope of the Code if it was placed there by Leo UK/with Leo UK's authority, or if it was placed there by an affiliate to Leo UK (or with its authority) and specifically referred to the availability or the use of a Leo medicine in the UK. Further, material directed at a UK audience would be within the scope of the Code.

The Panel considered that as a UK audience was directed to the global LinkedIn page it would fall within the scope of the Code. If this were not the case, then companies could refer to global LinkedIn pages as a means of circumventing the Code.

In addition, the Panel considered that the UK employees' engagement with the fourteen posts, on the balance of probabilities, had proactively disseminated the material to their connections on LinkedIn, and therefore also brought each post and its associated content within the scope of the Code. Any material associated with a social media post, for example a video or link within a post, would be regarded as being part of that post and the Panel made its rulings in that regard.

Post A

The Panel noted Leo's submission that the link within the post to www.everydaypsoriasis.com took users to information relating to psoriasis on the Leo Pharma A/S website, including stories of patient experiences. The Panel noted that the webpage referred to '... lots of different types of treatment that help people to manage [psoriasis] and improve quality of life' and referred to managing the condition via treatments and lifestyle changes. In the Panel's view, neither the webpage nor the video made a direct or indirect reference to a specific treatment and it appeared to be disease awareness information for the public.

Four of the individuals named by the complainant as having engaged with Post A were employed by Leo UK. The Panel considered that the UK employees' engagement with the post, on the balance of probabilities, had proactively disseminated the material to their connections on LinkedIn, not all of whom would meet the Code's definition of a health professional.

The Panel ruled no breach of the Code in relation to the requirement to certify promotional material as it was educational material for the public related to psoriasis. However the material had not been certified as required by the Code and a breach was ruled as acknowledged by Leo. This ruling was unsuccessfully appealed by Leo.

The Panel considered that it was sufficiently clear from the post that the reader was being directed to a Leo owned website; the post referred to learning more about our (Leo's) commitment '...by visiting www.everydaypsoriasis.com'. The Panel therefore ruled no breach of the Code in that regard.

Post B

The Panel noted its comments above about Post A in relation to the content of the website www.everydaypsoriasis.com.

The Panel noted that the video that was part of the LinkedIn post made no direct or indirect reference to a medicine; the video discussed a patient's experience of living with psoriasis.

Two of the individuals named by the complainant as having engaged with Post B were employed by Leo UK. The Panel considered that the UK employees' engagement with the post, on the balance of probabilities, had proactively disseminated the material to their connections on LinkedIn not all of whom would meet the Code's definition of a health professional.

The Panel ruled no breach of the Code in relation to the requirement to certify promotional material as it was educational material for the public related to psoriasis. However as the material had not been certified as required by the Code a breach was ruled as acknowledged by Leo.

The Panel considered that it was sufficiently clear from the post that the reader was being directed to a Leo owned website and therefore ruled no breach of the Code in that regard.

Post C

The Panel noted Leo's submission that the link to more information within the post directed readers to a Leo congress website where users had to declare that they were a health professional. Users could then access details of a symposium entitled 'Long-term topical management of psoriasis: the road ahead' which also included a link to register for the webinar and the date, time and agenda. The agenda did not name a specific medicine but stated that data from recently published new studies would be presented.

The LinkedIn post was accompanied by a video called 'EADV Teaser' which was a number of fast-moving images set to a background of music which appeared to show, amongst other things, slides with data from the PSO-LONG clinical trial. The claim 'No cases of skin atrophy' was stated boldly in the centre of one slide. The video did not directly name a medicine, however, the Panel noted Leo's submission that the PSO-LONG trial investigated Leo's prescription only medicine Enstilar (betamethasone dipropionate/calcipotriol monohydrate), which was a topical treatment for psoriasis vulgaris in adults.

Two of the individuals named by the complainant as having engaged with Post C were employed by Leo UK. The Panel further noted Leo's submission that one of those employees had no health professional LinkedIn contacts and the other who did have such contacts was limited to those health professionals who had expressed an interest in working in the pharmaceutical industry, including at Leo.

The Panel considered that the UK employees' engagement with the post, on the balance of probabilities, had proactively disseminated the material to their connections on LinkedIn. The Panel noted that not all the employees' connections on LinkedIn would meet the Code's definition of a health professional. However, the Panel considered that

members of the public were unlikely to make any connection between PSO-LONG and Enstilar. The Panel therefore considered, on the balance of probabilities, that a prescription only medicine had not been promoted to the public and no breach of the Code was ruled.

The Panel noted Leo's submission that one of the UK employees who engaged with Post C had connections who were health professionals. The Panel considered that some health professionals would link the information about PSO-LONG in the post to Enstilar. In the Panel's view, the video, which formed part of the post and which prominently displayed the name of the Enstilar clinical trial (PSO-LONG) and included claims such as 'No cases of skin atrophy' was promotional material for Enstilar. The LinkedIn post, which included the video, was promotional material which had not been certified and the Panel ruled a breach of the Code. This ruling was unsuccessfully appealed by Leo. The Panel ruled no breach in relation to the allegation that educational material had not been certified.

As prescribing information had not been provided the Panel ruled a breach of the Code which was unsuccessfully appealed by Leo.

As there was no display of the brand name within the post or associated video or link to further information there was no requirement to state the non-proprietary name and so the Panel ruled no breach of the Code.

The image of the LinkedIn post did not give the exact date it was posted. There was no date on when the promotional material was drawn up or last revised and therefore the Panel ruled a breach of the Code. This ruling was unsuccessfully appealed by Leo.

The Panel noted Leo's submission that Enstilar did not need to include an inverted black triangle; the Panel ruled no breach of the Code in that regard.

The Panel noted that section 4.8 of the Enstilar SPC stated:

'Betamethasone (as dipropionate):

Local reactions can occur after topical use, especially during prolonged application, including skin atrophy, telangiectasia, striae, folliculitis, hypertrichosis, perioral dermatitis, allergic contact dermatitis, depigmentation, and colloid milia.'

The Panel considered that the prominent claim within the video of 'No cases of skin atrophy', within the context of the fast-moving images in this short video, was misleading with respect to the safety of Enstilar and was inconsistent with the particulars listed in its SPC; breaches of the Code were ruled. These rulings were unsuccessfully appealed by Leo.

The Panel considered that as it was unlikely that the public would make a connection between PSO-LONG and Enstilar; in that regard, the post did not provide misleading information to the public about the side effects of Enstilar and no breach of the Code was ruled.

The Panel considered that the LinkedIn post and its associated video and link promoted a webinar and provided a trailer to elicit people's interest in the event and although it was unfortunate that it was referred to as a 'teaser', it was not teaser advertising as referred to in the Code. The Panel ruled no breach in that regard.

The Panel noted Leo's submission that the symposium was sponsored by Leo Pharma A/S and held virtually at the European Academy of Dermatology and Venereology Congress in November 2020. The Panel further noted that Leo accepted that the dissemination of invitations for the symposium to UK health professionals would mean that the content of the symposium would require certification in accordance with the Code and that this had not occurred.

The Panel considered that the employee's engagement with the post, on the balance of probabilities, had proactively disseminated the material to his/her connections on LinkedIn, most of whom would be UK based, and therefore he/she had invited UK health professionals to the symposium and therefore the symposium content required certification. The Panel therefore ruled a breach of the Code.

Post D

The Panel noted that the post included a video where a senior Leo employee referred to an investigational molecule as having a 'Completely unique mode of action' and that it was a 'true unique opportunity'.

Five Leo UK employees identified by the complainant had 'liked' the post at issue. The Panel considered that the UK employees' engagement with the post, on the balance of probabilities, had proactively disseminated the material to their connections on LinkedIn not all of whom would meet the Code's definition of a health professional.

It was not necessarily unacceptable for a company to refer in general terms to its pipeline products on its corporate accounts. However, language, context, location, layout, intended audience and overall impression were important factors. The Panel queried whether a social media platform such as LinkedIn with a varied audience was the appropriate forum to share such information.

The Panel noted Leo's submission that the oral compound discussed in Post D was in early development and clinical trials had not yet commenced. It was clear that Leo was a long way off having the compound available for use when the post was made or engaged with by UK employees. The Panel noted its comments above and did not consider that the post promoted a medicine prior to the grant of its marketing authorisation and no breach of the Code was ruled. The Panel consequently ruled no breaches of the Code in relation to the requirements for promotional material. The Panel did not consider that the post required certification and ruled no breaches of the Code in that regard.

The compound referred to was not a prescription only medicine when the LinkedIn post was made or 'liked' by the five Leo UK employees. The Panel therefore ruled no breach of the Code with regard to the allegation that the LinkedIn post raised the hopes of the public.

Posts E-J, M

The Panel noted that in relation to Posts E, F, G, H, I, J and M, the complainant had questioned if the posts had been certified.

The Panel noted Leo's submission that a number of Leo UK employees had 'liked' each post which ranged from 1 employee (Post I) to 8 employees (Post G).

The Panel considered that the UK employees' engagement with each post, on the balance of probabilities, had proactively disseminated the material to their connections on LinkedIn.

In the Panel's view, there was no direct or indirect reference to a specific prescription only medicine in Posts E, H, I, J and M. The webpage accessed from the link within each of posts E, H, J and M, from the evidence provided by Leo, made no direct or indirect reference to a specific prescription only medicine nor did the post from the Gorlin Syndrome Alliance included within Post I. On the evidence before it, the Panel considered that the complainant had not discharged his/her burden of proof that Posts E, H, I, J and M were promotional material and no breach of the Code in relation to the certification of promotional material was ruled in relation to each.

In the Panel's view, Posts E, H, J and M contained disease information about either eczema or psoriasis and were thus educational material for the public related to disease which required certification under the Code. The Panel disagreed with Leo's submission that the content of Post H was too limited to bring the text within the scope of the certification requirements for material for the public; the post described psoriasis as a skin condition that impacted more than 125 million people worldwide and linked to the US National Psoriasis Foundation website. A breach of the Code was ruled in relation to each of Posts E, J and M, as acknowledged by Leo, and also in relation to Post H. The ruling in relation to post H was unsuccessfully appealed by Leo.

Post I referred to a future virtual meeting between the Food and Drug Administration (FDA) and the Gorlin Syndrome Alliance which was a US patient organisation that Leo referred to as a 'partner'; the forthcoming meeting was to raise awareness of the condition. There was no disease information within the post and the Panel had no information before it as to the content of any links within the post. It was not clear if Leo UK had any relationship with the Gorlin Syndrome Alliance. On the evidence before it the Panel considered that the complainant had not discharged his/her burden of proof that the post required certification under the Code and the Panel ruled no breach of the Code in relation to Post I.

Posts F and G highlighted World Atopic Eczema Day but had no educational information about the disease or any direct or indirect reference to a specific prescription only medicine within the body of each post. The link within Post F led directly to the media page on the Leo Pharma A/S website which included a list of recent press releases below a bold prominent statement 'Our press releases are intended for the media'. Post G also appeared to link to the same webpage on the Leo Pharma A/S website but Leo had made no submission in that regard.

The Panel noted Leo's submission that the list of press releases on the media page would change over time and that it was standard practice for Leo Pharma A/S to delete

certain press releases after a period of 3 weeks. The Panel had no information before it as to what press releases were available on the webpage in question when the post was made or UK employees engaged with it. The Panel noted that the content of Posts F and G were in relation to World Atopic Eczema Day and not in relation to a Leo clinical trial. As noted above neither post contained any educational information about eczema. The Panel considered that the complainant had not established, on the balance of probabilities, that Posts F and G were promotional material or otherwise required certification under the Code and no breaches were ruled in relation to each post.

Post K

The Panel noted that the link within the post referred to by the complainant led to the media page of the Leo Pharma A/S website; it appeared to the Panel that the reader was being directed to read more about the results from PSO-LONG via a press release within the media section of the global Leo corporate website. The Panel did not have a copy of the press release; Leo made no submission in that regard although the complainant had stated that the post promoted a link to material which discussed study results of the long-term use of Enstilar.

The Panel considered that there was a difference between making a press release available only to the press, to be published or not, and proactively disseminating it on a publicly accessible social media platform with the inevitability that a wider audience would read it. The use of #PRESS at the beginning of the post would not be likely to restrict the audience to the relevant media.

In the Panel's view, the post, which referred to psoriasis and an Enstilar clinical trial by name (PSO-LONG) and directed users to a webpage to read results from the trial was promotional material for Enstilar.

The Panel had no information before it as to what press releases were available from the webpage in question when the post was made or when UK employees engaged with it but considered that, on the balance of probabilities, given that the post began with '#PRESS: Today, we announce results from the Phase 3 PSO-LONG study...' and ended with 'You can read more about the results here: [link]' that readers were being directed to view study results from PSO-LONG.

Two Leo UK employees identified by the complainant had 'liked' the post at issue. The Panel considered that the UK employees' engagement with the post, on the balance of probabilities, had proactively disseminated the material to their connections on LinkedIn not all of whom would meet the Code's definition of a health professional. Enstilar was classified as a prescription only medicine when the post in question was made and the UK employees 'liked' it. Although the Panel considered that it was unlikely that members of the public would link 'PSO-LONG' to Enstilar, the post referred to psoriasis and innovative products for the condition and as such would encourage readers to 'read more about the results' as invited; the link in the post would, on the balance of probabilities, have directed users to a webpage where they could view more information which would refer to the efficacy results of Leo's medicine. Therefore the post promoted a prescription only medicine to the public and a breach of the Code was ruled.

The Panel considered that as Leo employees who had 'liked' the post would, on the balance of probabilities, have had connections who met the Code's definition of a health professional, the post also promoted Enstilar to health professionals. The promotional material had not been certified nor did it include prescribing information and the Panel ruled breaches of the Code. No breach of the Code was ruled in relation to the requirement to certify material for the public as the material was promotional.

Post L

The Panel noted that the link within the post referred to by the complainant led to the media page of the Leo Pharma A/S website; it appeared to the Panel that the reader was being directed to read more about the results from a Phase 3 trial for adults with moderate-to-severe atopic dermatitis via a press release within the media section of the global Leo corporate website. The Panel did not have a copy of the press release; Leo made no submission in that regard although the complainant submitted that the post promoted a link to material which discussed the Phase 3 results of a yet to be authorised prescription medicine, tralokinumab.

The Panel disagreed with Leo's submission that the 'For more' link within the post related to the annual report rather than to any particular Phase 3 data and that there was no reference to any specific data. From the webpage provided by Leo, it was clear that it housed press releases in addition to the annual report. The Panel had no information before it as to what press releases were available from the webpage in question when the post was made or when UK employees engaged with it but considered, on the balance of probabilities, that readers were being directed to view study results.

The Panel considered that there was a difference between making a press release available only to the press, to be published or not, and proactively disseminating it on a publicly accessible social media platform with the inevitability that a wider audience would read it. The use of #PRESS at the beginning of the post would not, in the Panel's view, restrict the audience to the relevant media. In the Panel's view, the post, which referred to a Leo Phase 3 clinical trial in atopic dermatitis and directed users to a webpage where they could read results from the trial was promotional material for the medicine.

One Leo UK employee identified by the complainant had 'liked' the post at issue. The Panel considered that the UK employee's engagement with the post, on the balance of probabilities, had proactively disseminated the material to his/her connections on LinkedIn not all of whom would meet the Code's definition of a health professional.

The Panel noted the complainant's allegation that the data which was being referred to was Phase 3 data on a yet to be authorised product, tralokinumab, which was not a prescription only medicine when the post in question was 'liked' by the UK employee and on that narrow technical point the Panel ruled no breach of the Code. A further ruling of no breach was made in relation to the absence of prescribing information.

The Panel noted Leo's submission that in advance of the American Academy of Dermatology Virtual Meeting Experience (AADVMX) Leo UK employees were advised not to engage with social media posts from Leo global or US apart from one described UK/IE

post (which was not Post L); specific reference was made to LinkedIn channels in this regard.

The Panel considered, on the evidence before it, that the proactive dissemination of a LinkedIn post which, on the balance of probabilities, directed readers to find information on Phase 3 tralokinumab study results meant that tralokinumab had been promoted prior to the grant of its marketing authorisation. A breach of the Code was ruled.

As the promotional material had not been certified the Panel ruled a breach of the Code. This ruling was unsuccessfully appealed by Leo. No breach of the Code was ruled with regard to the requirement to certify material for the public.

Post N

The Panel noted that it appeared that the link within the post would direct users to the media page of the Leo Pharma A/S website as in Post L above. It appeared to the Panel, that the reader was being directed to read more about the results from the ECZTRA trial. The Panel did not have a copy of the press release; Leo made no submission in that regard although the complainant submitted that the post promoted a link to material which discussed the Phase 3 results of a yet to be authorised medicine, tralokinumab.

The Panel had no information before it as to what press releases were available from the webpage in question when the post was made or when UK employees engaged with it but considered that readers were being directed to view study results.

The Panel considered that there was a difference between making a press release available only to the press, to be published or not, and proactively disseminating it on a publicly accessible social media platform with the inevitability that a wider audience would read it. The use of #PRESS at the beginning of the post would not, in the Panel's view, restrict the audience to the relevant media.

In the Panel's view, the post, which referred to a Leo Phase 3 clinical trial in atopic dermatitis and directed users to a webpage where they could read results from the trial was promotional material for the medicine.

The UK employees' engagement with the post, on the balance of probabilities, had proactively disseminated the material to their connections on LinkedIn not all of whom would meet the Code's definition of a health professional.

The Panel noted that tralokinumab was not a prescription only medicine when the complaint was submitted. On that narrow technical point the Panel ruled no breach of the Code in relation to alleged promotion to the public.

The Panel considered, on the evidence before it, that the proactive dissemination of a LinkedIn post which, on the balance of probabilities, directed readers to Phase 3 study results on tralokinumab meant that tralokinumab had been promoted prior to the grant of its marketing authorisation. A breach of the Code was ruled.

The promotional material had not been certified and the Panel ruled a breach of the Code. This ruling was unsuccessfully appealed by Leo. No breach of the Code was ruled with regard to the requirement to certify material for the public.

Overall

The Panel noted its comments and rulings of breaches of the Code above and ruled a breach as Leo had failed to maintain high standards.

The Panel noted Leo's submission in relation to the training materials available contemporaneous to the complaint. The Panel noted that the Leo employees' personal use of social media policy was dated 2013 and contained statements which were ambiguous and did not reflect case precedence. For example:

'Personal posts relating to LEO products are strongly discouraged, and it is strictly forbidden for you to make any statement that implies any product benefit, efficacy, clinical trial, safety claim or any other content that may be regarded as promotional.'

The term 'strongly discouraged' did not, in the Panel's view, give employees an unequivocal instruction.

Furthermore, under the heading, 'reference to any topic related to our business' it stated:

'Be clear to separate your opinions from those of LEO, by including remarks such as "the views expressed here are my own, and do not necessarily reflect the views of my employer".'

However, the social media 'Dos and don'ts' reference card (UK/IE MAT-19232, August 2018) stated, amongst other things:

'Act as an ambassador for LEO Pharma UK/IE e.g. update your LinkedIn profile to All-Star status, like and engage with our social media posts.'

The Panel noted that although a number of email communications with more specific instructions about certain posts had been sent in 2020, some employees would likely be confused by the contradictory and unclear instructions.

The Panel noted its comments and rulings above which included multiple breaches of the Code including promoting a medicine prior to the grant of its marketing authorisation and considered that Leo had brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled. This ruling was unsuccessfully appealed by Leo.

An anonymous, contactable complainant alleged that Leo Pharma's use of LinkedIn did not comply with the Code. The complainant referred to fourteen separate LinkedIn posts and provided comments on each.

On receipt of Leo's response, the case preparation manager determined that in relation to a number of the complainant's comments, no *prima facie* case had been established and that those points 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 submitted that the Leo UK corporate website suggested a link to the Leo LinkedIn page, however, the reader was directed to 'Leo Pharmaceuticals Ballerup DK', which appeared to be the global LinkedIn page for Leo Pharma. That page contained a variety of postings but it was clear that Leo UK used that global page as it had posted recruitment notices for Leo UK jobs and some members of the Leo UK team were included in posts and videos. One webinar entitled 'Is telemedicine the new consulting room?' had been advertised on a post. The video advertising the webinar had a notice 'This webinar is a non-promotional event, initiated and facilitated by Leo Pharma UK/IR, intended for UK and IE healthcare professionals only'. The complainant submitted that based on those postings and other UK postings from Leo UK, and the direction from the Leo UK corporate site, both UK health professionals and members of the public were the intended audience for this page.

The complainant submitted that the material, which seemed to be very UK specific, appeared to carry an internal code identifier number, however, many posts did not have any identifier denoting they might not have been reviewed or certified by Leo UK. The complainant alleged that some posts and materials were not suitable for a UK audience and some did not contain all the requirements of the Code. As a result, it appeared that Leo UK was directing an intended UK audience to a site containing uncertified material. Leo UK employees had interacted with those posts through reactions to the posts on LinkedIn such as 'likes'.

The complainant queried whether Leo UK could confirm that all posts on Leo Pharmaceuticals Ballerup DK page had been certified under the UK Code.

The complainant submitted that activity conducted on social media, such as LinkedIn, that could potentially alert a member's connections to an activity might be considered proactive dissemination of material. In addition, individuals' activity and associated content might appear in the individuals' lists of activities on their LinkedIn profile pages which became visible to their connections. Some of the individuals' profile pages were also potentially visible to others outside their networks depending on the individuals' security settings. The sharing of this information represented sending material (in some cases promotional) to categories of persons who had no need or interest in it (health professionals in another discipline) or to whom it was not legal to send (members of the public).

The complainant stated that there was no accounting how many times a recipient might have received notice of an inappropriate post if multiple Leo employees had interacted with such a post and a health professional was connected with more than one Leo employee.

The complainant submitted that in the case of the following posts, based on their LinkedIn job titles, it would appear that Leo UK employees had engaged with posts through LinkedIn reactions ('likes', support or celebrate engagement).

Post A

The post, which was accompanied by a video of Leo employees, read:

'29th October is #worldpsoriasisday. At Leo Pharma, we're marking this day by launching a series of patient videos that outline everyday challenges of living with psoriasis. Learn more about our commitment to helping people with psoriasis, not just today – but every day – by visiting www.everydaypsoriasis.com #beinformed #WPD2020 #everydaypsoriasis.'

The complainant noted that the post was 'liked' and 'applauded' by Leo UK employees and therefore came under the Code as it was material aimed and shared with a UK audience. The complainant queried whether the post and video had been certified.

The complainant stated that on clicking the URL link, readers would be led to believe they were being directed to a psoriasis website, when in fact the link brought them to www.leo-Pharma.com and to a page which gave information on psoriasis. This was very misleading and on initial presentation disguised the possible source of information as another URL.

The complainant alleged that of the six Leo UK employees who had interacted with this post three had over 500 connections on LinkedIn. When the connections of all employees were added up, it amounted to the post being distributed potentially thousands of times to what appeared to be a predominately UK audience based on their connections.

Post B

The complainant submitted that the post, which was accompanied by a video of an animation with a UK patient read:

'Jane's Story.... "What makes me feel bad is when I see other people looking... Because you can see the cogs working like, oh, is she contagious?"

Psoriasis doesn't care what day it is. That's why we at Leo Pharma have chosen to mark #worldpsoriasisday this year with a series of patient stories about everyday challenges of living with psoriasis. Learn more about how we're committed to helping people with psoriasis not just today but every day by visiting www.everydaypsoriasis.com #beinformed #WPD2020 #everydaypsoriasis.'

The complainant noted that the post had been 'liked' and 'supported' by Leo UK employees and therefore came under the Code as it was material aimed and shared with a UK audience. The complainant queried whether the post and video had been certified.

On clicking the URL link, readers would be led to believe they were being directed to a psoriasis website, when in fact the link brought them to www.leo-Pharma.com and to a page which gave information on psoriasis. This was very misleading and on initial presentation disguised the possible source of information as another URL. The complainant queried whether the information had been assessed under the Code.

The complainant alleged that of the three named UK employees who had interacted with this post, one had over 500 connections on LinkedIn. When the connections of all employees were

added up, it amounted to the post being distributed thousands of times to what appeared to be a predominately UK audience based on their connections.

Post C

The post, which was accompanied by a video called 'EADV Teaser' featuring a UK health professional, read:

'Are you a healthcare professional planning to attend #EADVVirtual next week?

Then we've got a treat for you – our sponsored Satellite Symposium will take the "virtual" theme to another level. Watch [named health professionals from Germany, UK and Canada] as they use the power of digital visualisation to explore our theme "Long-term topical management of psoriasis: the road ahead" (SAT 3.3 virtual room Alibert).'

The complainant alleged that the post was promotional as it referred to a promotional symposium, the main topic of which, according to the accompanying video, appeared to be a long-term use study for Enstilar, a Leo product. The complainant submitted that the post acted as an invitation to a promotional event and was therefore promotional in itself. The complainant queried whether Leo UK had certified the presentations, videos, or content for the EADV symposium.

Leo UK employees had interacted with the post through 'likes' and 'applause' and so the post and video was aimed and shared with a UK audience and came under the Code. The invitation promoted a prescription only medicine to the public, in breach of the Code. The complainant noted that the text invitation did not contain prescribing information or any mandatory information which an advertisement should carry.

The complainant noted that teaser advertising, whereby promotional material was intended to elicit an interest in something that would be available at a later date, was not permitted under the Code. The video aspect of the post featured some very fast-moving preview shots of what the viewer could expect at the symposium and was called an 'EADV Teaser' by the company therefore breaching the Code.

In the video, results of the study for Enstilar were included with the wording 'No skin atrophy' on one slide. This video advertised a prescription only medicine to the public. The complainant alleged that the video did not contain prescribing information or date of revision.

The complainant alleged that the claim 'No skin atrophy' did not promote Enstilar in an ethical manner, in breach of the Code. Section 4.8 of the Enstilar summary of product characteristics (SPC) stated 'Local reactions can occur after topical use, especially during prolonged skin application, including skin atrophy...'. To state 'no skin atrophy' was misleading, not balanced, compromised safety and promoted a medicine outside of its authorisation.

The complainant stated that it appeared that Leo had not trained its employees on the correct use of social media. The use of LinkedIn to promote medicines through 'likes' and therefore sharing activity was not traditional promotion and represented disguised promotion for this post. By interacting with the post, Leo UK had invited a UK audience to the symposium at which one of the presentations was by a UK health professional. The complainant submitted that the content of the symposium should be certified.

The complainant alleged that two named UK employees had interacted with this post including one with over 500 connections on LinkedIn. When the connections of all employees were added up, it amounted to the post being distributed hundreds, potentially thousands of times to what appeared to be a predominately UK audience based on their connections.

Post D

The post read:

'We are proud to welcome our new oral IL-17A protein-protein interaction modulator to our clinical pipeline.

Did you know that it's very challenging to obtain an oral small molecule drug with the efficacy of an antibody?

Through clever design, our R&D team has come up with a drug candidate which has been selected to enter development. Why is this news so ground-breaking? We'll let our [named senior executive] explain the science behind. #PioneeringTogether.'

The post was accompanied by a video in which a senior Leo employee described the PPI-IL-17 and his/her statement included claims like 'The IL-17 PPI candidates work with a completely unique mode of action'; 'In the case of the IL-17 PPI molecule we have the opportunity to formulate a drug in to a tablet based treatment and that is a true unique opportunity and something that provides a lot of convenience to patients'.

The complainant noted that a senior Leo employee and other employees had 'liked' the post and therefore it came under the Code as it was material aimed and shared with a UK audience. By engaging with the post on PPI-IL-17, the Leo UK employees had shared content in which an unauthorised medicine had been positioned in a positive way, and contacts associated with those employees' accounts were a mix of health professionals and members of the public, therefore advertising to the public and advertising to a health professional audience before granting of the authorisation.

The complainant stated that the posting and video did not contain a black triangle or prescribing information. The complainant noted that the Code advised that care must be taken when using the word 'unique' and 'completely unique' and this did not appear to have been considered in this communication from Leo.

The information provided to the public on the PPI-IL-17 also raised a lot of hope, potentially unfounded given the stage of development, also breaching the Code. It appeared that Leo had not trained its employees on the correct use of social media. The use of LinkedIn to promote medicines through 'likes' and therefore sharing activity was not traditional promotion and represented disguised promotion for this post. The complainant alleged that of the five named Leo UK employees who had interacted with this post, two had over 500 connections on LinkedIn. When the connections of all employees were added up, it amounted to the post being distributed thousands of times to what appeared to be a predominately UK audience.

Post E

The post read:

'Eczema is not only a skin condition. Atopic dermatitis is a type of eczema that can have a significant, negative impact on quality of life, primarily due to distressing itch, sleep disturbance and social embarrassment due to visible lesions. On World Atopic Eczema Day, we are proud to support eczema warriors.'

Learn more about how we are working to make a difference in the lives of people living with skin diseases at www.leo-Pharma.com
#DermatologyBeyondTheSkin #LeoPharmaCares #AtopicEczemaDay.'

Leo UK employees had 'Liked' this post and therefore it came under the Code as it was material aimed and shared with a UK audience. The complainant queried whether the post and video had been certified under the Code.

The complainant alleged that of the six named Leo UK employees who had interacted with this post, one had over 500 connections on LinkedIn. When the connections of all employees were added up, it amounted to the post being distributed thousands of times to what appeared to be a predominately UK audience.

Post F

The post read:

'Thank you to writer and eczema warrior [name] for sharing your story with Leo Pharma on #AtopicEczemaDay to help us address the greatest needs of people living with eczema. We are inspired by your journey and passion for raising the voices of eczema warriors.'

Learn more about how we are working together to make a difference in the lives of people living with skin conditions at www.leoPharma.com #DermatologyBeyondTheSkin #LeoPharmaCares'.

This was accompanied by a picture asking the reader to 'Add your voice to World Atopic Eczema Day.'

The complainant noted that Leo UK employees had 'liked' this post and so it came under the Code as it was material aimed and shared with a UK audience. The complainant queried whether the post and picture had been certified.

The complainant queried whether the information had been assessed under the Code?

The complainant alleged that two named Leo UK employees had interacted with this post including one with over 500 connections on LinkedIn. When the connections of all employees were added up, it amounted to the post being distributed hundreds, potentially thousands of times to what appeared to be a predominately UK audience.

Post G

The post read:

'We're proud to stand with people living with eczema on #AtopicEczemaDay and every day. LEARN MORE about how we are working to make a difference in the lives of people living with skin diseases at www.leo-Pharma.com #DermatologyBeyondTheSkin #LeoPharmaCares.'

The text was accompanied by a picture giving the date of Atopic Eczema Day and the question:

'How do YOU care for atopic eczema?.'

The complainant noted that Leo UK employees had 'liked' the post and so it came under the Code as it was material aimed and shared with a UK audience. The complainant queried whether the post and picture had been certified under the Code and whether the information accessed via the link had been assessed under the Code.

The complainant alleged that of the eight named Leo UK employees who had liked this post, two had over 500 connections on LinkedIn. When the connections of all employees were added up, it amounted to the post being distributed thousands of times to what appeared to be a predominately UK audience.

Post H

The post read:

'August is Psoriasis Action Month. Psoriasis is a skin condition that impacts more than 8 million people in the United States and 125 million people worldwide. Raising awareness can be a first step toward changing the perception of psoriasis. Show your support by learning more about the disease and get involved. #PsoriasisActionMonth #ThisIsPsoriasis #PioneeringDermatology #DermatologyBeyondTheSkin.'

The complainant noted that Leo UK employees had 'liked' the post and therefore it came under the Code as it was material aimed and shared with a UK audience. A link was also provided and when clicking through, readers landed on 'psoriasis.org'. The complainant queried whether the post had been certified or if the information accessed via the link had been assessed under the Code.

The complainant alleged that the two named Leo UK employees who had interacted with this post each had over 500 connections on LinkedIn. When the connections of all employees were added up, it amounted to the post being distributed thousands of times to what appeared to be a predominately UK audience.

Post I

The post read:

'We are proud to share this great news regarding Gorlin Syndrome Alliance. On November 9, 2020, our patient organisation partner will conduct a Listening Session with FDA. This ninety-minute virtual meeting is a fantastic opportunity to raise awareness on [sic] Gorlin Syndrome and give a voice to people living with this condition. To learn more

about the session please refer to the post below #DermatologyBeyondTheSkin #PioneeringTogether.'

The complainant noted that a named senior Leo UK employee had 'liked' this post and therefore it came under the Code as it was material aimed and shared with a UK audience. The complainant queried whether the post and picture had been certified.

The named senior employee had over 500 connections on LinkedIn amounting to the post being distributed hundreds of times to what appeared to be a predominately UK audience.

Post J

The post read:

'Did you know atopic dermatitis (AD) – also known as atopic eczema – is the most common inflammatory skin disease in the developed world? Learn more at [a link was provided to a website called eczema.com which appeared to be a Leo website].'

A picture accompanied the post with a message:

'Atopic dermatitis affects up to 5% of adults across the United States, Canada, Europe and Japan.'

The complainant noted that Leo UK employees had 'liked' the post and therefore it came under the Code as it was material aimed and shared with a UK audience. The complainant queried whether the post had been certified under the Code and whether the material accessed via the link been assessed under the Code.

The complainant alleged the two named Leo UK employees who had interacted with this each had over 500 connections on LinkedIn. When the connections of both employees were added up, it amounted to the post being distributed thousands of times to what appeared to be a predominately UK audience.

Post K

The post stated:

'#PRESS: Today, we announce results from the Phase 3 PSO-LONG study of potential long-term, proactive psoriasis management as ePosters by American Academy of Dermatology. Leo Pharma is committed to building on our 30+ year heritage of pursuing innovative products for patients affected by psoriasis, as well as other chronic skin conditions. You can read more about the results here.'

The post was accompanied by a picture and the following statement attributed to a senior named executive:

'Our vision in psoriasis is to provide prescription solutions for patients with all severities of psoriasis. Our diverse pipeline of innovative late stage drug candidates aims to support a range of treatment options for people living with psoriasis and other chronic skin conditions across the globe.'

The complainant noted that Leo UK employees had 'liked' the post and therefore it came under the Code as it was material aimed and shared with a UK audience. The complainant queried whether the post text and picture been certified.

The complainant noted that the post promoted a link to material which discussed the long-term use study results for Enstilar to the public, therefore advertising a prescription only medicine to the UK public. The post was promotional and neither the post nor the item on the link had prescribing information.

The complainant stated that it appeared that Leo had not trained its employees on the correct use of social media. The use of LinkedIn to promote medicines through 'likes' and therefore sharing activity was not traditional promotion and represented disguised promotion for this post.

The complainant alleged that of the two named Leo UK employees who had interacted with this post, one had over 500 connections on LinkedIn. When the connections of all employees were added up, it amounted to the post being distributed thousands of times to what appeared to be a predominately UK audience.

Post L

The post read:

'#PRESS: Today we featured new Phase 3 data for adults with moderate-to-severe atopic dermatitis (AD) at the American Academy of Dermatology virtual meeting experience. We focus on advancing treatments that have the potential to address areas of high unmet need for the millions of people who experience some form of eczema, including AD.

Leo Pharma has devoted decades of research and development to advance the science of dermatology, setting new standards of care for people with skin conditions. For more: [link provided].'

The post was accompanied by a picture with the following statement:

'Leo Pharma's heritage in medical dermatology and strategic focus on advancing the science of skin inflammation diseases uniquely positions us to address the significant and varied unmet needs of people living with atopic dermatitis.'

The complainant noted that a named Leo UK employee had 'liked' the post and therefore it came under the Code as it was material aimed and shared with a UK audience. The post promoted a link to material which discussed the Phase 3 results of a yet to be authorised prescription medicine, tralokinumab, to the public in a promotional manner, therefore advertising a prescription only medicine to the UK public and promoting a product before authorisation to a health professional. The post was promotional and neither the post nor the item on the link had prescribing information. The complainant queried whether the post text and picture had been certified.

The complainant stated that it appeared that Leo had not trained its employees on the correct use of social media. The use of LinkedIn to promote medicines through 'likes' and therefore sharing activity was not traditional promotion and represented disguised promotion for this post.

The named Leo UK employee who had interacted with the post had almost 300 connections on LinkedIn amounting to the post being distributed several hundred times to a UK audience.

Post M

The post read:

‘Psoriasis is a chronic, systemic #inflammatorydisease that primarily affects the skin. Psoriasis does not just cause physical discomfort; the true burden of psoriasis is much bigger. Learn more at:’ – a web address was listed.

A picture accompanied the post with a statement that:

‘125 million people worldwide live with psoriasis.’

The complainant noted that Leo UK employees had ‘liked’ the post and therefore it came under the Code as it was material aimed and shared with a UK audience. The complainant queried whether the post and picture been certified under the Code and whether the material accessed via the link had been assessed under the Code.

The complainant alleged that of the seven named Leo UK employees who had interacted with this post, four had over 500 connections on LinkedIn. When the connections of all employees were added up, it amounted to the post being distributed thousands of times to what appeared to be a predominately UK audience.

Post N

The post read:

‘#PRESS: Today we announced top line results from the Phase 3 randomised, double blind, placebo controlled multinational 52 week ECZTRA 1-3 clinical studies evaluating an investigational treatment in adults with moderate-to-severe atopic dermatitis (AD). AD is the most common inflammatory skin disease in the developed world that affects up to 5 percent of adults across the United States, Canada, Europe and Japan. AD can have a significant, negative impact on patients well being, primarily due to distressing itch, sleep deprivation and social stigmatisation due to visible lesions.’

The complainant noted that Leo UK employees had ‘liked’ the post and therefore it came under the Code as it was material aimed and shared with a UK audience. The post promoted a link to material which discussed the Phase 3 results of a yet to be authorised prescription medicine, tralokinumab, to the public, in a promotional manner, therefore advertising a prescription only medicine to the UK public and promoting a product before authorisation to a health professional. The post was promotional and neither the post nor the item on the link had a prescribing information. The complainant queried whether the post text and link had been certified.

The complainant stated that it appeared that Leo had not trained its employees on the correct use of social media. The use of LinkedIn to promote medicines through ‘Likes’ and therefore sharing activity was not traditional promotion and represented disguised promotion for this post.

The complainant alleged that of the three named Leo UK employees who had interacted with this post, one had over 500 connections on LinkedIn. When the connections of all employees were added up, it amounted to the post being distributed thousands of times to what appeared to be a predominately UK audience.

When writing to Leo, the Authority asked it to consider the requirements of the clauses of the Code to each post as follows: Clauses 9.1 and 2 (overall), Clauses 14.1 and 14.3 (all posts (A-N)), Clause 7.2 (Post A), Clause 7.2 (Post B), Clause 26.1 in relation to alleged promotion to the public, Clause 4.1, 4.3, 4.8 and 4.10 in relation to the alleged absence of prescribing and other mandatory information, Clause 9.1 in relation to the alleged teaser advertising, Clause 26.2, Clause 7.2, 3.2, 7.9 in relation to the reference to no skin atrophy (Post C), Clause 3, Clauses 4.1, 4.10, Clause 7.10, Clause 26.2 (Post D), Clause 26.1, Clause 4.1 (Post K), Clause 3.1, Clause 26.1, Clause 4.1 (Post L), Clause 26.1, Clause 3.1 and Clause 4.1 (Post N).

RESPONSE

1 Background to the complaint

Leo noted the complainant's allegations regarding the Leo Pharma LinkedIn page itself, material posted on the Leo LinkedIn page and interactions/engagements with posts on the Leo Pharma LinkedIn page by Leo Pharma UK employees (ie 'like', support and celebrate).

The complainant claimed that the Leo Pharma UK corporate website suggested a link to the Leo Pharma LinkedIn page, but the reader was directed to Leo Pharmaceuticals Ballerup DK, which he/she stated appeared to be the global LinkedIn page for Leo Pharma.

Leo explained that the Leo Pharma LinkedIn page was the corporate page for Leo Pharma globally, as recognized by the complainant. The page was owned by Leo Pharma, Ballerup Denmark and this was stated prominently at the top of the page, which included a link to the website for Leo Pharma A/S, Leo Pharma's global headquarters. The content on the Leo Pharma LinkedIn page was managed by the Global Corporate Communications team in Denmark and directed globally, with contributions from Leo Pharma affiliates around the world. Leo Pharma's global team posted content targeted at all users, whereas Leo Pharma affiliates only posted content directed towards their local audiences. The Leo Pharma LinkedIn page had no specific UK focus and so while it included some recruitment notices for positions at Leo Pharma UK, it also included recruitment notices for roles at many other Leo Pharma affiliates; a review of the page on 28 January 2021 showed that 112 jobs from 20 countries were advertised only 3 of which related to positions within the UK.

The complainant asserted that some members of the Leo Pharma UK team were included in posts and videos, however, such posts and videos were not identified. References to UK staff in a proportion of posts and videos did not necessarily mean that such posts and videos were placed on the LinkedIn page by, or with the authority of Leo Pharma UK, or that the page was specifically directed to a UK audience.

In summary, the Leo Pharma LinkedIn page clearly stated, in the introduction section, that it was owned and managed by Leo Pharma A/S rather than Leo Pharma UK and the content was directed towards a global audience without focus or emphasis placed on the UK market. Leo thus suggested that the Leo Pharma LinkedIn page did not generally fall within the scope of the Code.

For the avoidance of doubt, while Leo Pharma UK did not believe that the Leo Pharma LinkedIn page was subject to the Code in its entirety, it recognized that, in accordance with Clause 28.2, the following were subject to the Code:

- Material posted by, or with the authority of, Leo Pharma UK.
- Material posted by, or with the authority of, an affiliate of Leo Pharma UK which made specific reference to the availability or use of a Leo medicine in the UK.

Leo submitted that the complainant also criticised interactions by Leo Pharma UK employees with posts on the Leo LinkedIn page, through reactions such as 'likes'. The complainant suggested generally that:

- Activity by a LinkedIn member could potentially constitute proactive dissemination of material to his/her connections.
- Activity by individuals and associated content might appear on their LinkedIn profile pages, which become visible to their connections and possibly people outside their network, depending on their security settings; and
- Sharing of information might involve sending material to categories of persons who have no interest in it (eg health professionals in unrelated disciplines) or members of the public, who might not be permitted to receive it.

2 Leo Pharma UK's social media policies and training

The Leo Pharma Group Policy ('Leo Employees' Personal Use of Social Media') was put in place in 2013 (copy provided). The policy stated that it only applied to the extent that reference was made to Leo, its products or services, its policies or research, work at Leo and its competitors and the company's relationships with them, or any other topic directly related to **company business** [emphasis in original]. Leo employees were informed that they must comply with the following principles:

Always separate your personal opinions from those of Leo, if you make **reference to any topic related to our business**.

Personal posts relating to Leo products are strongly discouraged, and it is strictly forbidden for you to make any statement that implies any product benefit, efficacy, clinical trial, safety claim or any other content that may be regarded as promotional.

Do not make any **unauthorised disclosures**, especially regarding confidential or sensitive information.

Do not use **Leo trademarks, designs, copyrights, etc.**

Do not use your **Leo email address** in connection with a personal social media account.

Report any possible **adverse reactions/events or other experiences** of Leo products that you might become aware of while using social media.

Never **communicate on behalf of Leo** on social media, unless you are duly authorized' [Emphasis in original].

Leo noted that it issued a Social Media 'Dos and Don'ts' document in August 2018 (copy provided), which supplemented the Leo Group Policy with particular focus on UK and Ireland requirements. Leo Pharma UK employees were encouraged to 'follow' Leo Pharma UK/IE on Facebook, Twitter, Instagram and LinkedIn (all posts by Leo Pharma UK were certified in accordance with the Code) and reminded employees of certain requirements including:

'Don't add links to Leo Pharma social media in your email signature

Don't promote Leo Pharma social media pages with external stakeholders, unless authorised to do so

Don't post anything on social media about Leo Pharma products or competitor companies and their products

Don't use your Leo Pharma email address in connection with a personal social media account.'

The 'Dos and Don'ts' document was updated in March 2021 (copy provided). While that update followed the posts, which were the subject of this complaint, it reinforced information provided to Leo Pharma UK employees to avoid certain social media activities including:

'**DON'T** post or engage with any content which mentions any Leo Pharma products or investigational compounds, about any competitor products or organisations, including any press releases

DON'T engage with any content from the Leo Pharma Global LinkedIn channel or any other Leo Pharma social media channel, as some of their content may contain product or disease awareness information and is not locally approved

DON'T use your work email address in connection with your social media account

DON'T include any social media channels in your work email signature.'

Leo noted that in advance of the American Academy of Dermatology Virtual Meeting Experience (AADVMX), an email dated 9 June 2020 headed 'Important Compliance Information: Employee use of social media, AADVMX and PSO-LONG' was sent to Leo Pharma UK employees attaching copies of the Leo Group Policy and Social Media 'Dos and Don'ts' (copy provided). The email advised Leo Pharma UK employees not to engage with social media posts from Leo Pharma global or US and made specific reference to Twitter and LinkedIn channels:

'Ahead of the American Academy of Dermatology Virtual Meeting Experience (AADVMX) 2020, between Friday, June 12 - Sunday, June 14, please note the following:

During the event, our Global and US colleagues are planning to conduct media and social media activity on Leo Pharma's Global and US Twitter and LinkedIn channels

that mention products and data. Their content has **not been certified in the UK or Ireland** and therefore if any UK or Ireland employees 'like', 'share' or 'comment' on their social media posts, this may constitute a breach of the ABPI Code and/or IPHA Code by way of promotion to members of the public (albeit unintentional).

We advise that, in this case, you do not engage with any social media posts from Leo Pharma Global or US that is related to the AADVMX 2020 Meeting; tralokinumab and PSO-LONG.

There is one UK/IE post that you can engage with which is the following and will be on Twitter and LinkedIn on Friday June 12. This will be UK/IE certified and contains no links. *(A copy of the post was incorporated into the email – the post informed the reader that Leo Pharma would be taking part in the first ever virtual AAD meeting and looked forward to sharing and connecting over the next three days about the latest in medical dermatology).*

We do not want to prevent you from engaging with Leo Pharma non-promotional content on social media, however, you must never engage with content that **includes or links through to product-related content.**

Further guidance:

- Please review the attached Group Policy on Employee Use of Social Media and the UK/IE Social Media Dos and Don'ts.
- Please visit the Pulse page Employees on Social Media for more guidance' [emphasis in original].

Leo noted that Leo Pharma UK employees were also reminded of the company's social media policy in an email sent on behalf of the UK general manager on 12 June 2020 (copy provided), which commenced with:

'Further to my update at our UKIE Team Forum on last week, I would like to share with you further updates below. There is a lot of detail in this week's update so please take the time to read to the end. There is one non-COVID update regarding the AAD at the end which is important to read.'

The 'non-COVID update' referenced in the opening paragraph of the email stated:

'AAD update

In non-COVID related news and ahead of the American Academy of Dermatology Virtual Meeting Experience (AADVMX) 2020, between Friday, June 12 - Sunday, June 14, please note the following:

We advise that, you do not engage with any social media posts from Leo Pharma Global or US that is related to the AADVMX 2020 Meeting; tralokinumab and PSO-LONG.

There is one UK/IE post that you can engage with which is the following and will be on Twitter and LinkedIn on Friday June 12. This will be UK/IE certified and contains no links.

We do not want to prevent you from engaging with Leo Pharma non-promotional content on social media, however, you must never engage with content that **includes or links through to product-related content.**

Further guidance:

- Please review the Group Policy on Employee Use of Social Media and the UK/IE Social Media Dos and Don'ts
- Please visit the Pulse page Employees on Social Media for more guidance

Additionally, unless you have been briefed to do so, you must refer any enquiries to the following colleagues if they request information:

Non-HCPs (media, patient advocacy groups):

All enquiries should be passed to the Communications team:

[Contact details provided]

HCPs: As always please refer related queries to Medical Information:

[Contact details provided].'

Leo noted that the UK general manager reiterated the same information in a further email sent to Leo Pharma UK employees on 15 June 2020 (copy provided) in relation to results of key clinical trials.

The Leo Group Policy, together with the UK/IE Social Media 'Dos and Don'ts' document was again drawn to the attention of Leo Pharma UK employees by email on 18 August 2020 (copy provided), in the context of an announcement that Leo Pharma UK had reached 1,000 followers on Instagram.

With regard to training, Leo noted that Leo Pharma A/S provided training on the use of social media to the global organisation, including Leo Pharma UK employees between 1 and 7 December 2020 (copy slides were provided). Leo's global social media policy was summarised in those slides as:

- Always protect confidential and proprietary information.
- Don't mention any Leo Pharma products or investigational compounds.
- Don't like, comment on or share any third-party social media posts that mention any of our products or investigational compounds.
- Be respectful in tone and content.
- Report any suspected adverse events.

3 Response to criticisms of the Leo LinkedIn page

Leo submitted that the issues raised by the complainant related solely to incidents where Leo Pharma UK employees, using their personal LinkedIn accounts, had 'liked' posts on the global Leo Pharma LinkedIn page. Leo Pharma UK understood, based on a series of past decisions, that the PMCPA took the view that such interaction with LinkedIn posts constituted proactive dissemination of the post in question to the connections of the relevant employee, for which Leo Pharma UK was responsible. The number of individuals who would receive the post in their LinkedIn feed, following such dissemination, would be determined by an algorithm operated by

LinkedIn. However, in view of the range of individuals connected via LinkedIn, any post 'liked' by a Leo Pharma UK employee would probably be disseminated to both health professionals and members of the public.

Leo Pharma UK noted that, as explained above, it had implemented social media policies both at global and UK level. Following the various decisions by the PMCPA in relation to the implications of 'liking' posts on LinkedIn, Leo Pharma UK advised its employees, in relation to engagement with social media, including that 'liking' posts on LinkedIn could bring such posts within the scope of the Code. Finally, further training was provided in early December 2020, coinciding with the receipt of this complaint and the UK social media 'Dos and Don'ts' had been updated in March 2021 to reinforce Leo Pharma UK's policy that its employees should not engage with social media posts issued by Leo Pharma global.

While Leo Pharma UK understood and supported the position of the PMCPA, implementation was challenging. Social media required rapid interaction, which was often not consistent with certification under the Code and dissemination of material to connections as a result of 'liking' a post, did not generally involve the same consideration as the provision of a document selected and provided in hard copy or electronically to a specific individual. Leo Pharma UK employees held LinkedIn accounts in a personal capacity and wished to engage with social media on their own behalf, including to express their personal support for non-promotional posts by third parties, such as patient organisations. While Leo Pharma UK had clearly notified its employees that engagement with LinkedIn posts referring to Leo Pharma authorised medicines or investigational compounds was not permitted, it recognized that, before March 2021, explicit guidance was not provided in relation to engagement with non-promotional posts. Leo was not aware of any case where 'liking' such posts had been found in breach of the Code, however, the PMCPA's general approach suggested that even non-promotional educational material, including that produced independently by third parties, might not be 'liked' by a Leo Pharma UK employee on a personal basis and using a personal account, unless the post had been certified in accordance with Clause 14.3. Leo questioned whether such an approach was appropriate and invited the PMCPA to clarify the position. In the meantime, Leo Pharma UK had stated that its employees should not engage with any social media posts by Leo Pharma global irrespective of whether they related to specific medicines or constituted non-promotional material relating, for example, to disease awareness.

Finally, and for completeness, Leo submitted that posts E, F, G, K and L included links which did not appear to access the material alleged by the complainant, but currently linked to the Leo Pharma A/S corporate website and a page showing the company's annual return and accounts, as well as press releases. Leo knew that Leo Pharma A/S might modify the content of certain links or delete some listed press releases as a matter of standard practice after a period of 3 weeks and that might be the position for the links in the identified posts. Leo could not, at this stage, confirm whether the links had been modified as described or whether they had always accessed the company's annual return and accounts. The response below was on the basis of the links as currently functioning.

Post A

This post was made by Leo Pharma A/S and stated:

'29th October is #worldpsoriasisday. At Leo Pharma, we're marking this day by launching a series of patient videos that outline everyday challenges of living with psoriasis. Learn

more about our commitment to helping people with psoriasis, not just today - but every day - by visiting www.everydaypsoriasis.com #beinformed #WPD2020 #everydaypsoriasis.'

The post was accompanied by a video prepared by Leo staff globally, which confirmed Leo's 'manifesto' to help patients with psoriasis; this was not promotional and did not provide information regarding medicines or diseases. A copy of the post and the accompanying video were provided.

Leo explained that Post A and the accompanying video as posted on the Leo Pharma LinkedIn page did not meet the criteria listed at Clause 28.2 of the Code which defined which material, placed on the internet outside the UK, fell within the scope of the Code. While Leo Pharma UK did contribute to the overall creation of the campaign and one Leo Pharma UK employee featured in the video, Leo Pharma UK was not responsible for Post A or the version of the video that accompanied it. Both Post A and the video were prepared and posted by Leo Pharma A/S on the global Leo LinkedIn page, without the involvement or authority of Leo Pharma UK. The post and video were directed at a global audience with no specific reference to the UK or use of medicines in the UK. For the reasons given below, Post A and the video posted on the Leo Pharma LinkedIn page were not certified or otherwise assessed in accordance with the Code.

Leo noted that the complainant identified six individuals alleged to have interacted with Post A; two were employed by Leo Pharma A/S and four were employed by Leo Pharma UK. Leo recognized that such activity by the four Leo Pharma UK employees potentially brought Post A within the scope of the Code.

The embedded link to www.everydaypsoriasis.com #beinformed #WPD2020 #everydaypsoriasis took the reader to information on the Leo Pharma A/S website about psoriasis, including stories of patient experiences. Leo Pharma UK accepted that if the position of the PMCPA was that 'liking' of such non-promotional information by Leo Pharma UK employees meant that (contrary to the intention when it was posted) it fell within the scope of the Code, then this post and the link should have been certified in accordance with Clause 14.3.

The content of the video published on Post A was, however, different and Leo did not believe it needed to be certified under Clause 14, even where Leo Pharma UK employees engaged with the post. The content was not promotional for the purposes of Clause 14.1 and did not constitute educational material relating to diseases or medicine or fall within any other category under Clause 14.3. Instead, the content comprised a corporate mission statement or manifesto, which did not require certification.

Leo noted that the complainant criticised the link in the post to www.everydaypsoriasis.com #beinformed #WPD2020 #everydaypsoriasis, claiming that readers would be led to believe that they were being directed to a psoriasis website, when in fact the link took them to the Leo Pharma A/S website and a page providing information on psoriasis. Leo disagreed. The description of the link on the Leo LinkedIn page stated explicitly that this allowed readers to 'learn more about our [Leo's] commitment to helping people with psoriasis', clearly indicating that the information would be provided by Leo. This was not misleading; dissemination of the link in Post A by Leo Pharma UK employees was thus not in breach of Clause 7.2.

Post B

Post B stated:

‘Jane’s story... “What makes me feel bad is when I see other people looking... Because you can see the cogs working like, oh, is she contagious?”.

Psoriasis doesn’t care what day it is. That’s why we at Leo Pharma have chosen to mark #worldpsoriasisday this year with a series of patient stories about everyday challenges of living with psoriasis. Learn more about how we’re committed to helping people with psoriasis not just today but every day by visiting www.everydaypsoriasis.com #beinformed #WPD2020 #everydaypsoriasis.’

The accompanying video was one also accessed via the link in Post A (copy provided); it showed an animated account of a patient experience with psoriasis. The video was not promotional but did provide information regarding disease. A copy of Post B and the accompanying video were provided. Leo submitted that Post B and the accompanying video as posted on the Leo Pharma LinkedIn page did not meet the criteria listed at Clause 28.2 of the Code which defined which material, placed on the internet outside the UK, fell within the scope of the Code. They were prepared and posted by Leo Pharma A/S on the global Leo LinkedIn page, without the involvement or authority of Leo Pharma UK. The post and video were directed at a global audience with no specific reference to the UK or use of medicines in the UK. For the reasons given below, Post B and the video were not certified or otherwise assessed in accordance with the Code.

Leo stated that the information accessed through the link www.everydaypsoriasis.com #beinformed #WPD2020 #everydaypsoriasis was not assessed under the Code because it was prepared and published by Leo Pharma A/S on the Leo Pharma A/S website and directed at a global audience with no specific reference to the UK or use of medicines in the UK.

Leo noted that the complainant identified three individuals alleged to have interacted with Post B; one of them was employed by Leo Pharma A/S and two were employed by Leo Pharma UK. Leo recognized that such activity by two Leo Pharma UK employees potentially brought Post B within the scope of the Code.

Leo submitted that Post B, the accompanying video and the link to www.everydaypsoriasis.com were not promotional and included no reference, direct or indirect, to specific medicines. There was accordingly no requirement to certify such material in accordance with Clause 14.1. However, Post B, the video and the material accessed via the link all provided educational information about psoriasis and Leo Pharma UK accepted that, if the PMCPA’s position was that ‘liking’ of such non-promotional information by Leo Pharma UK employees meant that (contrary to the intention when it was posted) it fell within the scope of the Code, then this post, the video and the link should have been certified in accordance with Clause 14.3 of the Code.

Leo did not agree that the link to www.everydaypsoriasis.com #beinformed #WPD2020 #everydaypsoriasis was misleading. The description of the link on the Leo LinkedIn page stated explicitly that this allowed the reader to ‘learn more about our [Leo’s] commitment to helping people with psoriasis’, and clearly indicated that the information would be provided by Leo; this was not misleading and dissemination of the link in Post B by Leo Pharma UK employees was thus not in breach of Clause 7.2.

Post C

Post C stated:

‘Are you a healthcare professional planning to attend **#EADV**Virtual next week?’

Then we’ve got a treat for you – our sponsored Satellite Symposium will take the “virtual” theme to another level. Watch [named health professionals from Germany, UK and Canada] as they use the power of digital visualisation to explore our theme “Long-term topical management of psoriasis: the road ahead” (SAT 3.3, virtual room Alibert).

More info here: <https://lnkd.in/dUYdYbU>.’

Leo noted that the post was accompanied by a video called ‘EADV Teaser’ which referred to the PSO-LONG trial and provided high speed images of the three experts presenting data. No speech was audible, and it was not possible to review the data due to the rapidity of the video footage. Leo Pharma UK understood that the video was intended to provide an indication only of the content of the satellite symposium sponsored by Leo Pharma A/S and held virtually at the European Academy of Dermatology and Venereology Congress in November 2020, but not to provide substantive information. A copy of Post C and the accompanying video were provided.

Leo explained that Post C and the accompanying video as posted on the Leo Pharma LinkedIn page did not meet the criteria listed at Clause 28.2 of the Code which defined which material, placed on the internet outside the UK, fell within the scope of the Code. They were prepared and posted by Leo Pharma A/S on the global Leo LinkedIn page, without the involvement or authority of Leo Pharma UK. They were directed at a global audience with no specific reference to the UK or use of medicines in the UK. While the video featured a UK health professional, Clause 28.2 did not suggest that a UK speaker brought material within the scope of the Code, unless the other listed criteria were met.

For the reasons given below, there was no requirement for Post C and the video posted on the Leo Pharma LinkedIn page to be certified or otherwise assessed in accordance with the Code.

Leo noted that the complainant identified two Leo Pharma UK employees alleged to have interacted with Post C. Leo recognized that such activity potentially brought Post C within the scope of the Code. However, in considering the contacts of the two identified Leo Pharma UK employees, one of them did not have any LinkedIn contacts who were health professionals and the health professional contacts of the other were limited to those who had expressed an interest in working in the pharmaceutical industry, including at Leo Pharma.

Post C and the embedded link to the registration page for the sponsored satellite symposium did not include any references to specific medicines. Post C clearly stated that the satellite symposium was sponsored by Leo Pharma and the registration page accessed via the link emphasized that only EU health professionals could proceed. The video did not name any specific medicines but did name the PSO-LONG study, which investigated the effects of Enstilar; the name of the study was, however, visible only very briefly and in the context of other, non-product related information about psoriasis. Leo did not consider that Post C, the embedded link and the video were promotional and so there was no requirement to certify the material in accordance with Clause 14.1, in circumstances where its employees engaged with the post. Leo relied upon the decision of the Panel in Case AUTH/3038/4/18.

For completeness, Leo submitted that the content of Post C and the embedded link did not fall within the categories listed under Clause 14.3 of the Code. The video did include information about psoriasis, but the video ran too rapidly to be informative and so did not comprise 'educational material for the public or patients'. In such circumstances, Clause 14.3 was not applicable.

As set out above, Post C, the embedded link and the video did not refer to any specific medicines and were not promotional. In those circumstances, there was no requirement to include prescribing information for any medicine, as provided by Clause 4.1, or to state the date when Post C, the link and/or the video were made or revised, as provided by Clause 4.8. Further, the post, link and the accompanying video did not include the brand names of any medicine and there was, accordingly, no requirement to include any non-proprietary name as provided by Clause 4.3. As Post C, the link and the video were not promotional, there could be no requirement for a black triangle to be included and accordingly, no breach of Clause 4.10. For completeness, while the PSO-LONG study was referenced briefly in the video, Enstilar was not subject to a requirement to include a black triangle.

Post C, the link and the accompanying video did not promote or provide information about a prescription only medicine to members of the public for the purposes of Clause 26.1 or Clause 26.2. Leo referred to its submission above.

There was no reference to any medicine in Post C, the link or the video and the name of the PSO-LONG trial, which appeared very briefly on the video, could not be adequately considered and would not suggest any specific medicine to members of the public.

The link to the invitation to the satellite symposium <https://lnkd.in/dUYdYbU>, clearly stated that it was intended for health professionals only and required confirmation of status prior to access.

Leo noted that the complainant criticised the video for allegedly including the words 'no skin atrophy', which he/she claimed was misleading, not balanced, compromised safety and promoted a medicine outside of its authorisation. Leo explained that the video was run rapidly with no oral accompaniment. With multiple repeat viewing it was possible to discern certain headline statements on the slides; these included 'PSO-LONG'; '80%'; 'treatment drivers of adherence'; 'topical adherence rates in psoriasis'; 'no cases of skin atrophy'; and 'long-term topical treatment model'. However, if viewed only once, the information obtained was substantially more limited. There was no reference to any medicine in the video although, as mentioned above, this did include, albeit briefly, the name of the PSO-LONG trial, which investigated Enstilar.

Leo noted that the video did not state 'no skin atrophy' as alleged by the complainant, but rather included the words 'no cases of skin atrophy'. The addition of 'cases' substantially altered the meaning, to make clear that the statement was not a broad assertion about topical treatments in general or any specific product but related to a particular situation or study. There was no proximity in the video between the reference to 'PSO-LONG' and the words 'no cases of skin atrophy' and the video made no connection between 'no cases of skin atrophy' and Enstilar.

In the above circumstances, and as stated above, Leo Pharma did not consider that the video made any safety claim in relation to Enstilar or otherwise promoted it. The video simply informed viewers of the information set out below in a visual, rather than a written form that:

- a Leo sponsored satellite symposium would be held at the EADV virtual congress;
- the satellite symposium would involve presentation of data from the PSO-LONG trial;
- these data would be discussed by three named experts.

Leo provided a copy of the Enstilar summary of product characteristics (SPC) which it noted, described at Section 4.2, different treatment regimens and dosages for use of the product for flare treatment and long-term maintenance. At Section 4.4, the SPC stated:

‘Long-term use of corticosteroids may increase the risk of local and systemic adverse reactions. Treatment should be discontinued in case of adverse reactions related to long-term use of corticosteroid (see section 4.8).’

At section 4.8, the SPC stated:

‘Local reactions can occur after topical use, especially during prolonged application, including skin atrophy, telangiectasia, striae, folliculitis, hypertrichosis, perioral dermatitis, allergic contact dermatitis, depigmentation, and colloid milia.’

Leo noted that the SPC thus warned of the possibility of local skin reactions, including skin atrophy, especially during prolonged application; it did not state that such effects occurred in all cases when the product was used. Accordingly, even if, contrary to Leo Pharma UK’s position as set out above, the statement in the video ‘no cases of skin atrophy’ had been clearly linked with certain data relating to particular treatment regimens with Enstilar, this did not, in any event, suggest that use of Enstilar was never associated with skin atrophy and would not have been inconsistent with the SPC or in breach of Clause 3.2 of the Code as a result of Leo Pharma UK employees engaging with the post.

Leo noted that the video did not name Enstilar and the words ‘no cases of skin atrophy’ on the video were not unethical and did not promote Enstilar or any specific medicine. In those circumstances, there was no breach of Clause 7.2 as a result of dissemination of the video by Leo Pharma UK employees.

Leo submitted that, as noted above, the complainant had misquoted the relevant text on the video such that even on his/her case that the video linked the statement with Enstilar, the wording did not indicate that the product was not associated with skin atrophy. In any event, the video did not name or otherwise promote Enstilar. There was accordingly no breach of Clause 7.9, following dissemination of the video by Leo Pharma UK employees.

With respect to the title of the video as ‘EADV Teaser’, Leo agreed that this description was unfortunate. However, the content of the video did not fall within the definition of ‘teaser’ advertising provided in the supplementary information to Clauses 9.1 and 9.2. In particular, Post C and the video did not seek to elicit an interest in something ‘without providing any actual information about it because visual information was provided to readers as noted above. There was accordingly no breach of Clause 9.1 following dissemination of the video by Leo Pharma UK employees.

Finally, Leo noted that the complainant stated that, by interacting with Post C, Leo Pharma UK employees had invited a UK audience to the virtual sponsored satellite symposium at EADV and claimed that the presentations/videos/content for the symposium itself should therefore have been certified in accordance with the Code. However, as stated above, one of the two Leo

Pharma UK employees identified by the complainant did not have any LinkedIn contacts who were health professionals and the health professional contacts of the other were limited to those who had expressed an interest in working in the pharmaceutical industry, including at Leo Pharma. Leo Pharma UK accepted that the dissemination of invitations to UK health professionals [to the virtual satellite symposium] by Leo Pharma UK employees would mean that the content of the satellite symposium should have been certified in accordance with Clause 14.1 the Code. In circumstances where the virtual satellite symposium was organised by Leo Pharma A/S with no involvement by Leo Pharma UK and where there was no intention that Leo Pharma UK employees would disseminate information regarding the symposium to UK health professionals, such certification did not take place.

Post D

Post D stated:

'We are proud to welcome our new Oral IL-17A protein-protein interaction modulator to our clinical pipeline.

Did you know that it's very challenging to obtain an oral small molecule drug with the efficacy of an antibody?

Through clever design, our R&D team has come up with a drug candidate which has been selected to enter development. Why is this news so ground-breaking? We'll let our [named senior executive] explain the science behind. **#PioneeringTogether.**'

Leo noted that Post D was accompanied by a video, in which the senior executive in question provided further information in relation to the medicine candidate, including the statements identified by the complainant. A copy of Post D and the accompanying video were provided.

Leo stated that Post D and the accompanying video as posted on the Leo Pharma LinkedIn page did not meet the criteria listed at Clause 28.2 which defined which material, placed on the internet outside the UK, fell within the scope of the Code. The post and video were prepared and posted by Leo Pharma A/S on the global Leo LinkedIn page, without the involvement or authority of Leo Pharma UK. They were directed at a global audience with no specific reference to the UK or use of medicines in the UK. For the reasons given below, Post D and the video posted on the Leo Pharma LinkedIn page were not certified or otherwise assessed in accordance with the Code.

Leo noted that the complainant had identified five Leo Pharma UK employees alleged to have 'liked' Post D. Leo recognized that such activity potentially brought the post within the scope of the Code. Post D concerned a compound under early development and, as such, communications might not be promotional. There was accordingly no requirement to certify materials referring to such compounds under Clause 14.1. For completeness, Leo submitted that the content of Post D and the accompanying video did not fall within the categories listed under Clause 14.3 and there was thus no requirement to certify the material in accordance with Clause 14.3 in the context of engagement with the post by Leo Pharma UK employees.

Leo stated that the oral IL-17A protein-protein interaction modulator compound discussed was in early development and clinical trials had not yet commenced. In those circumstances, Leo did not believe that the compound constituted a 'medicine' for the purposes of Clause 3.2 or that

statements made in Post D could be viewed as promotional, as defined by Clause 1.2; there was clearly no intention to 'promote the administration, consumption, prescription, purchase, recommendation, sale, supply or use' of the referenced compound at a time when clinical trials had not yet commenced. That the post was not promotional was also consistent with the fact that the individual featured in the video was a vice president of global research rather than someone employed in a commercial role. In circumstances where the compound referenced in Post D was in early stage development only, Leo did not believe the content breached Clause 3.2. This view was consistent with the Panel's decisions in Case AUTH/3336/4/20 and the Appeal Board's in Case AUTH/3364/6/20.

As indicated above, the oral IL-17A protein-protein interaction modulator referenced in Post D was in early development only. There was accordingly no prescribing information for the compound and no requirement to show a black triangle in materials which referred to the compound. In these circumstances, the fact that no prescribing information or black triangle was included with Post D and the video with which Leo Pharma UK employees engaged, did not constitute a breach of either Clause 4.1 or Clause 4.10. Leo referred to the decision of the Panel in Case AUTH/3287/12/19.

Leo noted that the complainant criticised the use of 'unique' and 'completely unique' in the video accompanying Post D. Clause 7.10 provided that:

'Promotion must encourage the rational use of a medicine by presenting it objectively and without exaggerating its properties. Exaggerated or all-embracing claims must not be made, and superlatives must not be used except for those limited circumstances where they relate to a clear fact about a medicine.'

As indicated above, Leo Pharma UK did not believe that the oral IL-17A protein-protein interaction modulator referenced constituted a 'medicine' or that the content was promotional as defined in Clause 1.2. In any event, the references in the video fairly reflected the situation in this case where the candidate compound was a first in class molecule and there was currently no oral medicine with the relevant mechanism of action. In summary, therefore, while Clause 7.10 referred to statements made in the context of the promotion of a medicine and was not therefore applicable when discussing a compound which was not simply unlicensed, but was in early stage development, there was on the facts of this case, no exaggeration in any event.

Leo further noted that the complainant criticised Post D and the video on the basis that the information raised a lot of hope, potentially unfounded given the stage of development. The 'hope' referenced by the complainant was unclear and, in circumstances where the observations in Post D and the video were limited to the fact that the candidate product could be administered orally, Leo did not believe the reference to 'a lot of hope' properly reflected the nature of the statements made. In any event, the oral IL-17A protein-protein interaction modulator referenced was not authorised and therefore did not constitute a prescription only medicine. In these circumstances, the engagement with the post by Leo Pharma UK employees did not breach the requirements of Clause 26.2 which related solely to information about prescription only medicines. Leo referred to the Panel's decision in Case AUTH/3037/4/18.

Post E

Post E stated:

‘Eczema is not only a skin condition. Atopic Dermatitis is a type of eczema that can have a significant, negative impact on quality of life, primarily due to distressing itch, sleep disturbance and social embarrassment due to visible lesions. On World Atopic Eczema Day, we are proud to support eczema warriors.

Learn more about how we are working to make a difference in the lives of people living with skin diseases at <https://leo-pharma.com>
#DermatologyBeyondTheSkin #LeoPharmaCares #AtopicEczemaDay.’

A copy of Post E was provided.

Leo submitted that Post E as posted on the Leo LinkedIn page did not meet the criteria listed at Clause 28.2 which defined which material, placed on the internet outside the UK, fell within the scope of the Code. It was prepared and posted by Leo Pharma A/S on the global Leo LinkedIn page, without the involvement or authority of Leo Pharma UK. It was directed at a global audience with no specific reference to the UK or use of medicines in the UK.

Leo noted that the complainant also referred to a video and asked whether this had been certified in accordance with the Code. However, no video accompanied Post E. The link embedded in the text accessed the Leo Pharma A/S website and provided a corporate statement entitled ‘Dermatology Beyond the Skin’ (copy provided). For the reasons given above, Post E as posted on the Leo LinkedIn page, including the link to the Leo Pharma A/S website, were not certified or otherwise assessed in accordance with the Code.

Leo noted that the complainant identified six Leo Pharma UK employees alleged to have ‘liked’ Post E. Leo recognized that such activity potentially brought the post within the scope of the Code. Post E was non-promotional and there was accordingly no requirement to certify the content under Clause 14.1, in the context of dissemination by Leo Pharma UK employees. However, Leo Pharma UK accepted that the post contained limited disease-related information and, to the extent that ‘likes’ of such LinkedIn post by its employees (contrary to the intention when it was posted) brought such material within the scope of the Code, this should have been certified in accordance with Clause 14.3. However, Leo believed that the link to the Leo Pharma A/S website did not require certification in any event. The link accessed a Leo Pharma A/S corporate statement entitled ‘Dermatology Beyond the Skin’, which was non-promotional and did not fall within any of the categories of non-promotional material listed in Clause 14.3.

Post F

Post F stated:

‘Thank you to writer and eczema warrior [name] for sharing your story with Leo Pharma on #AtopicEczemaDay to help us address the greatest needs of people living with eczema. We are inspired by your journey and passion for raising the voices of eczema warriors.

Learn more about how we are working to make a difference in the lives of people living with skin conditions at <https://leo-pharma.com>.

#DermatologyBeyondTheSkin #LeoPharmaCares.’

Leo noted that Post F was accompanied by a picture produced by the European Federation of Allergy and Airways Disease Patients Associations (EFA) for World Atopic Eczema Day including the wording 'Add your voice to World Atopic Eczema Day'. A copy of Post F and the accompanying picture were provided.

Leo submitted that Post F and the accompanying picture as posted on the Leo Pharma LinkedIn page did not meet the criteria listed at Clause 28.2 which defined which material, placed on the internet outside the UK, fell within the scope of the Code. They were prepared and/or posted by Leo Pharma A/S on the global Leo LinkedIn page, without the involvement or authority of Leo Pharma UK. They were directed at a global audience with no specific reference to the UK or use of medicines in the UK.

Leo noted that in addition to Post F and the accompanying picture, the complainant also asked whether the information accessed via the link had been assessed under the Code. This was the same link as that embedded in Post E above ie it accessed the Leo Pharma A/S website and provided a corporate statement entitled 'Dermatology Beyond the Skin' (copy provided). For the reasons given above, Post F and the accompanying picture, as posted on the Leo LinkedIn page, including the link to the Leo Pharma A/S website, were not certified or otherwise assessed in accordance with the Code.

Leo noted that the complainant identified two Leo Pharma UK employees alleged to have 'liked' post F. Leo recognized that such activity potentially brought post F within the scope of the Code. Post F was non-promotional and there was accordingly no requirement to certify the content under Clause 14.1, in the context of dissemination by Leo Pharma UK employees. Furthermore, post F did not provide information about diseases and the picture was one produced and issued by EFA for dissemination. It did not constitute 'material relating to working with patient organisations' as envisaged by Clause 14.3. Leo did not believe there was any requirement to certify Post F or the accompanying picture in the context of dissemination by Leo Pharma UK employees.

Post G

Post G stated:

'We're proud to stand with people living with eczema on #AtopicEczemaDay and every day. LEARN MORE about how we are working to make a difference in the lives of people living with skin diseases at <https://leo-pharma.com> #DermatologyBeyondTheSkin #LeoPharmaCares.'

Leo noted that Post G was accompanied by a picture produced by the European Federation of Allergy and Airways Disease Patients Associations (EFA) which stated 'SEPTEMBER 14th World Atopic Eczema Day' and asked the question 'How do YOU care for atopic eczema?'. A copy of Post G and the accompanying picture were provided.

Leo submitted that Post G and the accompanying picture as posted on the Leo Pharma LinkedIn page did not meet the criteria listed at Clause 28.2 which defined which material, placed on the internet outside the UK, fell within the scope of the Code. They were prepared and/or posted by Leo Pharma A/S on the global Leo LinkedIn page, without the involvement or

authority of Leo Pharma UK. They were directed at a global audience with no specific reference to the UK or use of medicines in the UK and so Post G and the accompanying picture as posted on the Leo Pharma LinkedIn page were not certified or otherwise assessed in accordance with the Code.

Leo noted that the complainant identified eight Leo Pharma UK employees alleged to have 'liked' Post G. Leo recognized that such activity potentially brought Post G within the scope of the Code. Leo submitted that Post G was non-promotional and there was accordingly no requirement to certify the content under Clause 14.1, in the context of dissemination by Leo Pharma UK employees. Furthermore, Post G did not provide information about diseases and the picture was one produced and issued by EFA for dissemination. It did not constitute 'material relating to working with patient organisations' as envisaged by Clause 14.3. Leo did not believe there was any requirement to certify Post G or the accompanying picture in the context of dissemination by Leo Pharma UK employees.

Post H

Post H stated:

'August is Psoriasis Action Month. Psoriasis is a skin condition that impacts more than 8 million people in the United States and 125 million people worldwide.

Raising awareness can be a first step toward changing the perception of psoriasis. Show your support by learning more about the disease and get involved.

#PsoriasisActionMonth #ThisIsPsoriasis #PioneeringDermatology
#DermatologyBeyondTheSkin

MORE: https://lnkd.in/gY6X_Sy.'

A copy of Post H was provided.

Leo submitted that Post H, as posted on the Leo LinkedIn page, did not meet the criteria listed at Clause 28.2 which defined which material, placed on the internet outside the UK, fell within the scope of the Code. It was prepared and posted by Leo Pharma A/S on the global Leo LinkedIn page, without the involvement or authority of Leo Pharma UK. It was directed at a global audience with no specific reference to the UK or use of medicines in the UK.

Leo noted that in addition to Post H, the complainant also asked whether the information accessed via the link had been assessed under the Code. For the reasons noted above, Post H, as posted on the Leo Pharma LinkedIn page, including the link which accessed the US National Psoriasis Foundation website at www.psoriasis.org, were not certified or otherwise assessed in accordance with the Code.

Leo noted that the complainant had identified two Leo Pharma UK employees alleged to have 'liked' Post H. Leo recognized that such activity potentially brought the post within the scope of the Code. Post H was non-promotional and there was accordingly no requirement to certify the content under Clause 14.1, in the context of dissemination by Leo Pharma UK employees. While the post referred to the number of people impacted by psoriasis in the US and worldwide, Leo suggested that the content was too limited to bring the text within the scope of Clause 14.3

and that accordingly there was no requirement for it to be certified in accordance with Clause 14.3 prior to dissemination by Leo Pharma UK's employees.

The link referenced by the complainant accessed the US National Psoriasis Foundation website (copy provided), at a page entitled '*About Psoriasis*' that addressed disease but did not include details of any named psoriasis medicines. Leo Pharma UK did not believe that the material accessed via this link, containing factual information about disease and provided independently and at arm's length from Leo Pharma by a patient organisation, fell within the scope of the Code. This view was consistent with the supplementary information to Clause 28.6, which stated that 'sites linked via company sites are not necessarily covered by the Code' and meant that the National Psoriasis Foundation website did not require certification under the Code, including when the link was disseminated by Leo Pharma UK employees.

Post I

Post I stated:

'We are proud to share this great news regarding Gorlin Syndrome Alliance. On November 9, 2020, our patient organisation partner will conduct a Listening Session with the FDA. This ninety-minute virtual meeting is a fantastic opportunity to raise awareness on Gorlin Syndrome and give a voice to the people living with this condition.

To learn more about the session, please refer to the post below.

#DermatologyBeyondTheSkin #PioneeringTogether.'

Leo noted that the complainant also referred to a 'picture'. Post I included only a copy of a post by the Gorlin Syndrome Alliance, a patient organisation. Leo assumed that that was the 'picture' referenced by the complainant. A copy of Post I and the post by the Gorlin Syndrome Alliance were provided.

Leo noted that Post I, as posted on the Leo Pharma LinkedIn page, did not meet the criteria listed at Clause 28.2 which defined which material, placed on the internet outside the UK, fell within the scope of the Code. It was prepared and posted by Leo Pharma A/S on the global Leo LinkedIn page, without the involvement or authority of Leo Pharma UK. It was directed at a global audience with no specific reference to the UK or use of medicines in the UK.

In addition to Post I, the complainant also asked whether the post by the Gorlin Syndrome Alliance had been assessed under the Code. For the reasons given above, Post I and the post by the Gorlin Syndrome Alliance, as posted on the Leo Pharma LinkedIn page, were not certified or otherwise assessed in accordance with the Code.

Leo noted that the complainant identified one Leo Pharma UK employee alleged to have 'liked' Post I. Leo recognized that such activity potentially brought the post within the scope of the Code.

Leo submitted that Post I was non-promotional and there was accordingly no requirement to certify the content under Clause 14.1, in the context of dissemination by Leo Pharma UK employees. Furthermore, while the post referred to a proposed discussion between the FDA and the Gorlin Alliance, and identified the Alliance as 'our patient organisation partner', neither

Post I nor the post by the Gorlin Alliance constituted 'material relating to working with patient organisations' or any other material within the scope of Clause 14.3. Leo therefore did not believe there was any requirement to certify Post I or the accompanying post by the Gorlin Alliance in the context of dissemination by Leo Pharma UK employees.

Post J

Post J stated:

'Did you know atopic dermatitis (AD) – also known as atopic eczema – is the most common inflammatory skin disease in the developed world? Learn more at <https://lnkd.in/dKjFk5q> #AADVMX2020.'

Post J was accompanied by a picture which stated: 'atopic dermatitis affects up to 5% of adults across the United States, Canada, Europe and Japan'. A copy of Post J together with the accompanying picture were provided.

Post J and the accompanying picture, as posted on the Leo Pharma LinkedIn page, did not meet the criteria listed at Clause 28.2 which defined which material, placed on the internet outside the UK, fell within the scope of the Code. They were prepared and posted by Leo Pharma A/S on the global Leo LinkedIn page, without the involvement or authority of Leo Pharma UK. They were directed at a global audience with no specific reference to the UK or use of medicines in the UK.

Leo noted that in addition to Post J, the complainant also asked whether the information accessed via the link had been assessed under the Code. For the reasons given in paragraph above, Post J, and the accompanying picture as posted on the Leo Pharma LinkedIn page, including the link which accessed Leo Pharma's eczema.com website, were not certified or otherwise assessed in accordance with the Code.

Leo noted that the complainant identified two Leo Pharma UK employees alleged to have 'liked' Post J. Leo recognized that such activity potentially brought the post within the scope of the Code.

Leo submitted that Post J was non-promotional and there was accordingly no requirement to certify the content under Clause 14.1, in the context of dissemination by Leo Pharma UK employees. Post J and the accompanying picture referred to the number of people impacted by atopic eczema in the US, Canada, Europe and Japan and the post included a link to Leo Pharma's eczema.com website, which included disease related information. Leo Pharma UK accepted that, assuming 'liking' such information brought it within the scope of the Code, Post J, the picture and the material accessed via the link fell within the scope of Clause 14.3 and that accordingly they should have been certified in accordance with Clause 14.3 prior to dissemination by Leo Pharma UK's employees.

Post K

Post K stated:

#PRESS: Today, we announce results from the Phase 3 PSO-LONG study of potential long-term, proactive psoriasis management as ePosters by American Academy of Dermatology.

Leo Pharma is committed to building on our 30+ year heritage of pursuing innovative products for patients affected by psoriasis, as well as other chronic skin conditions.

You can read more about the results here: <https://lnkd.in/dWapsR8>.'

Leo noted that the complainant also referred to a picture which accompanied Post K and included a quotation from the executive vice president of Leo Pharma Research and Development:

'Our vision in psoriasis is to provide prescription solutions for patients with all severities of psoriasis. Our diverse pipeline of innovative late-stage drug candidates aims to support a range of treatment options for people living with psoriasis and other chronic skin conditions across the globe.'

A copy of Post K and the accompanying picture were provided.

Leo submitted that Post K and the accompanying picture, as posted on the Leo Pharma LinkedIn page, did not meet the criteria listed at Clause 28.2 which defined which material, placed on the internet outside the UK, fell within the scope of the Code. They were prepared and posted by Leo Pharma A/S on the global Leo Pharma LinkedIn page, without the involvement or authority of Leo Pharma UK. They were directed at a global audience with no specific reference to the UK or use of medicines in the UK. Press releases such as that in Post K might be published on social media in accordance with Danish rules, as long as the content was accurate, fair and balanced. Post K complied with Danish rules and the Danish Code.

Leo noted that in addition to Post K, the complainant also asked whether the embedded link, which he/she stated accessed results of the PSO-LONG study had been assessed under the Code. For the reasons given with regard to Post E and above, Post K and the embedded link, as posted on the Leo Pharma LinkedIn page, were not certified or otherwise assessed in accordance with the Code.

Leo noted that the complainant identified two Leo Pharma UK employees alleged to have 'liked' Post K. Leo recognized that such activity potentially brought the post within the scope of the Code.

Leo stated that Post K stated factually that the results from the Phase 3 PSO-LONG study had been announced. This was not promotional. The embedded link accessed the Leo Pharma A/S website at the page entitled 'Our performance and results'. That page, in turn, included a link to Leo Pharma's annual report. When the complaint was received, there would have been no articles about the Phase 3 PSO-LONG study results on that page. Leo Pharma UK did not believe there was any requirement to certify such material in accordance with Clause 14.1, including to the extent that Post K was disseminated by Leo Pharma UK employees. The content of the post did not fall within the categories of material listed at Clause 14.3 and there was accordingly no requirement to certify it in accordance with that clause.

Leo stated that in circumstances where, for reasons explained above, Post K was not promotional, Leo did not believe that engagement with the post by Leo Pharma UK employees constituted promotion of Enstilar to members of the public contrary to Clause 26.1. Finally, in circumstances where, for reasons explained above, Post K did not promote Enstilar, engagement with the post by Leo Pharma UK employees did not mean that it should have been accompanied by prescribing information as provided by Clause 4.1.

Post L

Post L stated:

‘#PRESS: Today we featured new Phase 3 data for adults with moderate-to-severe atopic dermatitis (AD) at the American Academy of Dermatology virtual meeting experience. We focus on advancing treatments that have the potential to address areas of high unmet need for the millions of people who experience some form of eczema, including AD.

Leo Pharma has devoted decades of research and development to advance the science of dermatology, setting new standards of care for people with skin conditions.

For more: [#AADVMX2020.](https://lnkd.in/dWapsR8)’

Leo noted that the complainant also referred to an accompanying picture which included a quotation from the executive vice president of Leo Pharma Research and Development:

‘Leo Pharma’s heritage in medical dermatology and strategic focus on advancing the science of skin inflammation diseases uniquely positions us to address the significant and varied unmet needs of people living with atopic dermatitis.’

A copy of Post L and the accompanying picture were provided.

Leo submitted that Post L and the accompanying picture, as posted on the Leo Pharma LinkedIn page, did not meet the criteria listed at Clause 28.2 which defined which material, placed on the internet outside the UK, fell within the scope of the Code. They were prepared and posted by Leo Pharma A/S on the global Leo Pharma LinkedIn page, without the involvement or authority of Leo Pharma UK. They were directed at a global audience with no specific reference to the UK or use of medicines in the UK. Press releases such as that in Post L might be published on social media in accordance with Danish rules, as long as the content was accurate, fair and balanced. Leo submitted that Post L complied with Danish rules and the Danish Code.

Leo noted that in addition to Post L and the picture, the complainant asked whether the embedded link, which he/she stated accessed results of a study involving tralokinumab, had been assessed under the Code. For the reasons given above, Post L and its embedded link, as well as the accompanying picture, as posted on the Leo Pharma LinkedIn page, were not certified or otherwise assessed in accordance with the Code.

Leo noted that the complainant identified one Leo Pharma UK employee alleged to have ‘liked’ the post. Leo recognized that such activity potentially brought Post L within the scope of the Code. Leo submitted that Post L and the accompanying picture mentioned no specific medicines and were not promotional. While the post stated that Leo Pharma ‘featured Phase 3

data for adults with moderate-to-severe atopic dermatitis (AD) at the American Academy of Dermatology virtual meeting experience', this was a neutral statement of fact and details of the Phase 3 data (including the name of any specific medicine and whether the data were favourable or not) were not stated. The rest of the text in Post L, as well as that in the accompanying picture, comprised corporate history and mission statements which did not relate to or promote any medicine.

Leo noted that the text relating to Leo Pharma's corporate history and mission statement in Post L was followed by wording advising readers that, if they wished to know 'more' they should follow the embedded link, which accessed the Leo Pharma A/S website at the page entitled 'our performance and results'. This page, in turn, included a link to Leo Pharma's 2020 annual report (the same link as that for Post K was provided). The link therefore related to the annual report, rather than to particular Phase 3 data and, contrary to the complainant's allegation, there was no reference to tralokinumab or any other specific medicine.

Leo submitted that the information described above did not promote medicines and did not require certification in accordance with Clause 14.1, including where Leo Pharma UK employees engaged with Post L.

Leo stated that for completeness, Post L and the accompanying picture did not fall within the categories of material listed at Clause 14.3 and there was accordingly no requirement to certify them in accordance with that clause.

Post L, the embedded link and the accompanying picture did not promote any specific medicines, licensed or unlicensed. Leo noted the information given above and stated that in these circumstances there was no promotion of a medicinal product prior to grant of a marketing authorisation contrary to Clause 3.1; no medicine was promoted to the public contrary to Clause 26.1 and there was no promotion of a medicine requiring the provision of prescribing information in accordance with Clause 4.1. Leo submitted that the complainant's assertion that Post L was in breach of Clause 3.1 as well as Clause 4.1 was, in any event, inconsistent, as a medicine with no marketing authorisation could not require prescribing information in accordance with Clause 4.1.

Post M

Post M stated:

'Psoriasis is a chronic, systemic #inflammatorydisease that primarily affects the skin. Psoriasis does not just cause physical discomfort; the true burden of psoriasis is much bigger. Learn more at: <https://lnkd.in/dv7XiKc>.'

Leo noted that the complainant also referred to a picture, which accompanied Post M and stated '125 Million people worldwide live with psoriasis'. A copy of Post M and the accompanying picture were provided.

Leo submitted that Post M and the accompanying picture, as posted on the Leo Pharma LinkedIn page, did not meet the criteria listed at Clause 28.2 which defined which material, placed on the internet outside the UK, fell within the scope of the Code. They were prepared and posted by Leo Pharma A/S on the global Leo Pharma LinkedIn page, without the

involvement or authority of Leo Pharma UK. They were directed at a global audience with no specific reference to the UK or use of medicines in the UK.

Leo noted that in addition to Post M and the picture, the complainant asked whether the embedded link had been assessed under the Code. Leo stated that for the reasons given above, Post M and its embedded link, as well as the accompanying picture, as posted on the Leo Pharma LinkedIn page, were not certified or otherwise assessed in accordance with the Code.

Leo noted that the complainant identified seven Leo Pharma UK employees alleged to have 'liked' Post M. Leo recognized that such activity potentially brought the post within the scope of the Code.

Leo submitted that Post M was non-promotional and so there was no requirement to certify the content under Clause 14.1, in the context of dissemination by Leo Pharma UK employees. However, while the post and accompanying picture included no substantive information about psoriasis as a disease, the embedded link accessed the Leo Pharma A/S website and a page relating to World Psoriasis Day entitled 'Psoriasis does not care which day it is' (copy provided) which provided educational, disease related information within the scope of Clause 14.3. Leo Pharma UK therefore accepted that if the PMCPA considered that 'liking' such non-promotional information by Leo Pharma UK employees meant that (contrary to the intention when it was posted) it fell within the scope of the Code, then the link should have been certified in accordance with Clause 14.3.

Post N

Leo noted that the complainant alleged that Post N stated:

'#PRESS: Today we announced top line results from the Phase 3 randomised, double blind, placebo controlled multinational 52 week ECZTRA 1-3 clinical studies evaluating an investigational treatment in adults with moderate-to-severe atopic dermatitis (AD). AD is the most common inflammatory skin condition in the developed world that affects up to 5% of adults across the United States, Canada, Europe and Japan. AD can have a significant negative impact on patients well-being, primarily due to distressing itch, sleep deprivation and social stigmatisation due to visible lesions.

MORE: <https://www.leo-pharma.com/media-center.>'

Leo stated that Post N was not present on the Leo Pharma LinkedIn page. It was Leo Pharma's standard policy, as well as that of LinkedIn, to take posts down after a certain amount of time and it was possible that Leo Pharma UK had been unable to locate Post N because of the length of time between the date the post was posted and the date when the complaint was submitted. However, in any event, Leo Pharma UK had been unable to verify the fact or content of Post N. Leo thus suggested that the PMCPA should request images of Post N from the complainant and in the absence of those, the post should not be considered by the Panel.

4 Conclusion

Leo stated that none of the 14 LinkedIn posts identified by the complainant were posted by, or with the authority of, Leo Pharma UK and none of them related specifically to use of medicines

in the UK. However, Leo accepted that, in relation to five posts on the Leo Pharma LinkedIn page, the engagement of Leo Pharma UK employees by 'liking' LinkedIn posts and the resulting dissemination to the contacts of such employees, had resulted in breaches of the Code arising from the fact that non-promotional posts were not certified in accordance with Clause 14.3.

While the position regarding the requirement to certify non-promotional material before it was 'liked' on LinkedIn had not, so far as Leo were aware, been the subject of any case decided by the PMCPA and the scope of at least some of the non-promotional statements identified by the complainant were very limited, Leo Pharma UK took any allegation of breach of the Code very seriously. Therefore, following receipt of the complaint and pending clarification from the PMCPA, Leo had reviewed its own procedures and had revised the UK 'Dos and Don'ts' document to make clear that engagement with social media (such as 'likes' on LinkedIn) might bring a post within the scope of the Code, whether the post was promotional or non-promotional. Leo reiterated that its employees had been reminded both before and after the activities that were the subject of the current complaint that they should not engage with any content from the Leo Pharma global LinkedIn page or any other Leo Pharma global social media channel, as some of the content might contain product or disease awareness information which had not been locally approved. The revisions to the UK 'Dos and Don'ts' document had been reinforced through training.

In addition, Leo Pharma UK had set up a UK and Ireland LinkedIn page which would house approved UK and Ireland content suitable for UK and Irish employees to 'like' or share. Leo would also encourage UK employees to 'unfollow' the Leo Pharma A/S LinkedIn page, in an effort to reduce the risk that they might inadvertently and, despite internal procedures, guidance and training, 'like' content which had not been certified in accordance with the Code. Comprehensive, interactive training regarding this matter had been delivered to the UK and Ireland organisation in recent weeks.

Leo therefore respectfully suggested that its procedures and the five cases where breaches of the Code might have occurred did not, in all the circumstances, demonstrate a failure to meet high standards, contrary to Clause 9.1 and did not bring the industry into disrepute, contrary to Clause 2.

PANEL RULING

The Panel noted Leo's submission that the LinkedIn page at issue was the corporate page for Leo Pharma globally; it was owned by Leo Pharma Ballerup Denmark which Leo submitted was stated at the top of the page and managed by the global corporate communications team in Denmark. The Panel did not have a copy of this LinkedIn page before it. The Panel further noted Leo's submission that the content posted was directed globally, with contributions from Leo affiliates around the world; Leo's global team posted content for all users, whereas Leo affiliates only posted content directed towards their local audiences.

The Panel considered that in accordance with Clause 28.2, information or promotional material about medicines placed on the Leo Pharma global LinkedIn page outside of the UK would be within the scope of the Code if it was placed there by Leo UK/with Leo UK's authority, or if it was placed there by an affiliate to Leo UK (or with its authority) and specifically referred to the availability or the use of a Leo medicine in the UK. Further, material directed at a UK audience would be within the scope of the Code.

The complainant noted that the UK corporate site directed its users to the LinkedIn page in question which was not disputed by Leo and queried whether Leo could confirm that all posts on the Leo Pharma A/S LinkedIn page had thus been certified under the Code. The Panel considered, noting its comments above, that as a UK audience was directed to the global LinkedIn page it would fall within the scope of the Code. If this were not the case, then companies could refer to global LinkedIn pages as a means of circumventing the Code. The Panel further noted Leo's submission that since being notified of this complaint it had created a UK and Ireland LinkedIn page which would house approved UK and Ireland content.

The Panel noted that the content of each post was relevant in determining whether the Code applied to the particular post and if so whether certification was required. The Panel noted that the complainant had referred to all posts requiring certification but only specifically referred to fourteen posts which had been engaged with by UK employees.

The Panel considered that *all* content posted on the Leo Pharma A/S LinkedIn page might not meet the criteria of material that required certification under Clauses 14.1 or 14.3 of the Code. Whilst the complainant referred in general terms to all content, he/she only provided details in relation to posts A to N and therefore the Panel considered the complainant's comments with regard to each specific post (A-N) highlighted.

In addition, the Panel considered that the UK employees' engagement with the fourteen posts, on the balance of probabilities, had proactively disseminated the material to their connections on LinkedIn, and therefore also brought each post and its associated content within the scope of the Code.

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 noted that material could be disseminated or highlighted by an individual on LinkedIn in a number of ways. In the Panel's view, activity conducted on social media that could potentially alert one's connections to the activity might be considered proactive dissemination of material. In addition, an individual's activity and associated content might appear in the individual's list of activities on his/her LinkedIn profile page which was visible to his/her connections; an individual's profile page was also potentially visible to others outside his/her network depending on the individual's security settings. Company employees should assume that such activity 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. Employees should consider whether such platforms were appropriate for the distribution of the material in question. 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. Companies must have comprehensive and up to date social media policies that provide clear and unequivocal guidance on what was, and what was not, acceptable and it was extremely important that employees were trained upon them and followed them.

The Panel understood that employees might feel inclined to endorse posts related to their company's corporate social media posts but noted that depending on the content such activity might or might not fall within the scope of the Code; companies would be well advised to cover the possibility of that activity in their social media policies. This was particularly important if UK employees were likely to follow the social media accounts of overseas affiliates which might have Codes, laws and regulations that differed to the UK.

The Panel considered that any material associated with a social media post, for example a video or link within a post, would be regarded as being part of that post and it made its rulings in that regard. The Panel was not an investigatory body as such, and it made its rulings on the evidence provided by both parties.

Post A

The Panel noted that Post A stated:

'29th October is #worldpsoriasisday. At Leo Pharma, we're marking this day by launching a series of patient videos that outline everyday challenges of living with psoriasis. Learn more about our commitment to helping people with psoriasis, not just today - but every day - by visiting www.everydaypsoriasis.com #beinformed #WPD2020 #everydaypsoriasis'

and included a video which according to Leo was prepared by staff globally and confirmed Leo's 'manifesto' to help patients with psoriasis.

The Panel noted Leo's submission that the link within the post to www.everydaypsoriasis.com took users to information relating to psoriasis on the Leo Pharma A/S website, including stories of patient experiences. The Panel noted that the webpage referred to '... lots of different types of treatment that help people to manage [psoriasis] and improve quality of life' and referred to managing the condition via treatments and lifestyle changes. In the Panel's view, the webpage made no direct or indirect reference to a specific treatment and appeared to be disease awareness information for the public.

The Panel noted that the 52 second video that was part of the LinkedIn post also made no direct or indirect reference to a medicine; the video included Leo employees referring to World Psoriasis Day and the need for recognition beyond that day. The video ended with a slide stating that Leo chose to mark World Psoriasis Day by sharing some everyday conversations of people with psoriasis talking about the challenges they faced.

The Panel noted Leo's submission that four of the individuals named by the complainant as having engaged with Post A (ie 'like', support or celebrate) were employed by Leo UK. The Panel considered that the UK employees' engagement with the post, on the balance of probabilities, had proactively disseminated the material to their connections on LinkedIn. The

Panel noted that not all the employees' connections on LinkedIn would meet the Code's definition of a health professional.

In the Panel's view, the LinkedIn post was non-promotional material for the public and so Clause 14.1 was not relevant; no breach of Clause 14.1 was ruled.

The Panel considered that the LinkedIn post constituted educational material for the public related to psoriasis. The material had not been certified as required by Clause 14.3 and a breach was ruled as acknowledged by Leo. This ruling was appealed by Leo.

In relation to the allegation that readers would be misled that the everydaypsoriasis.com link within the LinkedIn post at issue would direct to a psoriasis website but instead it took readers to a Leo webpage which gave information on psoriasis, the Panel considered that it was sufficiently clear from the post (which was from Leo) that the reader was being directed to a Leo owned website; the post referred to learning more about our (Leo's) commitment '...by visiting www.everydaypsoriasis.com'. The Panel therefore ruled no breach of Clause 7.2 in that regard.

Post B

The Panel noted that Post B stated:

'Jane's story... "What makes me feel bad is when I see other people looking... Because you can see the cogs working like, oh, is she contagious?"

Psoriasis doesn't care what day it is. That's why we at LEO Pharma have chosen to mark #worldpsoriasisday this year with a series of patient stories about everyday challenges of living with psoriasis. Learn more about how we're committed to helping people with psoriasis not just today but every day by visiting www.everydaypsoriasis.com #beinformed #WPD2020 #everydaypsoriasis'

and included a video titled 'Jane's story'.

The Panel noted its comments above about Post A in relation to the content of the website www.everydaypsoriasis.com.

The Panel noted that the 96 second video that was part of the LinkedIn post made no direct or indirect reference to a medicine; the video discussed a patient's experience of living with psoriasis.

The Panel noted Leo's submission that two of the individuals named by the complainant as having engaged with Post B (ie 'like', support or celebrate) were employed by Leo UK.

The Panel considered that the UK employees' engagement with the post, on the balance of probabilities, had proactively disseminated the material to their connections on LinkedIn. The Panel noted that not all the employees' connections on LinkedIn would meet the Code's definition of a health professional.

In the Panel's view, the LinkedIn post was non-promotional material for the public and it therefore ruled no breach of Clause 14.1.

The Panel noted Leo's submission that Post B, which included the video and the material accessed via the link, provided educational information about psoriasis. The Panel noted that the material had not been certified as required by Clause 14.3 and a breach was ruled as acknowledged by Leo.

In relation to the allegation that readers would be misled that the link within the post at issue would direct to a psoriasis website but instead it took readers to a Leo webpage which gave information on psoriasis, the Panel considered that it was sufficiently clear from the post (which was from Leo) that the reader was being directed to a Leo owned website; the post stated 'Learn more about how we're (Leo is) committed to helping people with psoriasis not just today but every day by visiting www.everydaypsoriasis.com'. The Panel therefore ruled no breach of Clause 7.2 in that regard.

Post C

The Panel noted that Post C stated:

'Are you a healthcare professional planning to attend #EADVVirtual next week? Then we've got a treat for you – our sponsored Satellite Symposium will take the "virtual" theme to another level. Watch [named health professionals from Germany, UK and Canada] as they use the power of digital visualisation to explore our theme "Long-term topical management of psoriasis: the road ahead" (SAT 3.3, virtual room Alibert). More info here: <https://lnkd.in/dUYdYbU> #EADV2020 #DermatologyBeyondTheSkin.'

The Panel noted Leo's submission that the link to more information within the post directed readers to a Leo congress website where users had to declare that they were a health professional. Users could then access a webpage with details of a symposium entitled 'Long-term topical management of psoriasis: the road ahead' which also included a link to register for the webinar and the date, time and agenda for the meeting. The agenda did not name a specific medicine but stated that data from recently published new studies would be presented.

The LinkedIn post was accompanied by a 33 second video called 'EADV Teaser' which was a number of fast-moving images set to a background of music which appeared to show, amongst other things, slides with data from the PSO-LONG clinical trial. The claim 'No cases of skin atrophy' was stated boldly in the centre of one slide. The video did not directly name a medicine, however, the Panel noted Leo's submission that the PSO-LONG trial investigated Leo's prescription only medicine Enstilar (betamethasone dipropionate/calcipotriol monohydrate), which was a topical treatment for psoriasis vulgaris in adults.

The Panel noted Leo's submission that two of the individuals named by the complainant as having engaged with Post C ('like', support or celebrate) were employed by Leo UK. The Panel further noted Leo's submission that one of those employees had no health professional LinkedIn contacts and the other who did have such contacts was limited to those health professionals who had expressed an interest in working in the pharmaceutical industry, including at Leo.

The Panel considered that the UK employees' engagement with the post, on the balance of probabilities, had proactively disseminated the material to their connections on LinkedIn. The Panel noted that not all the employees' connections on LinkedIn would meet the Code's definition of a health professional. However, the Panel considered that members of the public

were unlikely to make any connection between PSO-LONG and Enstilar. The Panel therefore considered, on the balance of probabilities, that a prescription only medicine had not been promoted to the public and no breach of Clause 26.1 was ruled.

The Panel noted Leo's submission that one of the UK employees who engaged with Post C had connections who were health professionals. The Panel considered that some health professionals would link the information about PSO-LONG in the post to Enstilar. In the Panel's view, the video, which formed part of the post and which prominently displayed the name of the Enstilar clinical trial (PSO-LONG) and included claims such as 'No cases of skin atrophy' was promotional material for Enstilar. The LinkedIn post, which included the video, had not been certified as required by the Code and the Panel ruled a breach of Clause 14.1. This ruling was appealed by Leo. The Panel consequently ruled no breach of Clause 14.3.

Prescribing information had not been provided as required by the Code and the Panel therefore ruled a breach of Clause 4.1. This ruling was appealed by Leo.

There was no display of the brand name within the post or associated video or link to further information and so there was no requirement to state the non-proprietary name and so the Panel ruled no breach of Clause 4.3.

The image of the LinkedIn post did not give the exact date it was posted. There was no date on when the promotional material was drawn up or last revised and therefore the Panel ruled a breach of Clause 4.8. This ruling was appealed by Leo.

The Panel noted Leo's submission that the licensing authority did not require promotional material for Enstilar to include of an inverted black triangle; the Panel ruled no breach of Clause 4.10 in that regard.

The Panel noted that section 4.8 of the Enstilar SPC stated:

'Betamethasone (as dipropionate):

Local reactions can occur after topical use, especially during prolonged application, including skin atrophy, telangiectasia, striae, folliculitis, hypertrichosis, perioral dermatitis, allergic contact dermatitis, depigmentation, and colloid milia.'

The Panel considered that the prominent claim within the video of 'No cases of skin atrophy', within the context of the fast-moving images in this short video, was misleading with respect to the safety of Enstilar and was inconsistent with the particulars listed in its SPC; a breach of Clauses 7.2, 7.9 and 3.2 were ruled. These rulings were appealed by Leo.

The Panel noted its comment above that in its view a prescription only medicine had not been promoted to the public as it was unlikely that the public would make a connection between PSO-LONG and Enstilar; in that regard, the post did not provide misleading information to the public about the side effects of Enstilar and no breach of Clause 26.2 was ruled.

The Panel noted that the supplementary information to Clause 9.1 stated that the standards set for the promotion of medicines were higher than those which might be acceptable for general commodity advertising. In that context the supplementary information further stated that certain types, styles and methods of promotion were unacceptable, including 'teaser' advertising ie

promotional material intended to tease the recipient by eliciting an interest in something which would be available at a later date without providing any actual information about it. In the Panel's view, 'something' referred to a medicine. The Panel considered, however, that the LinkedIn post and its associated video and link promoted a webinar and provided a trailer to elicit people's interest in the event and although it was unfortunate that it was referred to as a 'teaser', the Panel did not consider that it was teaser advertising as described in the supplementary information to Clause 9.1 of the Code; the Panel therefore ruled no breach of Clause 9.1 in that regard.

The Panel noted that the complainant had queried whether Leo UK had certified the presentations/videos/content for the EADV symposium. The Panel noted Leo's submission that the symposium was sponsored by Leo Pharma A/S and held virtually at the European Academy of Dermatology and Venereology Congress in November 2020. The Panel further noted that Leo accepted that the dissemination of invitations for the symposium to UK health professionals would mean that the content of the symposium would require certification in accordance with Clause 14.1 of the Code and that this had not occurred.

The Panel noted its comments above in that one of the UK employees who engaged with Post C had connections who were health professionals. The Panel considered that the employee's engagement with the post, on the balance of probabilities, had proactively disseminated the material to his/her connections on LinkedIn, most of whom would be UK based, and therefore he/she had invited UK health professionals to the symposium and therefore the symposium content required certification. The Panel therefore ruled a breach of Clause 14.1.

Post D

The Panel noted that Post D stated:

'We are proud to welcome our new Oral IL-17A protein-protein interaction modulator to our clinical pipeline.

Did you know that it's very challenging to obtain an oral small molecule drug with the efficacy of an antibody?

Through clever design, our R&D team has come up with a drug candidate which has been selected to enter development. Why is this news so ground-breaking? We'll let our [named senior executive] explain the science behind. #PioneeringTogether'

The post included a 69 second video where the Leo vice president of global research referred to an investigational molecule as having a 'Completely unique mode of action' and that it was a 'true unique opportunity'.

The Panel noted Leo's submission that five Leo UK employees identified by the complainant had 'liked' the post at issue. The Panel considered that the UK employees' engagement with the post, on the balance of probabilities, had proactively disseminated the material to their connections on LinkedIn. The Panel noted that not all the employees' connections on LinkedIn would meet the Code's definition of a health professional.

In the Panel's view, it was not necessarily unacceptable for a company to refer in general terms to its pipeline products on its corporate accounts. However, language, context, location, layout,

intended audience and overall impression were important factors. The Panel queried whether a social media platform such as LinkedIn with a varied audience was the appropriate forum to share such information.

Clause 3.1 stated that a medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply.

The Panel noted Leo's submission that the oral compound discussed in Post D was in early development and clinical trials had not yet commenced. The Panel considered that it was clear that Leo was a long way off having the compound available for use when the post was made or engaged with by UK employees. The Panel noted its comments above and did not consider that the post promoted a medicine prior to the grant of its marketing authorisation and no breach of Clause 3.1 was ruled. The Panel consequently ruled no breach of Clause 4.1, 4.10 and 7.10.

The Panel did not consider that the post was material covered by either Clause 14.1 or 14.3 and therefore it ruled no breach of Clauses 14.1 and 14.3.

The compound referred to was not a prescription only medicine when the LinkedIn post was made or 'liked' by the five Leo UK employees. Clause 26.2 only applied to prescription only medicines and the Panel therefore ruled no breach of Clause 26.2 with regard to the allegation that the LinkedIn post raised the hopes of the public.

Posts E-J, M

The Panel noted that in relation to Posts E, F, G, H, I, J and M, the complainant had questioned if the posts had been certified.

The Panel noted Leo's submission that a number of Leo UK employees had 'liked' each post which ranged from 1 employee (Post I) to 8 employees (Post G).

The Panel considered that the UK employees' engagement with each post, on the balance of probabilities, had proactively disseminated the material to their connections on LinkedIn.

In the Panel's view, there was no direct or indirect reference to a specific prescription only medicine in Posts E, H, I, J and M. The webpage accessed from the link within each of posts E, H, J and M, from the evidence provided by Leo, made no direct or indirect reference to a specific prescription only medicine nor did the post from the Gorlin Syndrome Alliance included within Post I. Whilst it was evident that some of the linked websites did have sections that discussed treatments (eg the US National Psoriasis Foundation website accessed from Post H) the webpage content as provided by Leo which the link directed to made no reference to a specific prescription only medicine; readers would have to navigate through the website, the content of which was not available to the Panel. On the evidence before it, the Panel considered that the complainant had not discharged his/her burden of proof that Posts E, H, I, J and M were promotional material and no breach of Clause 14.1 was ruled in relation to each.

In the Panel's view, Posts E, H, J and M contained disease information about either eczema or psoriasis and were thus educational material for the public related to disease which required certification under Clause 14.3. The Panel disagreed with Leo's submission that the content of Post H was too limited to bring the text within the scope of Clause 14.3; the post described psoriasis as a skin condition that impacted more than 125 million people worldwide and linked to

the US National Psoriasis Foundation website. A breach of Clause 14.3 was ruled in relation to each of Posts E, J and M, as acknowledged by Leo, and also in relation to Post H. This ruling in relation to post H was appealed by Leo.

Post I referred to a future virtual meeting between the Food and Drug Administration (FDA) and the Gorlin Syndrome Alliance which was a US patient organisation that Leo referred to as a 'partner'; the forthcoming meeting was to raise awareness of the condition. There was no disease information within the post and the Panel had no information before it as to the content of any links within the post. It was not clear if Leo UK had any relationship with the Gorlin Syndrome Alliance. On the evidence before it the Panel considered that the complainant had not discharged his/her burden of proof that the post required certification under Clause 14.3 of the Code and the Panel ruled no breach of Clause 14.3 in relation to Post I.

Posts F and G highlighted World Atopic Eczema Day but had no educational information about the disease or any direct or indirect reference to a specific prescription only medicine within the body of each post. The link within Post F, from the webpage provided by Leo, led directly to the media page on the Leo Pharma A/S website which contained, amongst other things, a list of recent press releases below a bold prominent statement 'Our press releases are intended for the media'. Post G also appeared to link to the same webpage on the Leo Pharma A/S website but Leo had made no submission in that regard.

The Panel noted Leo's submission that the list of press releases on the media page would change over time and that it was standard practice for Leo Pharma A/S to delete certain press releases after a period of 3 weeks. The Panel noted from the webpage provided by Leo, which was available when the company wrote its response to the complaint, the title of the first press release on the list referred to a Phase 3 trial of delgocitinib cream in moderate-to-severe chronic hand eczema. The Panel queried the appropriateness of a LinkedIn post aimed at the public which linked directly to the company's media page which listed press releases that referred to clinical trials. However, the Panel had no information before it as to what press releases were available on the webpage in question when the post was made or UK employees engaged with it. The Panel noted that the content of Posts F and G were in relation to World Atopic Eczema Day and not in relation to a Leo clinical trial. As noted above neither post contained any educational information about eczema. The Panel considered that the complainant had not established, on the balance of probabilities, that Posts F and G were promotional material and no breach of Clause 14.1 was ruled in relation to each post. Furthermore, the complainant had not shown that Posts F and G were material that required certification under Clause 14.3 of the Code; no breach of Clause 14.3 was ruled in relation to each.

Post K

The Panel noted that Post K stated:

'#PRESS: Today, we announce results from the Phase 3 PSO-LONG study of potential long-term, proactive psoriasis management as ePosters by American Academy of Dermatology.

Leo Pharma is committed to building on our 30+ year heritage of pursuing innovative products for patients affected by psoriasis, as well as other chronic skin conditions. You can read more about the results here: [link].'

The Panel noted that the link within the post referred to by the complainant led to the media page of the Leo Pharma A/S website which contained, amongst other things, a list of recent press releases below a bold prominent statement 'Our press releases are intended for the media'. It appeared to the Panel, from the information before it, that the reader was being directed to read more about the results from PSO-LONG via a press release within the media section of the global Leo corporate website. The Panel did not have a copy of the press release; Leo made no submission in that regard although the complainant had stated that the post promoted a link to material which discussed study results of the long-term use of Enstilar.

The Panel considered that there was a difference between making a press release available only to the press, to be published or not, and proactively disseminating it on a publicly accessible social media platform with the inevitability that a wider audience would read it. The use of #PRESS at the beginning of the post would not be likely to restrict the audience to the relevant media.

In the Panel's view, the post, which referred to psoriasis and an Enstilar clinical trial by name (PSO-LONG) and directed users to a webpage to read results from the trial was promotional material for Enstilar.

The Panel noted Leo's submission that the 'You can read more about the results here' link when accessed at the time Leo was notified of the complaint, did not have any articles pertaining to the PSO-LONG study results. The Panel noted that a statement on the webpage in question read:

'To comply with applicable regulation, product-related press releases are removed from our website within three weeks of publication. They are available upon request [hyperlink to email Leo]. For updated information about clinical trials, please visit <https://clinicaltrials.gov/> <https://clinicaltrials.gov/>.'

The Panel had no information before it as to what press releases were available from the webpage in question when the post was made or when UK employees engaged with it but considered that, on the balance of probabilities, given that the post began with '#PRESS: Today, we announce results from the Phase 3 PSO-LONG study...' and ended with 'You can read more about the results here: [link]' that readers were being directed to view study results from PSO-LONG.

The Panel noted Leo's submission that two Leo UK employees identified by the complainant had 'liked' the post at issue. The Panel considered that the UK employees' engagement with the post, on the balance of probabilities, had proactively disseminated the material to their connections on LinkedIn. The Panel noted that not all the employees' connections on LinkedIn would meet the Code's definition of a health professional. Enstilar was classified as a prescription only medicine when the post in question was made and the UK employees 'liked' it. Although the Panel considered that it was unlikely that members of the public would link 'PSO-LONG' to Enstilar, the post referred to psoriasis and innovative products for the condition and as such would encourage readers to 'read more about the results' as invited; the link in the post would, on the balance of probabilities, have directed users to a webpage where they could view more information which would refer to the efficacy results of Leo's medicine. The Panel considered therefore that the post promoted a prescription only medicine to the public and a breach of Clause 26.1 was ruled.

The Panel considered that Leo employees who had 'liked' the post would, on the balance of probabilities, have had connections who met the Code's definition of a health professional, and therefore the post also promoted Enstilar to health professionals. The promotional material had not been certified and the Panel ruled a breach of Clause 14.1. As in the Panel's view, the material was promotional, Clause 14.3 which referred to educational material for the public or patients was not relevant; no breach of Clause 14.3 was ruled.

Prescribing information had not been provided as required by the Code and the Panel therefore ruled a breach of Clause 4.1.

Post L

The Panel noted that Post L stated:

'#PRESS: Today we featured new Phase 3 data for adults with moderate-to-severe atopic dermatitis (AD) at the American Academy of Dermatology virtual meeting experience. We focus on advancing treatments that have the potential to address areas of high unmet need for the millions of people who experience some form of eczema, including AD.

Leo Pharma has devoted decades of research and development to advance the science of dermatology, setting new standards of care for people with skin conditions.

For more: [#AADV2020](https://lnkd.in/dWapsR8).'

The Panel noted that the link within the post referred to by the complainant led to the media page of the Leo Pharma A/S website which contained, amongst other things, a list of recent press releases below a bold prominent statement 'Our press releases are intended for the media'. It appeared to the Panel, from the information before it, that the reader was being directed to read more about the results from a Phase 3 trial for adults with moderate-to-severe atopic dermatitis via a press release within the media section of the global Leo corporate website. The Panel did not have a copy of the press release; Leo made no submission in that regard although the complainant submitted that the post promoted a link to material which discussed the Phase 3 results of a yet to be authorised prescription medicine, tralokinumab.

The Panel disagreed with Leo's submission that the 'For more' link within the post related to the annual report rather than to any particular Phase 3 data and that there was no reference to any specific data. From the webpage provided by Leo, it was clear that it housed press releases in addition to the annual report. The Panel had no information before it as to what press releases were available from the webpage in question when the post was made or when UK employees engaged with it but considered, on the balance of probabilities, that readers were being directed to view study results.

The Panel considered that there was a difference between making a press release available only to the press, to be published or not, and proactively disseminating it on a publicly accessible social media platform with the inevitability that a wider audience would read it. The use of #PRESS at the beginning of the post would not, in the Panel's view, restrict the audience to the relevant media. In the Panel's view, the post, which referred to a Leo Phase 3 clinical trial in atopic dermatitis and directed users to a webpage where they could read results from the trial was promotional material for the medicine.

The Panel noted Leo's submission that one Leo UK employee identified by the complainant had 'liked' the post at issue. The Panel considered that the UK employee's engagement with the post, on the balance of probabilities, had proactively disseminated the material to his/her connections on LinkedIn. The Panel noted that not all the employee's connections on LinkedIn would meet the Code's definition of a health professional.

The Panel noted the complainant's allegation that the data which was being referred to was Phase 3 data on a yet to be authorised product, tralokinumab. The Panel noted that tralokinumab was not a prescription only medicine when the post in question was 'liked' by the UK employee. On that narrow technical point the Panel ruled no breach of Clauses 26.1 and 4.1.

The Panel noted Leo's submission that in advance of the American Academy of Dermatology Virtual Meeting Experience (AADVMX) Leo UK employees were advised not to engage with social media posts from Leo global or US apart from one described UK/IE post (which was not Post L); specific reference was made to LinkedIn channels in this regard. The advice stated, *inter alia*:

'During the event, our Global and US colleagues are planning to conduct media and social media activity on LEO Pharma's Global and US Twitter and LinkedIn channels that mention products and data. Their content has **not been certified in the UK or Ireland** and therefore if any UK or Ireland employees "like", "share" or "comment" on their social media posts, this may constitute a breach of the ABPI Code and/or IPHA Code by way of promotion to members of the public (albeit unintentional).

We advise that, in this case, you do not engage with any social media posts from LEO Pharma Global or US that is related to the AADVMX 2020 Meeting; tralokinumab and PSO-LONG.'

...

'We do not want to prevent you from engaging with LEO Pharma non-promotional content on social media, however, you must never engage with content that *includes or links through to product-related content*.'

The Panel considered, on the evidence before it, that the proactive dissemination of a LinkedIn post which, on the balance of probabilities, directed readers to find information on Phase 3 tralokinumab study results meant that tralokinumab had been promoted prior to the grant of its marketing authorisation. A breach of Clause 3.1 was ruled.

The promotional material had not been certified and the Panel ruled a breach of Clause 14.1. This ruling was appealed by Leo. As, in the Panel's view, the material was promotional, Clause 14.3 which referred to educational material for the public or patients was not relevant; no breach of Clause 14.3 was ruled.

Post N

The Panel noted, from Leo's submission, that Post N had allegedly stated:

'#PRESS: Today we announced top line results from the Phase 3 randomised, double blind, placebo controlled multinational 52 week ECZTRA 1-3 clinical studies evaluating an investigational treatment in adults with moderate-to-severe atopic dermatitis (AD). AD is the most common inflammatory skin condition in the developed world that affects up to 5% of adults across the United States, Canada, Europe and Japan. AD can have a significant negative impact on patients well-being, primarily due to distressing itch, sleep deprivation and social stigmatisation due to visible lesions.

MORE: <https://www.leo-pharma.com/media-center>'

However, the Panel noted, that in his/her complaint, the complainant did not give the URL for the link but just stated that a link was provided.

The Panel noted Leo's submission that Post N was not present on the Leo LinkedIn page possibly due to the length of time that had elapsed between when the post was made and when Leo was notified of the complaint. Leo UK stated that it had been unable to verify the fact or content of this post; however, the Panel noted that Leo had provided the link that was allegedly within the post at issue (MORE: <https://www.leo-pharma.com/media-center>) which was more detail than the complainant had provided.

The Panel was not an investigatory body and judged complaints on the balance of probabilities on the evidence provided by both parties. The Panel considered, on the balance of probabilities, that the post had been made on the Leo Pharma A/S LinkedIn page and that it had been 'liked' by UK employees as alleged. Regardless of the engagement by UK employees, noting its comments above regarding the Leo global LinkedIn page being directed to a UK audience, the Panel considered that the post fell within the scope of the Code.

The Panel noted that it appeared that the URL of the 'MORE' link within the post would direct users to the media page of the Leo Pharma A/S website as in Post L which contained, amongst other things, a list of recent press releases below a bold prominent statement 'Our press releases are intended for the media'. It appeared to the Panel, from the information before it, that the reader was being directed to read more about the results from the ECZTRA trial which was a Phase 3 trial for adults with moderate-to-severe atopic dermatitis via a press release within the media section of the global Leo corporate website. The Panel did not have a copy of the press release; Leo made no submission in that regard although the complainant submitted that the post promoted a link to material which discussed the Phase 3 results of a yet to be authorised medicine, tralokinumab.

The Panel had no information before it as to what press releases were available from the webpage in question when the post was made or when UK employees engaged with it but considered that readers were being directed to view study results.

The Panel considered that there was a difference between making a press release available only to the press, to be published or not, and proactively disseminating it on a publicly accessible social media platform with the inevitability that a wider audience would read it. The use of #PRESS at the beginning of the post would not, in the Panel's view, restrict the audience to the relevant media.

In the Panel's view, the post, which referred to a Leo Phase 3 clinical trial in atopic dermatitis and directed users to a webpage where they could read results from the trial was promotional material for the medicine.

The Panel noted the complainant's submission that Leo UK employees had 'liked' the post at issue. The Panel considered that the UK employees' engagement with the post, on the balance of probabilities, had proactively disseminated the material to his/her connections on LinkedIn. The Panel noted that not all the employees' connections on LinkedIn would meet the Code's definition of a health professional.

The Panel noted the complainant's allegation that the data referred to was Phase 3 data on a yet to be authorised product, tralokinumab. The Panel noted that tralokinumab was not a prescription only medicine when the complaint was submitted. On that narrow technical point the Panel ruled no breach of Clauses 26.1 and 4.1.

The Panel considered, on the evidence before it, that the proactive dissemination of a LinkedIn post which, on the balance of probabilities, directed readers to Phase 3 study results on tralokinumab meant that tralokinumab had been promoted prior to the grant of its marketing authorisation. A breach of Clause 3.1 was ruled.

The promotional material had not been certified and the Panel ruled a breach of Clause 14.1. This ruling was appealed by Leo. As in the Panel's view, the material was promotional, Clause 14.3 which referred to educational material for the public or patients was not relevant; no breach of Clause 14.3 was ruled.

Overall

The Panel noted its comments and rulings of breaches of the Code above and considered that Leo had failed to maintain high standards; a breach of Clause 9.1 was ruled.

Clause 2 was a sign of particular censure and reserved for such use. The Panel noted that the supplementary information to this clause stated that the types of activities likely to be found in breach of Clause 2 included promotion prior to the grant of a marketing authorisation.

The Panel noted that the complainant stated several times that it appeared that Leo had not trained its staff on the correct use of social media. The Panel noted Leo's submission in relation to the training materials available contemporaneous to the complaint.

The Panel noted that the Leo employees' personal use of social media policy was dated 2013 and contained statements which were ambiguous and did not reflect case precedence. For example, it was stated:

'Personal posts relating to LEO products are strongly discouraged, and it is strictly forbidden for you to make any statement that implies any product benefit, efficacy, clinical trial, safety claim or any other content that may be regarded as promotional.'

The term 'strongly discouraged' did not, in the Panel's view, give employees an unequivocal instruction.

Furthermore, under the heading, 'reference to any topic related to our business' it stated:

‘Be clear to separate your opinions from those of LEO, by including remarks such as “the views expressed here are my own, and do not necessarily reflect the views of my employer”.’

However, the social media ‘Dos and don’ts’ reference card (UK/IE MAT-19232, August 2018) stated, amongst other things:

‘Act as an ambassador for LEO Pharma UK/IE e.g. update your LinkedIn profile to All-Star status, like and engage with our social media posts.’

The Panel noted that although a number of email communications with more specific instructions about certain posts had been sent in 2020, some employees would likely be confused by the contradictory and unclear instructions.

The Panel noted its comments and rulings above which included multiple breaches of the Code including promoting a medicine prior to the grant of its marketing authorisation and considered that Leo had brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled. This ruling was appealed by Leo.

APPEAL FROM LEO

Leo appealed the decisions of the Panel with regard to the following posts and associated clause breaches as set out in the table below, as well as the overall finding of a breach of Clause 2:

Post/Activity	Clause
A	14.3
C	14.1, 4.1, 4.8, 7.2, 7.9, 3.2
H	14.3
L	14.1
N	14.1

Leo submitted that the issues raised by the complainant related solely to incidents where Leo Pharma UK employees, using their personal LinkedIn accounts, had ‘liked’ posts on the global Leo Pharma LinkedIn page. All of the posts in question were prepared and posted by Leo Pharma A/S on the global Leo LinkedIn page, without the involvement or authority of Leo Pharma UK, as accepted by the Panel. They were directed at a global audience with no specific reference to the UK or use of medicines in the UK. For these reasons, the posts and associated videos or links were not certified or otherwise assessed in accordance with the Code. Leo Pharma UK submitted that it understood, based on a series of past decisions, that the PMCPA took the view that such interaction with LinkedIn posts constituted proactive dissemination of the post in question to the connections of the relevant employee, for which Leo Pharma UK was responsible. It should be noted that LinkedIn, in a similar vein to other social networks, also had a ‘Share’ function, where a user could proactively and intentionally share a post with all their network. The issues raised by the complaint did not pertain to an intentional ‘sharing’ of posts on the Global Leo Pharma LinkedIn page.

Post A

Leo submitted that Post A, made by Leo Pharma A/S, was accompanied by a video prepared by Leo staff globally, which confirmed Leo's 'manifesto' to help patients with psoriasis; this was not promotional and did not provide information regarding medicines or diseases. The Panel had not explained why it concluded that Post A comprised educational material. The post itself clearly did not include educational material and the embedded video comprised, as recognized in the Panel's decision, a 'manifesto' from Leo A/S rather than educational information relating to disease. Leo therefore assumed that the Panel's findings that this post included educational information must refer to the link in the post, which was a step away from Post A with which Leo Pharma UK employees engaged. The 2019 Code stated that links to different sites would not necessarily fall within the scope of the Code, but provided no further clarification as to the factors which should be taken into account when reaching a determination in this context. Leo suggested that a link to non-promotional educational material on a different site should not be viewed as falling within the scope of the Code.

Leo submitted that irrespective of its comments above that Post A fell outside the scope of the Code, the company asked the Appeal Board to consider whether it was in any event right and proportionate as a matter of principle, to find that engagement by UK employees with non-promotional educational material through LinkedIn required certification under the Code. Leo submitted that this was the first such case in which 'liking' a non-promotional 'disease education' post, had been the subject of a complaint. The position of the Panel was that proactive (albeit unintentional) dissemination of such posts through use of the 'like' function on LinkedIn, even where the post had not been placed online by the UK and the content did not refer or direct to a UK audience, still represented a breach of Clause 14.3 if not certified. In Leo's original response to this complaint, it had questioned whether such an approach was appropriate, however, the Panel did not address this point of principle in its decision. Leo submitted that its general concerns in relation to requiring certification of educational material were set out below.

The requirement to certify educational material for the public or patients (which related to diseases or medicines) had been present in the Code since at least 2006. At this time, social networking was in its relative infancy, and this clause, indeed the Code, was not written with the use of social media in mind. Leo Pharma fully agreed and supported the requirement to certify such material, where it had been produced by a UK company, the content was specifically directed at a UK audience, or was deliberately disseminated by the UK company. The reasons for certifying such material were clear – apart from a medical and scientific accuracy standpoint, it was important that such material remained balanced, did not exaggerate or misrepresent the disease area in question, and did not become disguised promotion for medicines.

Leo submitted that the precedent set by this ruling of a breach of Clause 14.3, for the unintentional dissemination of such material on a professional social networking site such as LinkedIn, was far outside of the original intent of Clause 14.3. Due to the similarity of legislation in European countries pertaining to advertising of prescription medicines, the majority of posts on LinkedIn by global parent pharmaceutical companies were likely to be disease area subject matter rather than product related. Therefore, a ruling of a breach of Clause 14.3 in this instance would essentially serve to sever this link between UK affiliates and the global parent companies as far as LinkedIn was concerned. UK companies would have to instruct their employees to not interact in any way with any posts made by the global company or another affiliate – while it was entirely reasonable and fair to prohibit employee engagement with product related posts, it would not be practical or reasonable to expect all company employees, working

in a variety of diverse functions to use their judgement in determining what constituted disease area education.

Leo submitted that this ruling which essentially required certification of all posts on LinkedIn made by the global company if a UK employee was to interact with it, did not serve to encourage rational prescribing or promote patient safety. Companies should absolutely be held to account if promoting disease area information which was inaccurate or misleading. A blanket requirement for certification was extending rules far beyond their original intended scope and became unnecessary enforcement for the sake of it.

Post C

Leo submitted that the post was accompanied by a video which referred to the PSO-LONG trial and provided high speed images of the three [named] experts presenting data. No speech was audible, and it was not possible to review the data due to the rapidity of the video footage. Leo Pharma UK understood that the video was intended to provide an indication only of the content of the satellite symposium sponsored by Leo Pharma A/S and held virtually at the European Academy of Dermatology and Venereology Congress in November 2020, but not to provide substantive information.

The complainant identified two Leo Pharma UK employees who, he/she alleged, had interacted with Post C. Leo submitted that it recognized that such activity potentially brought Post C within the scope of the Code. However, in considering the contacts of the two identified Leo Pharma UK employees, one of these (named) did not have any LinkedIn contacts who were health professionals and the health professional contacts of the other [named employee] were limited to those who had expressed an interest in working in the pharmaceutical industry, including at Leo Pharma.

Leo submitted that Post C and the embedded link to the registration page for the sponsored satellite symposium did not include any references to specific medicinal products. Post C clearly stated that the satellite symposium was sponsored by Leo Pharma and the registration page accessed via the link, emphasized that only EU health professionals could proceed. The video did not name any specific medicinal products but did name the PSO-LONG study, which investigated the effects of Enstilar (betamethasone dipropionate, calcipotriol monohydrate); the name of the study was however visible only very briefly and in the context of other, non-product related information about psoriasis. It was Leo Pharma UK's position that Post C, the embedded link and the video were not promotional and that there was therefore no requirement to certify this material in accordance with Clause 14.1, in circumstances where its employees engaged with the post. Nor did this post fall within scope of Clause 14.3, as it was not disease area information, as concluded by the Panel.

Leo disagreed with the Panel's ruling that this 30 second video, which was designed to generate interest amongst health professionals in signing up for a virtual symposium held at an international dermatology congress, was promotional. The Panel had made this ruling based on two main features of the video:

- The name of a clinical trial 'PSO-Long'.
- A claim 'no cases of skin atrophy'.

Leo submitted that the ruling of whether this video was promotional was based on the theoretical assumption that clinicians would make the link between the name of the study, and the medicine being studied. The complainant had not discharged his/her burden of proof in demonstrating that this was the case for any physician viewing the video. In reality, with thousands of clinical trials ongoing at any one time, clinicians were usually unaware of clinical trial names, or the medicine or indication being studied. For the purposes of this complaint, all parties involved (the complainant, Leo Pharma and the Panel) were well aware that this was the name of a clinical trial, but it was not self-evident from the video itself. The word 'Pso' itself, was a well-known abbreviation for the dermatological condition, psoriasis. Although it might be reasonable for a physician to make the link that 'PSO-Long' referred in some way to psoriasis, or even to a psoriasis study, it was a leap to say that they would obviously link this to Enstilar. At no time in the video was the name of the medicine being investigated, Enstilar, visible.

Leo submitted that on the point of the claim of 'no cases of skin atrophy', this referred to the fact that in the PSO-Long study, no cases of the adverse event of skin atrophy were observed. This was an adverse event which was sometimes observed in long term topical corticosteroid usage. The study in question looked at long term, intermittent usage of Enstilar as maintenance therapy. In this study, no cases of skin atrophy were observed. These were the facts of the study and the particular use of Enstilar under investigation. This video was intended to trail the virtual seminar, and not intended to promote any efficacy or safety claims for Enstilar. It was worth considering the circumstances around the trailing of this seminar, which took place during the Covid-19 pandemic. With face-to-face congresses cancelled, the majority of congresses were converted to virtual ones, and company sponsored symposia which would have been face-to-face and 'live' were instead converted to pre-recorded virtual ones. The fact that the company sponsored symposium was pre-recorded because of the Covid-19 pandemic, allowed the use of a brief 30-second, heavily edited clip of the symposium to be used to draw attention to it, and encouraged health professionals to sign-up. The use of specific graphics within this, was simply a way to highlight the dynamic nature of the presentation. Other 'bold' highlights within this teaser, apart from 'PSO-Long' and 'no cases of skin atrophy' included:

- 80% of patients.
- Topical adherence rates in psoriasis.
- Treatment drivers of adherence.
- A graphic of a brain.
- 2021 NIHR statement encouraging further research on the use of topical agents for maintaining long term disease control.
- A graphic of a globe with several countries listed.
- Kaplan Meier curve from showing time to first relapse from an unnamed study.
- A graphic on the long-term topical treatment model.
- That 80% of psoriasis patients have localised mild-moderate disease which can be treated with topical therapy.
- Graphics of the three presenters.
- Coming to EADV in 2020.

Leo submitted that the majority of these were on screen for a second of time, or less. The statement on 'no cases of skin atrophy' was visible for less than a second.

Again, Leo submitted that the brief flashes of information provided above were purely illustrative to convey the nature of the virtual symposium, rather than acting as promotion for any medicine. Indeed, it would be implausible for a material to deliberately or accidentally attempt to promote a

medicine, with no mention of the medicine in question, no efficacy claim, and the briefest mention of a single safety claim. Clause 1.2 defined promotion as any activity undertaken by a pharmaceutical company or with its authority which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines. Leo submitted that it was not plausible that this 30 second video fulfilled this definition in any meaningful, practical way. Leo refuted breaches of Clauses 14.1, 4.1 or 4.8.

Leo submitted that with regard to the ruling of breaches of Clauses 7.2, 7.9 and 3.2 for being inconsistent with the particulars of the SPC, Leo again drew attention to the argumentation provided above. On the point of the claim of 'no cases of skin atrophy', this referred to the fact that in the PSO-Long study, no cases of the adverse event of skin atrophy were observed. This was an adverse event which was sometimes observed in long term topical corticosteroid usage. The study in question looks at long term, intermittent usage of Enstilar as maintenance therapy. In this study, no cases of skin atrophy were observed. These were the facts of the study.

The Enstilar SPC stated that:

'The following adverse reactions are considered to be related to the pharmacological classes of calcipotriol and betamethasone, respectively:

Betamethasone (as dipropionate):

Local reactions can occur after topical use, especially during prolonged application, including skin atrophy, telangiectasia, striae, folliculitis, hypertrichosis, perioral dermatitis, allergic contact dermatitis, depigmentation, and colloid milia.'

Leo submitted that the SPC stated that this adverse event could occur. It did not state that this would occur. The PSO-Long study investigated prolonged use of Enstilar, but given intermittently as maintenance treatment, with a gap of 2-3 days between each application, rather than the daily applications needed during an acute flare. Therefore, the finding that intermittent application over a prolonged period did not lead to any cases of skin atrophy in this study was relevant. The statement in question merely stated that there were no cases of skin atrophy in the study. It did not claim that this could never occur, and indeed, the SPC did not claim that skin atrophy would always occur. Therefore, Leo did not consider this statement to be inconsistent with the SPC, and Leo refuted a breach of Clauses 7.2, 7.9 and 3.2.

Post H

Leo noted that in addition to Post H, the complainant also asked whether the information accessed via the link in Post H had been assessed under the Code. For the reasons given in Leo's original response, Post H, as posted on the Leo Pharma LinkedIn page, including the link which accessed the US National Psoriasis Foundation website at www.psoriasis.org, were not certified or otherwise assessed in accordance with the Code.

Leo submitted that it repeated the argumentation stated above for Post A. Post H also concerned the first such case in which 'liking' a non-promotional 'disease education' post, had been the subject of a complaint and Leo respectfully questioned whether the approach taken by the Panel in its ruling here was appropriate or, indeed, desirable over the longer term. Leo respectfully disagreed with the Panel in its decision that this brief, one sentence statement on the number of people affected by psoriasis in the United States and worldwide, constituted

'educational material for the public or patients issued by companies which relates to diseases'. For this reason, as well as all the reasons cited for Post A, Leo refuted a breach of Clause 14.3.

Post L

Leo submitted that press releases such as that in Post L might be published on social media in accordance with Danish rules, as long as the content is accurate, fair and balanced. Post L was compliant with Danish rules and the Danish Code. Denmark, like the UK, also operated under the jurisdiction of the EFPIA Code.

Leo Pharma submitted that it accepted the ruling of a finding of Clause 3.1 in this instance. It should be noted that the breach pertained not necessarily to the content of the press release, but rather to the specifics of the method of dissemination of this type of press release – it was this aspect, specifically, which differed between Denmark and the UK, though this approach was not incompatible with the EFPIA Code. Leo however refuted the breach of Clause 14.1. The breach of Clause 3.1 pertained to promotion of a medicine before marketing authorisation. As this was an activity not allowed under the Code, Leo submitted that it would consider it impossible, and indeed, inappropriate to certify something considered to be pre-licence promotion. Therefore, a finding of a breach of Clause 14.1 in this instance should not be upheld.

Post N

Leo submitted that press releases such as that in Post N may be published on social media in accordance with Danish rules, as long as the content was accurate, fair and balanced. Post N was compliant with Danish rules and the Danish Code. Denmark, like the UK, also operated under the jurisdiction of the EFPIA Code.

Leo Pharma submitted that it accepted the ruling of a finding of Clause 3.1 in this instance. It should be noted that the breach pertained not necessarily to the content of the press release, but rather to the specifics of the method of dissemination of this type of press release – it was this aspect, specifically, which differed between Denmark and the UK, though this approach was not incompatible with the EFPIA code. Leo submitted however that it refuted the breach of Clause 14.1. The breach of Clause 3.1 pertained to promotion of a medicine before marketing authorisation. As this was an activity not allowed under the Code, Leo would consider it impossible, and indeed, inappropriate to certify something considered to be pre-licence promotion. Therefore, a finding of a breach of Clause 14.1 in this instance should not be upheld.

Clause 2

Leo submitted that the overall finding of a breach of Clause 2 in this case was inappropriate and based on a fundamentally flawed rationale.

Clause 2 in the 2019 Code was described thus:

'Discredit to, and Reduction of Confidence in, the Industry

Activities or materials associated with promotion must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry.'

Supplementary information:

'A ruling of a breach of this clause is a sign of particular censure and is reserved for such circumstances. Examples of activities that are likely to be in breach of Clause 2 include prejudicing patient safety and/or public health, excessive hospitality, inducements to prescribe, unacceptable payments, inadequate action leading to a breach of undertaking, promotion prior to the grant of a marketing authorization, conduct of company employees/agents that falls short of competent care and multiple/cumulative breaches of a similar and serious nature in the same therapeutic area within a short period of time.'

Leo submitted that it appreciated that the list given in the supplementary information was not exhaustive. However, in terms of the specifics of this case, the Panel had found a breach of Clause 2 seemingly based on 'multiple breaches of the Code including promoting a medicine prior to the grant of its marketing authorisation' and criticisms of Leo Pharma's social media policies and communications.

Leo submitted that the Panel cited Leo Pharma's social media guidelines from 2013 and 2018 as being factors in the overall finding of Clause 2. Social media had been an evolving area for the pharmaceutical industry, with little in the way of Code precedent existing in the area of social media 'likes' until recently. Indeed, this very case was potentially precedent setting. The understanding of how social media 'likes' worked had been growing over years. Therefore, Leo questioned whether it was reasonable to require companies to have comprehensive social media guidance in place in 2013 and 2018, when there was little guidance available for companies, and use of such platforms was developing at a rapid pace. Significantly, the PMCPAs own guidance on digital communications, which incorporated social media, dated back to March 2016, now archived. Within this guidance, there was no mention of LinkedIn, nor any guidance given on the 'like' function and the potential implications of this, despite the well-established use of 'likes' and similar functions, not only on LinkedIn but also on sites such as Twitter and Facebook. Furthermore, while PMCPA had published some decided cases dealing with dissemination of promotional material through engagement on LinkedIn, there had been no cases dealing with dissemination of non-promotional material and the majority of cases pertaining to LinkedIn had been published only this year. These observations highlighted the difficulty companies face in providing up to date guidance on this rapidly evolving area. The Panel also seemingly disregarded the specific guidance which was issued to employees in an email dated 9 June 2020. This email specifically and clearly instructed employees not to interact with posts pertaining to the congress, tralokinumab or PSO-Long, and indeed, took into account recent Code cases. Therefore, Leo refuted the criticism of its procedures here as a factor in the overall finding of a Clause 2 breach.

Leo submitted that the greatest number of breaches of the Code found by the Panel involved Clause 14.3. Leo asked the Appeal Board to take into account the fact that certification of disease area information prior to engagement via LinkedIn had no precedent, and Leo again questioned whether it was appropriate to bring the liking of such posts from the Global organisation within scope of certification and, in particular within scope of Clause 2.

Leo submitted that the subject of promotion prior to the grant of a marketing authorisation, pertained here to press releases. Press releases, which cited new data, licensing, or reimbursement, if deemed genuinely newsworthy, were allowable under Clause 26.2 of the 2019 Code if directed to an appropriate audience, and do not generally fall into the category of promotion, though care must be taken to avoid this. The information in such press releases,

might be intended, as per the supplementary information in Clause 26.2, to find its way to patients and/or the public, should a journalist and news publication deem it sufficiently newsworthy. The press releases behind the links contained in these posts, might ordinarily be allowed in the UK, subject to examination and if the releases were directed towards an appropriate audience. Therefore, the issue here arose as a result of the specifics of the UK Code as it pertained to dissemination of press releases. Dissemination of such press releases on social media was allowed under the Danish Code, but not the UK Code. Both countries were subject to the EFPIA Code. The actions of the Danish headquarters were not in conflict with EFPIA.

Leo submitted that it queried if a breach of Clause 3.1 due to a difference between two EFPIA countries, Denmark and the UK, in the specifics of how press releases could be disseminated is genuinely, 'bringing discredit upon, or reducing confidence in, the pharmaceutical industry'? In particular, Leo submitted that this activity, acceptable under the EFPIA Code and acceptable under the Danish Code could not constitute the most serious misconduct that warranted the particular censure associated with a finding of breach of Clause 2 of the Code.

Leo submitted that it was important that all parties involved, whether it be patients, health professionals, patient organisations, or pharmaceutical companies themselves had confidence in the rulings and sanctions imposed by self-regulation. A Clause 2 ruling should be reserved for the most serious instances of misconduct by pharmaceutical companies. Inappropriate and overuse of a Clause 2 ruling, as had happened in this case, not only served to diminish the perceived severity of a Clause 2, but in itself, might lead to a reduction of confidence in and discredit to the industry. Leo therefore appealed the ruling of a breach of Clause 2.

COMMENTS FROM COMPLAINANT

There was no response from the complainant on the appeal.

APPEAL BOARD RULING

The Appeal Board noted Leo's submissions in regard to the Danish Code but did not consider that they were relevant in relation to this case which concerned the activities of employees in the UK.

Post A

The Appeal Board noted that Post A stated:

'29th October is #worldpsoriasisday. At Leo Pharma, we're marking this day by launching a series of patient videos that outline everyday challenges of living with psoriasis. Learn more about our commitment to helping people with psoriasis, not just today - but every day - by visiting www.everydaypsoriasis.com #beinformed #WPD2020 #everydaypsoriasis'

and included a video which according to Leo was prepared by staff globally and confirmed Leo's 'manifesto' to help patients with psoriasis.

The Appeal Board noted Leo's submission that the link within the post to www.everydaypsoriasis.com took users to information relating to psoriasis on the Leo Pharma

A/S website, including stories of patient experiences; in the Appeal Board's view, the webpage appeared to be disease awareness information for the public.

The Appeal Board considered that the four UK employees' engagement with the post, on the balance of probabilities, had proactively disseminated the material to their connections on LinkedIn. The Appeal Board noted that not all the employees' connections on LinkedIn would meet the Code's definition of a health professional.

The Appeal Board considered that the LinkedIn post, which included a link to a psoriasis website, constituted educational material for the public related to psoriasis. The material had not been certified as required by Clause 14.3 and it upheld the Panel's ruling of a breach of that clause. The appeal on this point was unsuccessful.

Post C

The Appeal Board noted that Post C stated:

'Are you a healthcare professional planning to attend #EADVVirtual next week? Then we've got a treat for you – our sponsored Satellite Symposium will take the 'virtual' theme to another level. Watch [named health professionals from Germany, UK and Canada] as they use the power of digital visualisation to explore our theme "Long-term topical management of psoriasis: the road ahead" (SAT 3.3, virtual room Alibert). More info here: [#EADV2020 #DermatologyBeyondTheSkin.](https://lnkd.in/dUYdYbU)'

The Appeal Board noted Leo's submission that the link to more information within the post directed readers to a Leo congress website where users had to declare that they were a health professional. Users could then access a webpage with details of a symposium entitled 'Long-term topical management of psoriasis: the road ahead'. The agenda did not name a specific medicine but stated that data from recently published new studies would be presented.

The LinkedIn post was accompanied by a 33 second video called 'EADV Teaser' which was a number of fast-moving images set to a background of music which appeared to show, amongst other things, slides with data from the PSO-LONG clinical trial. The claim 'No cases of skin atrophy' was stated boldly in the centre of one slide. The video did not directly name a medicine, however, the Appeal Board noted Leo's submission that the PSO-LONG trial investigated Leo's prescription only medicine Enstilar (betamethasone dipropionate/calcipotriol monohydrate), which was a topical treatment for psoriasis vulgaris in adults. It was an established principle that it was possible to promote a medicine without its name being mentioned. The Appeal Board considered that the claim 'No cases of skin atrophy' would be of great interest to health professionals who prescribed psoriasis treatments as skin atrophy was an important consideration for their patients and therefore the information might entice health professionals to look up the details of the PSO-LONG trial.

The Appeal Board noted Leo's submission that one of the UK employees who engaged with Post C had connections who were health professionals. In the Appeal Board's view, the video, which formed part of the post was promotional material for Enstilar. The LinkedIn post, which included the video, had not been certified as required by the Code and it upheld the Panel's ruling of a breach of Clause 14.1. The appeal on this point was unsuccessful.

The Appeal Board noted that prescribing information had not been provided as required by the Code and it upheld the Panel's ruling of a breach of Clause 4.1. The appeal on this point was unsuccessful.

The Appeal Board noted that the image of the LinkedIn post did not give the exact date it was posted. There was no date on when the promotional material was drawn up or last revised and therefore the Appeal Board upheld the Panel's ruling of a breach of Clause 4.8. The appeal on this point was unsuccessful.

The Appeal Board noted that section 4.8 of the Enstilar SPC stated:

'Betamethasone (as dipropionate):

Local reactions can occur after topical use, especially during prolonged application, including skin atrophy, telangiectasia, striae, folliculitis, hypertrichosis, perioral dermatitis, allergic contact dermatitis, depigmentation, and colloid milia.'

The Appeal Board considered that the prominent claim within the video of 'No cases of skin atrophy', as it appeared within the context of the fast-moving images in this short video, would likely be viewed broadly as a claim about Leo's medicine; it was unlikely that such a claim would only be viewed in the narrow context of the study as submitted by Leo. In the Appeal Board's view, the claim was misleading with respect to the safety of Enstilar and was inconsistent with the particulars listed in its SPC; the Appeal Board upheld the Panel's ruling of a breach of Clauses 7.2, 7.9 and 3.2. The appeal on this point was unsuccessful.

Post H

The Appeal Board noted Leo's submission that Leo UK employees had 'liked' post H. The Appeal Board considered that the UK employees' engagement with this post, on the balance of probabilities, had proactively disseminated the material to their connections on LinkedIn.

The Appeal Board disagreed with Leo's submission that the content of Post H was too limited to bring the text within the scope of Clause 14.3; the post described psoriasis as a skin condition that impacted more than 125 million people worldwide and linked to the US National Psoriasis Foundation website. Educational material for the public related to psoriasis had not been certified as required by Clause 14.3. The Appeal Board upheld the Panel's ruling of a breach of Clause 14.3. The appeal on this point was unsuccessful.

Post L

The Appeal Board noted that Leo had accepted the Panel's ruling of a breach of Clause 3.1 in that the likely proactive dissemination of the LinkedIn post (Post L) as a result of a UK employee engaging with it meant that tralokinumab had been promoted prior to the grant of its marketing authorisation. The Appeal Board noted that this promotional material had not been certified. The Appeal Board did not accept Leo's submission that because the material would not have passed the certification process there could be no breach of Clause 14.1. Clause 14.1 required that promotional material be certified prior to being issued and as this had not happened the Appeal Board upheld the Panel's ruling of a breach of Clause 14.1. The appeal on this point was unsuccessful.

Post N

The Appeal Board noted that Leo had accepted the Panel's ruling of a breach of Clause 3.1 in that the likely proactive dissemination of this LinkedIn post (Post N) as a result of UK employees engaging with it meant that tralokinumab had been promoted prior to the grant of its marketing authorisation. The Appeal Board noted that this promotional material had not been certified and it upheld the Panel's ruling of a breach of Clause 14.1. The appeal on this point was unsuccessful.

Overall Clause 2

The Appeal Board noted that Clause 2 was a sign of particular censure and reserved for such use and that the supplementary information to this clause stated that the types of activities likely to be found in breach of Clause 2 included promotion prior to the grant of a marketing authorisation.

The Appeal Board noted Leo's submission in relation to the training materials available contemporaneous to the complaint.

The reference to 'Personal posts relating to LEO products are strongly discouraged...' in the personal use of social media policy dated 2013, in the Appeal Board's view, did not give employees an unequivocal instruction.

Furthermore, the social media 'Dos and don'ts' reference card (UK/IE MAT-19232, August 2018) stated, amongst other things:

'Act as an ambassador for LEO Pharma UK/IE e.g. update your LinkedIn profile to All-Star status, like and engage with our social media posts.'

The Appeal Board noted that although a number of email communications with more specific instructions about certain posts had been sent in 2020, from the available contemporaneous evidence submitted, some employees would likely be confused by the contradictory and unclear instructions.

The Appeal Board noted its and the Panel's comments and rulings above which included multiple breaches of the Code including promoting a medicine prior to the grant of its marketing authorisation and considered that Leo had brought discredit upon and reduced confidence in the pharmaceutical industry. The Appeal Board upheld the Panel's ruling of a breach of Clause 2. The appeal on this point was unsuccessful.

Complaint received **11 November 2020**

Case completed **12 January 2022**