

**CASE AUTH/3405/10/20**

## **COMPLAINANT v LEO**

### **Global YouTube channel**

**An anonymous, contactable complainant who described him/herself as a pharmaceutical physician working in the pharmaceutical/healthcare industry (but not an employee or consultant to pharmaceutical companies), complained about sixty videos of UK health professionals and/or UK patients which appeared on the Leo Pharma Global YouTube channel.**

**On receipt of Leo's response, the case preparation manager determined that in relation to thirty-seven of the videos, no *prima facie* case had been established. The remaining twenty-three videos were referred to the Panel.**

**The complainant stated that in each of the videos in question, it was reasonable to believe that the intended audience included health professionals, patients and members of the public in the UK. The intended audience for each video was not clearly stated. There was no distinction between information for health professionals, members of the public or patients. The videos did not appear to adhere to the Code in terms of mandatory requirements or those for claims and comparisons. The complainant noted that many of the videos were several years old and he/she questioned if they had been certified and whether a written transcript of the material had been certified.**

**The complainant stated that in all of the Group A videos, UK patients discussed their experience of cancer and having a blood clot and therefore the intended audience could only be the UK public and UK health professionals. The complainant noted that the videos contained information for patients who might be using a medicine for cancer or cancer-associated thrombosis. However, if patients were the intended audience, the videos did not contain the adverse event reporting wording required. If the intended audience was health professionals, they were subject to the requirements of prescribing information and other obligatory information. The videos did not have a date on which they were drawn up or last revised.**

**The complainant stated that it was also not clear what the company's involvement was in the videos; its logo was shown so it was reasonable to assume it had sponsored them. However, if a patient organisation had been contracted, that had not been clearly acknowledged from the outset of the videos and there was no wording to reflect the nature of the company's involvement.**

**The complainant stated that it was unclear if the patients received a gratuity or if they were actors employed or if they were representing patient organisations, the patient organisations being the recipients of Leo funding.**

Regardless of how Leo chose to classify the videos, they failed to meet certification requirements. The complainant asked if Leo could show that each video had been certified.

The complainant noted that in all of the Group B videos, UK health professionals discussed various aspects of cancer and thrombosis and therefore the intended audience could only be the UK public and UK health professionals. However, if patients were the intended audience, the videos did not contain the adverse event reporting wording required. If health professionals were the intended audience, the videos were then subject to the requirements of prescribing information and other obligatory information. The videos did not have a date on which they were drawn up or last revised. Regardless of how Leo chose to classify the videos, they failed to meet certification requirements.

The complainant noted that in each video, a slide advised viewers to visit cancerclot.info for more information. Cancerclot.info was a website from Leo although this was not made clear when the website was mentioned in the videos.

The complainant stated that as the company website was signposted in a video which was for a UK audience that website was also within the scope of the Code. Cancerclot.info appeared to be aimed at patients. The site contained videos from UK patients and a UK health professional. Some of those videos were similar to the ones from YouTube. Cancerclot.info did not appear to have any mandatory UK information as per the Code.

The complainant asked if Leo could show that the videos and website had been certified.

The complainant submitted that the content of video T58 'Pharmacists' role in CAT [cancer-associated thrombosis] management' suggested that it came under the Code as it was reasonable that UK audiences would assume the video was intended for them given it was presented by a UK health professional. The information appeared to be aimed at health professionals and appeared to be from a congress. The video included information on prescribing medication and developing guidelines in the therapy area. Tinzaparin was referred to as a medicine used in the pharmacist's hospital and he/she discussed administration and specific issues related to its use. The pharmacist also referred to the CancerClot website but did not state that it was a site from Leo. The complainant stated that if health professionals were the intended audience, then the video needed prescribing information and other obligatory information. There was no date of revision. The complainant noted that in a quiz at the end of the presentation, the questions were promotional in nature and not a bona fide test of skill. The complainant asked if Leo could show that the video had been certified.

The complainant also raised concerns about video V60 'Leo Pharma' on YouTube from a named YouTube user. The video opened with the statement 'Leo Pharma has provided funding and editorial input into this film'. A senior executive of Leo UK and some UK health professionals featured in the video, therefore the video came under the Code.

A dermatologist discussed actinic keratosis and referred to treatments. The dermatologist went on to state freezing was an option but actinic keratoses were a marker of global skin damage and even if actinic keratoses could not be seen in an area,

they were involved clinically so that was the rationale for a cream based treatment - treating the field could reverse some of that sun damage and prevent future change.

The complainant noted that Leo marketed Picato for actinic keratosis and that the commentary positively positioned the company's product over other options; the video was thus promotional. The complainant noted the video was uploaded 8 years ago so it was not clear if Picato was launched when this video was created or if this was made pre-authorisation.

In the video the Leo UK senior executive stated 'We are 100% committed to help people achieve healthy skin'. In the context of the information just provided on actinic keratoses, the complainant alleged that that raised unfounded hope for the public.

The video did not include any of the mandatory requirements of the Code. The complainant asked if Leo could state the context and audience to whom the video was presented and if it had been certified.

The detailed response from Leo is given below.

The Panel noted that the complainant's allegations were all, bar one, in relation to videos hosted on the Leo Global (based in Denmark) YouTube Channel; one video (V60) which appeared to have been commissioned by Leo was hosted on a non-Leo YouTube channel.

The Panel noted that most of the videos hosted on the Leo Global channel referred to by the complainant made no reference to the availability or use of a Leo medicine in the UK and were therefore not within the scope of the Code. Nonetheless, the Panel noted the company's submission that Leo UK also hosted some of these videos, or parts of these videos, on its own UK sites and channels and the company acknowledged that those videos which were on Leo UK websites and channels would be within the scope of the Code. Although the complaint appeared to be in relation to the videos on the Leo Global YouTube channel, the Panel noted Leo's submission in relation to its own UK sites and channels and considered the complaint in that regard where applicable.

#### **Group A videos**

The Panel noted that all fourteen videos were hosted on the Leo Global YouTube channel and featured either a patient (A1-A7, A15, A18, A19) or a carer (A8 -A11) discussing their experience of cancer-associated thrombosis. The Panel noted that neither the patient nor the carer specifically referred to the availability or use of a Leo medicine in the UK in any of the videos.

The Panel noted Leo's submissions that the carer was from Ireland and Leo UK/Ireland had sourced him/her from an Irish patient organisation on behalf of the global team and that the patient was from the UK and Leo UK had sourced him/her on behalf of the global team. In the Panel's view, these factors were not such as to automatically bring the videos within the scope of the Code.

The Panel considered that the fourteen videos or parts of them which were also hosted on Leo UK websites and/or the Leo UK YouTube channel were within the scope of the Code and considered the videos under the Code in that regard.

The Panel noted that the Leo Pharma logo appeared at the beginning and end of each Group A video hosted on the Leo Global YouTube channel. The Panel did not have copies of the videos which were hosted on the Leo UK sites/channels before it. Based on the copies of the videos before it, and Leo's submission that they or parts of them were hosted on Leo UK sites/channels, the Panel considered that the material was clearly owned by Leo and was not material sponsored by the company. In that regard, in the Panel's view, the requirements in the Code which related to sponsored material, were not relevant and no breach was ruled in relation to each of the fourteen Group A videos.

The Panel noted that there was no direct or indirect reference to a specific medicine in any of the fourteen videos. One video (A1/16) referred to injecting a medicine, however, the Panel noted that there were a number of anticoagulants which might be self-injected from different companies. In the Panel's view, the Group A videos were non-promotional disease awareness videos aimed at the public and did not need to be certified as promotional material. The Panel therefore ruled no breaches of the Code in relation to each Group A video.

The words spoken by the featured individuals were displayed as text within the video and so the written transcript was an inherent part of the video and did not need to be separately certified. The Panel did not consider that the videos were directed at patients taking a particular medicine and therefore they did not require the inclusion of the reporting of side effects statement. No breaches of the Code were ruled in these regards.

The Panel noted Leo's submissions that there was no association with a patient organisation in relation to videos A1-A7, A15, A18, A19, and in relation to videos A8-A11, that although the carer was sourced via a patient organisation, the video was not created in partnership with a patient organisation. No breaches of the Code were ruled in relation to each video in these regards.

#### **Group B videos**

The Panel noted Leo's submission that the four Group B videos were produced by a Canadian patient organisation with an educational grant from Leo Canada as part of a country speaker tour for Leo Canada, during which the patient organisation partnered with a named UK health professional. Each video recorded a conversation between a patient ambassador from the patient organisation and the UK health professional. Leo UK's only involvement was to ascertain the health professional's availability and willingness to conduct the speaker tour for Leo Canada. In the Panel's view, use of a UK health professional sourced by Leo UK in Leo Canada material hosted on the Leo Global YouTube channel would not *de facto* bring the videos within the scope of the Code. However, the four videos were also used on the Leo UK/Ireland website, CATHrombosis.com and thus were within the scope of the Code.

The Panel noted Leo's submission that the videos were on a Leo UK/IE non-promotional website for health professionals behind account registration and password protection; they were not directed at the public or patients.

The Panel noted Leo's submission that the videos were not downloadable, and were for health professionals to watch, in order to support discussions with patients on the topic of cancer-associated thrombosis. The videos were hosted in a section called 'Patient Support' with the text 'These materials are intended to support your communication with your patients who may be experiencing symptoms or are at risk of CAT [Cancer-Associated Thrombosis]'. Neither speaker in the videos referred directly or indirectly to a specific medicine.

The Panel did not consider that the complainant had discharged his/her burden of proof that each of the four videos were promotional or that the videos were available to the public or patients and therefore no breaches of the Code were ruled in those regards.

As the videos were not directed at patients taking a particular medicine, they did not require the inclusion of the reporting of side effects statement and the Panel therefore ruled no breach of the Code in that regard.

The Panel noted the complainant's allegation that in each video, a slide advised viewers to visit cancerclot.info for more information without making clear that they were being directed to a Leo owned website. The Panel noted that the videos in question appeared on a Leo website and that the CancerClot websites were also Leo websites and not sponsored material. No breach was ruled in that regard.

The Panel noted that a UK website for health professionals (CATHrombosis.com), within a section about patient support, contained videos referring to a Leo Global website (cancerclot.info), which was aimed at patients. The Panel noted Leo's submission that it had a UK version of this patient website (cancerclot.com) which was certified. The Panel noted that the Group B videos directed health professionals to refer their patients to look at cancerclot.info, which had not been certified and the Panel therefore ruled a breach of the Code in relation to cancerclot.info.

The Panel did not consider that the complainant had established that cancerclot.info was intended for patients taking a particular medicine and therefore it ruled no breach of the Code in that regard.

#### **T58**

The Panel noted Leo's submission that this video was of a presentation given by a UK pharmacist at the 2018 European Association of Hospital Pharmacists congress, in a Leo Global symposium. Leo Global produced the 27-minute video which was mostly about patient counselling in managing cancer-associated thrombosis. Within the video the pharmacist briefly mentioned that tinzaparin (a Leo low molecular weight heparin) was used in his/her hospital.

The Panel noted that video T58 was within the scope of the Code as it specifically referred to the availability or the use of a Leo prescription only medicine in the UK,

tinzaparin (brand name Innohep), in thrombosis and it was therefore promotional material. The video was not certified and therefore a breach of the Code was ruled.

The Panel noted that there was no prescribing information or adverse event reporting statement for tinzaparin and no statement as to where the prescribing information could be found. The Panel therefore ruled breaches of the Code.

The Panel noted that the material was dated in that it was clear it was added to the YouTube channel on 15 June 2018. The Panel therefore ruled no breach of the Code in that regard.

As the brand name was not used the Panel ruled no breach of the requirement in relation to the positioning of the non proprietary name.

The Panel did not consider that the three questions asked in the quiz promoted a Leo medicine or that the complainant had made out why in his/her view they were inappropriate and no breach of the Code was ruled in that regard.

With regard to the allegation that the presentation referred to the cancerclot website but there was no mention that this was a Leo website, the Panel noted the requirement for material sponsored by a company and noted that the video in question appeared on a clearly signposted Leo YouTube channel and that the cancerclot websites were Leo owned websites and not sponsored material. No breach was ruled.

#### V60

The Panel noted Leo's submission that the video appeared to have been uploaded onto a named YouTube channel (a non-Leo channel) in 2012. It displayed the Leo logo at the beginning and end of the film, as well as a statement at the beginning that 'LEO Pharma has provided funding and editorial input into this film.'

It appeared to the Panel that the video was commissioned by Leo for a UK audience but it was unclear as to how it came to be uploaded to YouTube.

The Panel noted Leo's submission that an ex-employee could remember the video being created but that Leo could find no record of the video or its certification. The Panel further noted Leo's submission that it had no knowledge of how or why the video was on the named YouTube channel and that it might have originally been created as a corporate video and uploaded to YouTube by the agency that created it although the company had no evidence in that regard.

The Panel considered that, on the balance of probabilities, Leo commissioned the video in the pre-licence period for Picato. The Panel queried whether the video was setting the scene for the forthcoming authorisation of Leo's new medicine, Picato, in 2012. The Panel had no information before it regarding how many medicines were available to treat actinic keratosis either at the time the material was posted on YouTube or when it was viewed by the complainant; neither party made any submission in that regard.

The Panel noted Leo's submission that the video was not hosted on any Leo website or channel page and that there was no evidence that Leo was responsible for the upload of the video onto YouTube.

The Panel noted that companies were responsible under the Code for the acts and omissions of their third parties which came within the scope of the Code, even if they acted contrary to the instructions which they had been given. However, the Panel had no information before it that a relationship had existed between Leo and the named YouTube channel and considered that the complainant had not discharged his/her burden of proof that Leo, or a third party acting on its behalf, had uploaded the material to YouTube. In that regard, the Panel considered that the complainant had not shown that Leo was accountable under the Code for the presence of the material on YouTube. The Panel therefore ruled no breaches of the Code.

### Overall

The Panel noted that the complainant provided no evidence that relevant personnel had not been adequately trained or were not conversant with the Code. A breach of the Code was not in itself evidence in that regard. The Panel considered that the complainant had not discharged his/her burden of proof and therefore no breach of the Code was ruled.

The Panel noted its comments and rulings above and considered that the rulings of breaches of the Code in relation to video T58 and in relation to directing a UK audience to cancerclot.info in the Group B videos meant that Leo had failed to maintain high standards and a breach of the Code was ruled.

Given its comments and rulings above, overall, the Panel did not consider that Leo had brought discredit upon or reduced confidence in the pharmaceutical industry and no breach of Clause 2 was ruled.

An anonymous, contactable complainant who described him/herself as a pharmaceutical physician working in the pharmaceutical/healthcare industry (but not an employee or consultant to pharmaceutical companies), complained about sixty videos of UK health professionals and/or UK patients which appeared on the Leo Pharma Global YouTube channel.

When writing to Leo, the Authority asked it to consider the requirements of the clauses cited by the complainant and in some matters, it also asked that additional clauses be considered. These are noted below. The Authority also asked that overall, Leo consider the requirements of Clauses 2 and 9.1.

On receipt of Leo's response in relation to all sixty videos, the case preparation manager determined that in relation to thirty-seven of the videos, no *prima facie* case had been established and that those videos were not to be referred to the Panel. The remaining twenty-three videos were referred to the Panel. The original numbering of the videos has been retained below.

### COMPLAINT

The complainant stated that in each of the videos in question, it was reasonable to believe that the intended audience included health professionals, patients and members of the public in the UK, and each fell under Clause 28 of the Code. The complainant stated, however, that on first presentation to the viewer it was not clearly stated who the intended audience for each video was. There was no distinction between information for health professionals, members of the public or patients. The videos did not appear to adhere to Code requirements in terms of mandatory requirements or information claims and comparisons on medicines. The complainant further noted that many of the videos were several years old and he/she questioned if they had been certified and whether a written transcript of the material had been certified under Clause 14. It appeared that the function who had created and uploaded the videos was not conversant with UK Code requirements as per Clause 16.1.

The complainant grouped the videos together when they shared commonalities in terms of the Code, with each video being assessed individually under the Code.

### **GROUP A**

1. 'Accepting a blood clot diagnosis'
2. 'There is not sufficient information on blood clots in cancer patients'
3. '[Name] developed blood clots in her lungs but never knew there could be a link to cancer'
4. 'It is important for cancer patients to know about the risk of blood clots'
5. 'People need to know about the risks'
6. 'I want to help create awareness about blood clots and cancer'
7. 'I do not recall being told about blood clots'
8. 'Emphasise the prevalence of thrombosis to cancer patients and their families'
9. 'We never suspected a link between cancer and blood clots'
10. 'We were shocked when my mother developed a blood clot'
11. 'Cancer patients should be aware of blood clots'
15. 'How blood clots affected my life'
16. 'Accepting a blood clot diagnosis'
17. 'Infection AND blood clot risks important'
18. 'You need to regularly hear about the risk'
19. 'Cancer patients must know risk of blood clots'



The complainant stated that in all of the videos listed above, UK patients discussed their experience of cancer and having a blood clot and therefore the intended audience could only be the UK public and UK health professionals as per Clause 28 of the Code. The complainant noted that the videos contained information for patients who might be using a medicine for cancer or cancer-associated thrombosis. However, if patients were the intended audience, the videos did not contain the adverse event reporting wording required by Clause 26.3. If the intended audience was health professionals, they were subject to the requirements of Clause 4.1, 4.2, 4.3, 4.5, 4.6 and 4.9.

The videos did not have a date on which they were drawn up or last revised, in breach of Clause 4.8.

The complainant stated that it was also not clear what the company's involvement was in the videos, its logo was shown so it was reasonable to assume it had sponsored them. However, if a patient organisation had been contracted, that had not been clearly acknowledged from the outset of the videos and there was no wording to reflect the nature of the company's involvement as per Clause 27.9.

The complainant stated that it was unclear if the patients received a gratuity or if they were actors employed or if they were representing patient organisations, the patient organisations being the recipients of Leo funding.

The complainant stated that given the requirements of Clause 14, regardless of how Leo chose to classify the videos, they failed to meet those requirements. The complainant asked if Leo could show that each video had been certified according to Clause 14.

*In addition to the clauses cited by the complainant, the Authority asked Leo to consider the requirements of Clause 9.10 in relation to the alleged lack of clarity as to the company's involvement.*

## **GROUP B**

30 'Which clot symptoms should I watch for?'

31 'Which cancer patients get blood clots?'

32 'What do patients really need?'

33 'Meet [named health professional]'

The complainant noted that in all of the videos listed above, UK health professionals discussed various aspects of cancer and thrombosis and therefore the intended audience could only be the UK public and UK health professionals as per Clause 28 of the Code. However, if patients were the intended audience, the videos did not contain the adverse event reporting wording required by Clause 26.3. If health professionals were the intended audience, the videos were then subject to the requirements of Clause 4.1, 4.2, 4.3, 4.5, 4.6 and 4.9.

The videos did not have a date on which they were drawn up or last revised, in breach of Clause 4.8.

The complainant stated that given the requirements of Clause 14, regardless of how Leo chose to classify the videos, they failed to meet those requirements.

The complainant noted that in each video, a slide advised viewers to visit cancerclot.info for more information. Cancerclot.info was a website from Leo although this was not made clear when the website was mentioned in the videos.

The complainant stated that as the company website was signposted in a video which was for a UK audience that website was also within the scope of the Code as per Clause 28.2. Cancerclot.info appeared to be aimed at patients. The site contained videos from UK patients and a UK health professional. Some of those videos were similar to the ones from YouTube. Cancerclot.info did not appear to have any mandatory UK information as per Clause 26.3.

The complainant asked if Leo could show that the videos and website had been certified according to Clause 14.

*In addition to the clauses cited by the complainant, the Authority asked Leo to consider the requirements of Clause 9.10 in relation to the reference to a website.*

## **GROUP T**

### 58. 'Pharmacists' role in CAT [cancer-associated thrombosis] management'

The complainant submitted that the content of this video suggested that it came under Clause 28 as it was reasonable that UK audiences would assume the video was intended for them given it was presented by a UK health professional. The information appeared to be aimed at health professionals and appeared to be from a congress. The video included information on prescribing medication and developing guidelines in the therapy area. Tinzaparin was referred to as a medicine used in the pharmacist's hospital and he/she discussed administration and specific issues related to its use. The pharmacist also referred to the CancerClot website but did not state that it was a site from Leo. The complainant submitted that if health professionals were the intended audience, then the video was subject to the requirements of Clause 4.1, 4.2, 4.3, 4.5, 4.6 and 4.9.

The video did not have a date of revision as per Clause 4.8.

The complainant noted that in a quiz at the end of the presentation, one of the questions was 'What was the optimal treatment for cancer-associated thrombosis for the first 6 months?'. Answer options were 'unfractionated heparin', 'low molecular weight heparin', 'vitamin K antagonist' and 'direct oral anticoagulants'. The following question, 'What medications could interact with direct oral anticoagulants?' had answer options of 'P glycoprotein inhibitors' 'P glycoprotein inducers', 'CYP3A4 inhibitors/inducers' and 'all of the above'. The final question was 'How can pharmacists play a role?' and answers included 'medication review', 'protocol development', 'patient support programmes' and 'all of the above'. The complainant alleged that the questions were promotional in nature and not a *bona fide* test of skill, in breach of Clause 18.1.

The complainant stated that given the requirements of Clause 14, regardless of how Leo chose to classify the video, it failed to meet those requirements. The complainant asked if Leo could show that the video had been certified according to Clause 14.

*In addition to the clauses cited by the complainant, the Authority asked Leo to consider the requirements of Clause 9.10 in relation to the reference to a website.*

## **GROUP U**

59. 'Thromboprophylaxis in active cancer: That is the question?'

The complainant submitted that content of this video suggested that it came under Clause 28 as it was reasonable that UK audiences would assume the video was intended for them given it was presented by a UK health professional. The information appeared to be aimed at health professionals and appeared to be from a congress. However, if the intended audience was a patient, the videos did not contain the adverse event reporting wording as required by Clause 26.3. If the intended audience was health professionals then it was subject to the requirements of Clause 4.1, 4.2, 4.3, 4.5, 4.6 and 4.9.

The video did not have a date of revision as per Clause 4.8.

The complainant stated that the video discussed the evidence around different types of cancer patients and venous thromboembolism prophylaxis, including recommendations around low molecular weight heparin. The health professional said that in some areas where there was very little evidence, low molecular weight heparin was still used. That statement appeared to promote use outside of the SPC for low molecular weight heparin, in breach of Clause 3.2.

The complainant noted that several studies were discussed, including one in tinzaparin prophylaxis use.

The complainant stated that given the requirements of Clause 14, regardless of how Leo chose to classify the video, it failed to meet those requirements. The complainant asked if Leo could show that the video had been certified according to Clause 14.

## **GROUP V**

60. 'Leo Pharma'

The complainant also raised concerns about this video on YouTube from a named YouTube user. The video opened with the statement 'Leo Pharma has provided funding and editorial input into this film'. A Leo UK senior executive and some UK health professionals featured in the video, therefore the video came under Clause 28 of the Code.

A dermatologist discussed the condition stating the lesions might become very thickened and confluent over time; he referred to treatments like creams, curettage, freezing and photodynamic therapy. The dermatologist went on to state freezing was an option but actinic keratoses were a marker of global skin damage and even if actinic keratoses could not be seen in area, they were involved clinically so that was the rationale for a cream based treatment - treating the field could reverse some of that sun damage and prevent future change.

The complainant noted that Leo marketed Picato for actinic keratosis and that the commentary positively positioned the company's product over other options; the video was thus promotional. The complainant noted the video was uploaded 8 years ago so it was not clear if Picato was launched when this video was created or if this was made pre-authorisation. The date of authorisation in the UK according to the SPC was 15 November 2012.

In the video the Leo senior executive stated 'We are 100% committed to help people achieve healthy skin'. In the context of the information just provided on actinic keratoses, the complainant alleged that that raised unfounded hope for the public, in breach of Clause 26.3 [sic].

The video did not include any of the mandatory requirements of the Code, namely Clauses 4 and 26.

The complainant stated that given the requirements of Clause 14, regardless of how Leo chose to classify the video, it failed to meet those requirements. The complainant asked if Leo could state the context and audience to whom the video was presented and if it had been certified as per Clause 14.

*In addition to the clauses cited by the complainant, the Authority asked Leo to consider the requirements of Clause 3.1 in relation to the alleged promotion prior to the grant of the marketing authorisation.*

## **RESPONSE**

Leo stated that it welcomed scrutiny and was proud to abide by the requirements of the Code but was disappointed by the nature of this particular complaint, the second from what appeared to be the same complainant (the previous being Case AUTH/3397/10/20). Far from being a genuine complaint, this was an unfounded, misunderstood complaint, to which Leo would respond, robustly.

Leo noted that the majority of the points raised were not opinion, but 'what if' scenarios; this suggested that the complainant's intent was to tie up the resource of its business for non-genuine reasons. As an example of these 'what if' scenarios, Leo referred to the complainant's queries as to whether the company had contracted with a patient organisation, and if it had then that had not been acknowledged from the outset and there was no wording to reflect the nature of the company's involvement as per Clause 27.9. In a number of other comments throughout the complaint, the complainant stated he/she was 'unclear' on various aspects of the videos, without providing evidence to suggest an actual breach of the Code. Leo considered that there must be some obligation on the part of the complainant to provide a shred of evidence or to have at least formed an opinion on the matter otherwise what were they actually complaining about? Leo did not consider that it was in the spirit, letter or constitution and procedure of the Code for a complaint to be tested through debating hypotheses; rather the burden of proof fell to the complainant to establish his/her complaint on the balance of probabilities. It was unreasonable to accept complaints based on purely theoretical scenarios rather than reasonable assumption.

Leo stated that it would answer the points raised by the complainant but requested that the Panel lift the veil of secrecy concerning the complainant's connections with the industry. The sheer scale of the case and the efforts put into the complaint strongly suggested that the

individual had a vested interest. While his/her concerns might (or might not) address genuine Code matters, the motivation should not be hidden, and Leo asked the Panel to actively look into this aspect of this series of complaints.

Leo noted that the complainant described him/herself as a pharmaceutical physician but one that was neither employed by a pharmaceutical company nor a consultant to one. By definition, that was impossible; to be a pharmaceutical physician he/she must have (or have had) an affiliation with one or more pharmaceutical companies.

### **Applicability of the Code**

Leo contended that the majority of the videos fell outside the Code; 59 of the 60 videos were hosted on the Leo Pharma Global YouTube channel. As Leo Pharma was headquartered in Denmark, the Leo Pharma Global YouTube channel fell within the scope of Danish regulations unless proven otherwise. The complainant however alleged that they fell in scope of the UK Code simply because they appeared to feature English-language speaking individuals that might be of a British heritage

In that regard, Leo believed there to be four broad clusters of videos to consider:

- Videos hosted solely by Leo Pharma UK
  - in scope, however none fell in that category
- Videos hosted by Leo Pharma Global but that were additionally hosted by Leo UK
  - potentially in scope
- Videos hosted solely by Leo Pharma Global that featured UK citizens
  - out of scope because none of them referred to the use of a product in the UK
- Videos hosted solely by Leo Global that did not feature UK citizens
  - out of scope because none of them referred to the use of a product in the UK

### **Scope of ABPI Code**

Leo noted that Clause 1.1 stated:

‘This Code applies to the promotion of medicines to members of the United Kingdom health professions and to other relevant decision makers.

The Code also applies to a number of areas which are non-promotional, including information made available to the public about prescription only medicines’

The supplementary information (Clause 1.11 Applicability of Codes) stated:

‘Pharmaceutical companies must ensure that they comply with all applicable codes, laws and regulations to which they are subject. This is particularly relevant when activities/materials involve more than one country or when a pharmaceutical company based in one country is involved in activities in another country.

Activities carried out and materials used by a pharmaceutical company located in a European country must comply with the national code of that European country as well as the national code of the country in which the activities take place or the materials are used.

Activities carried out and materials used in a European country by a pharmaceutical company located in a country other than a European country must comply with the EFPIA Code as well as the national code of the country in which the activities are carried out and materials are used.'

Clause 28.2 clearly indicated the applicability of the UK Code to material on the internet:

'Information or promotional material about medicines covered by Clause 28.1 which is placed on the Internet outside the UK will be regarded as coming within the scope of the Code, if:

- it was placed there by a UK company/with a UK company's authority, or
- it was placed there by an affiliate of a UK company, or with the authority of such a company **and** it makes specific reference to the availability or use of the medicine in the UK' (emphasis added by Leo)

Leo stated that it was clear both from the Code itself, but also case precedent set in Case AUTH/2046/9/07, that unless the Leo Global videos specifically referred to the 'availability or use of the medicine in the UK' they were not within the scope of the Code.

Leo noted that some videos were hosted by Leo Global but featured specific references to the UK as a location; Leo contended that those were also outside the scope of the UK Code, as above, because they did not identify the use or availability of a medicine within the UK. However, Leo accepted that some videos were also hosted by a Leo UK site, therefore Leo had made comments in relation to the UK Code for those videos.

Leo further noted that the complainant made the point that because certain videos featured UK voices or images they were targeted at the UK. This was completely incorrect. In fact, it was culturally, ethnically and racially insensitive to imply that any particular accent or ethnicity was representative of an individual's nationality or of the audience they might be projecting to.

Leo stated that the English language was now universal, so it was no surprise that the global assets of most pharmaceutical companies used English as the communication medium. In that regard it was also not a surprise that the natural speakers of that language might feature in videos, etc. However, this did not necessarily mean that the target audience included the British people, nor did it mean that the videos fell within the scope of the Code.

In many instances, the individuals shown were not identified as living or working in the UK; for all the viewer knew, the featured individuals might live and work abroad. Even if they were shown as being 'from' the UK, that still did not dictate that the intended audience was the UK.

Leo noted that the Leo Pharma Global YouTube channel identified by the complainant was clearly described as run by the global team, without specifically identifying any target audience,

including the UK. In fact, visible on the home page of the Leo Pharma Global YouTube channel were several prominent links to channels intended for specific nations, including the UK.

Leo stated that there was a separate YouTube channel run by Leo Pharma UK/IE which was signposted from the global site. Leo provided screenshots of the Leo Pharma UK/IE channel.

Leo submitted that the complaint was against Leo Global rather than Leo UK, however, in recognition of the fact that the UK also hosted the videos or parts of the videos on its own sites and channels, Leo would comment on the individual videos and allegations accordingly. Leo emphasised that it did not consider the videos on the Leo Global YouTube channel, run out of Denmark, and not referring to the availability of medicines in the UK, to be formally within scope of the UK Code. The videos in question were A1- A11 and A15 - A19.

Some videos referred to websites indicated by the complainant. Comments on those websites were also included in the response below.

Additionally, Leo had commented on video V60, as although this was not hosted on a Leo channel, it featured a Leo UK senior executive.

These videos only had been provided as attachments to this complaint, and the accompanying links were in the body of the text.

Leo submitted that in relation to videos hosted solely by Leo Pharma Global that featured UK citizens, they were outside the scope of the Code as they were essentially hosted on a Danish (ie Global) YouTube channel and made no specific reference to the use of a Leo medicine within the UK. The content was not information about medicines, nor promotional. The videos at issue were B30-B33. Additionally, Leo was initially unable to locate videos T58 and U59. On making enquiries with Leo Global, it appeared that those videos were 'unlisted' ie they were invisible and could not be found or accessed by searching anywhere, rather the individual had to have the actual YouTube link in order to view the video. Upon clicking the link, the videos opened within the Leo Pharma Global YouTube channel. Therefore, only individuals who had the link could view the videos. Those videos, which featured UK health professionals and were aimed at health professionals were not currently hosted by the UK, and Leo therefore also considered that they were outside the scope of the Code.

## **Response to allegations**

### **General allegations**

Members of staff were not conversant with UK Code requirements (Clause 16.1).

Leo noted that like the majority of his/her allegations, the complainant had provided no evidence to substantiate this allegation. However, Leo noted that staff received regular training on the Code. Apart from online modules provided by a named third party, staff were most recently trained (by another named third party) on 1 September with scheduled training sessions throughout 2021.

Leo Global was also relatively recently trained by this third-party (2 October 2019); a session that was attended by some UK staff.

### **Videos hosted by Leo Global but that are additionally hosted by Leo UK**

The videos in question were A1 - A11 and A15 - A18

Leo noted that the complainant had essentially made the same allegations for each video. Leo would address their concerns directly.

Leo noted that the complaints were a little unclear but included:

- Failure to certify (14.1; 14.3)
- Failure to certify transcript (14.1)
- Failure to exclude the public from health professional promotional material (28.1)
- Promotion to the public (26.1) (for some videos)
- Patient mandatory information (26.3)
- Disguised promotion (for some videos) (12.1)
- Health professional mandatory information (4.1; 4.2; 4.3; 4.4; 4.5; 4.6; 4.8; 4.9)
- Patient organisation partnership (27.9)
- Disguised link to cancerclot.info as being Leo's (9.10).

Leo stated that while some of the points above were not specifically related to group A videos, Leo had, nevertheless addressed them for completeness. Leo had also made specific reference to the two CancerClot websites as some group A videos mentioned CancerClot despite not being mentioned by the complainant.

Leo noted that these videos were shot and created by Leo Global, subsequently hosted on the Leo Pharma Global YouTube channel. Where appropriate, Leo had used edits of some of these videos and certified them for use on its own local UK channels, as described below. Copies of relevant certificates were provided. The thrombosis patient videos featuring two named patients could be viewed at <https://www.youtube.com/c/LeoPharmaUKIE>.

However, as the complaint concerned the videos on the Leo Global channel rather than UK channels, Leo would focus on that below.

#### **A1 and A16 'Accepting a blood clot diagnosis'**

Leo noted that this video, hosted on the Leo Global YouTube channel, lasted 1 minute and 24 seconds – A1 and A16 referred to the same video, despite being identified separately by the complainant. The first half of the video only was certified for use on a Leo UK website [www.cancerclot.com](http://www.cancerclot.com), [CATHrombosis.com](http://CATHrombosis.com), and the Leo UK YouTube channel. The second half was not used in the UK. The UK certificate was: UK/IE/MAT-27606 v.1 certified on 18/9/2019.

Leo noted that the words spoken by the featured patient were shown as text on the video, thus the written transcript was an inherent part of the video. The individual was from the UK and Leo UK sourced the patient on behalf of the global team .

The global video was clearly hosted on the Leo YouTube channel page and opened with the Leo logo. Midway through, the Leo logo and the Leo Global address in Denmark was displayed. The video ended by displaying the Leo logo and the Leo Global address in Denmark. As the video was not limited to any type of audience (eg health professionals only) it



was clearly intended for a general public audience. The video did not name or identify a specific product. It was not therefore promotion to the public or promotion to health professionals. The video was not created in partnership with a patient organisation.

Leo therefore denied all breaches:

- Clause 14 – the global material was not required to be certified for a UK audience
- Clause 28.1 – as the content was intended for the general public, it did not need to be limited to health professionals
- Clause 26.1 - there was no mention of, or hint about, a specific product therefore there was no promotion to the public
- Clause 26.2 - there was no mention of, or hint about, a specific product therefore there was no encouragement for the public to ask for a specific medicine by name
- Clause 26.3 – as no product was identified, there was no need to include the adverse event reporting statement
- Clause 12.1 - as no product was identified or hinted at, there could be no disguised promotion
- Clauses 4.1; 4.2; 4.3; 4.4; 4.5; 4.6; 4.8; 4.9 – as no product was identified and the video was aimed at the general public, the content was not promotional and the mandatory information associated with promotional material was not required, indeed it would be wholly inappropriate
- Clause 27.9 – as there were no payments or partnerships with a patient organisation in association with the video
- Clause 9.10 – as Leo's responsibility for the video was patently evident, bearing the Leo logo prominently at the beginning and end of the video and by virtue of being hosted on the Leo Pharma Global YouTube channel.

A2 and A17 'There was not sufficient information on blood clots in cancer patients'/ 'Infection AND blood clot risks important'

Leo noted that the video lasted 1 minute and 18 seconds - A2 and A17 referred to the same video, despite being identified separately by the complainant.

Although the video was on the Leo Global website [www.cancerclot.info](http://www.cancerclot.info), it was actually hosted on the Leo Pharma Global YouTube channel under the title 'Infection AND blood clot risks important'. In fact, clicking on the video within [www.cancerclot.info](http://www.cancerclot.info) simply opened up the embedded video within the Leo Pharma Global YouTube channel. Parts of the video were also used in videos on a Leo UK website [www.cancerclot.com](http://www.cancerclot.com), [CATHrombosis.com](http://CATHrombosis.com), and the Leo UK YouTube channel. Copies of the UK certificates for the videos were provided [UK/IE/MAT-27611 v.1 certified on 18/9/2019 and UK/IE/MAT-27608 certified on 9/9/2019].

The words spoken by the patient were displayed in text on the video; thus the written transcript was an inherent part of the video. The patient was from the UK and Leo UK sourced the patient on behalf of the global team.

Leo stated that if the video was viewed directly via the Leo Pharma Global YouTube channel (rather than via [www.cancerclot.info](http://www.cancerclot.info)) the text beneath the video specifically informed viewers about [cancerclot.info](http://cancerclot.info) on the global YouTube Channel. It did not specifically indicate that the

website was a Leo site, however the link was immediately beneath the Leo logo and the top banner of the landing page displayed the same Leo logo .

Leo submitted that the global video was clearly hosted on the Leo webpage and opened with the Leo logo. The video ended by displaying the Leo logo and the Leo Global address in Denmark. As the video was not limited to any type of audience (eg health professionals only) it was clearly intended for a general public audience. The video did not name or identify a specific product and so it was not promotion to the public or promotion to health professionals. The video had not been created in partnership with a patient organisation.

Leo therefore denied all breaches:

- Clause 14 – this global material was not required to be certified for a UK audience
- Clause 28.1 – as the content was intended for the general public, it did not need to be limited to health professionals
- Clause 26.1 - there was no mention of, or hint about, a specific product therefore there was no promotion to the public
- Clause 26.2 - there was no mention of, or hint about, a specific product therefore there was no encouragement for the public to ask for a specific medicine by name
- Clause 26.3 – as no product was identified there was no need to include the adverse event reporting statement
- Clause 12.1 - as no product was identified or hinted at, there could be no disguised promotion
- Clauses 4.1; 4.2; 4.3; 4.4; 4.5; 4.6; 4.8; 4.9 – as no product was identified the content was not promotional and the mandatory information associated with promotional material was not required, indeed it would be wholly inappropriate
- Clause 27.9 – as there were no payments or partnerships with a patient organisation in association with this video
- Clause 9.10 – as Leo’s responsibility for the video was patently evident, bearing the Leo logo prominently at the beginning and end of the video and by virtue of being hosted on the Leo Pharma Global YouTube website as well embedded in the Leo website cancerclot.info
- Clause 9.10 – if the video was viewed directly via the Leo Pharma Global YouTube channel, while the text beneath the video referred to cancerclot.info, there was no suggestion that it was not a Leo information source and it was highlighted from a page bearing a Leo video within a Leo YouTube channel. As stated below, the website did bear clear indications of Leo’s ownership of the website.

A3 ‘[Name] developed blood clots in her lungs but never knew there could be a link to cancer’

Leo noted that this video, hosted on the Leo Global YouTube channel, lasted 1 minute and 50 seconds. The majority of the video was also used on a Leo UK website, [www.cancerclot.com](http://www.cancerclot.com), [CATHrombosis.com](http://CATHrombosis.com), and the Leo UK YouTube channel. A copy of the UK certificate was provided [UK/IE/MAT-27611 v.1 certified on 18/9/2019].

The words spoken by the featured individual were shown as text in the video and so the written transcript was an inherent part of the video. The individual was from the UK and Leo UK sourced the patient on behalf of the global team.

Leo noted that the global video was clearly hosted on the Leo Pharma Global YouTube channel page and opened with the Leo logo. The video ended by displaying the Leo logo and the Leo Global address in Denmark. As the video was not limited to any type of audience (eg health professionals only) it was clearly intended for a general public audience. The video did not name or identify a specific product and so it was not promotion to the public or promotion to health professionals. The video had not been created in partnership with a patient organisation.

Leo therefore denied all breaches:

- Clause 14 – this global material was not required to be certified for a UK audience
- Clause 28.1 – as the content was intended for the general public, it did not need to be limited to health professionals
- Clause 26.1 - there was no mention of, or hint about, a specific product therefore there was no promotion to the public
- Clause 26.2 - there was no mention of, or hint about, a specific product therefore there was no encouragement for the public to ask for a specific medicine by name
- Clause 26.3 – as no product was identified there was no need to include the adverse event reporting statement
- Clause 12.1 - as no product was identified or hinted at, there could be no disguised promotion
- Clauses 4.1; 4.2; 4.3; 4.4; 4.5; 4.6; 4.8; 4.9 – as no product was identified the content was not promotional and the mandatory information associated with promotional material was not required, indeed it would be wholly inappropriate
- Clause 27.9 – as there were no payments or partnerships with a patient organisation in association with this video
- Clause 9.10 – as Leo's responsibility for the video was patently evident, bearing the Leo logo prominently at the beginning and end of the video and by virtue of being hosted on the Leo Pharma Global YouTube channel.

#### A4 'It is important for cancer patients to know about the risk of blood clots'

This video, hosted on the Leo Global YouTube channel, lasted 59 seconds. The video was also used on a Leo UK website [www.cancerclot.com](http://www.cancerclot.com), [CATHrombosis.com](http://CATHrombosis.com), and the Leo UK YouTube channel. A copy of the UK certificate for the full video was provided [UK/IE/MAT-27607v.1 certified on 9/9/2019].

The words spoken by the featured individual were displayed in text in the video and so the written transcript was an inherent part of the video. The individual was from the UK and Leo UK sourced the patient on behalf of the global team .

Leo submitted that the global video was clearly hosted on the Leo Pharma Global YouTube channel page and opened with the Leo logo. The video ended by displaying the Leo logo and the Leo Global address in Denmark. As the video was not limited to any type of audience (eg health professionals only) it was clearly intended for a general public audience. The video did not name or identify a specific product and so it was not promotion to the public or promotion to health professionals. The video was not created in partnership with a patient organisation.

Leo therefore denied all breaches:

- Clause 14 – the global material was not required to be certified for a UK audience
- Clause 28.1 – as the content was intended for the general public, it did not need to be limited to health professionals
- Clause 26.1 - there was no mention of, or hint about, a specific product therefore there was no promotion to the public
- Clause 26.2 - there was no mention of, or hint about, a specific product therefore there was no encouragement for the public to ask for a specific medicine by name
- Clause 26.3 – as no product was identified there was no need to include the adverse event reporting statement
- Clause 12.1 - as no product was identified there could be no disguised promotion
- Clauses 4.1; 4.2; 4.3; 4.4; 4.5; 4.6; 4.8; 4.9 – as no product was identified the content was not promotional and the mandatory information associated with promotional material was not required, indeed it would be wholly inappropriate
- Clause 27.9 – as there were no payments or partnerships with a patient organisation in association with this video
- Clause 9.10 – as Leo’s responsibility for the video was patently evident, bearing the Leo logo prominently at the beginning and end of the video and by virtue of being hosted on the Leo Pharma Global YouTube channel.

#### A5 ‘People need to know about the risks’

Leo noted that this video, hosted on the Leo Global YouTube channel, lasted 40 seconds. The latter part of the video was used on a Leo UK website [www.cancerclot.com](http://www.cancerclot.com), [CATHrombosis.com](http://CATHrombosis.com), and the Leo UK YouTube channel. A copy of the UK certificate for the video was provided [UK/IE/MAT-27610.1 certified on 30/9/2019].

The words spoken by the featured individual were displayed as text in the video and so the written transcript was an inherent part of the video. The individual was from the UK and Leo UK sourced the patient on behalf of the global team.

The video drew attention to the CancerClot website but did not specify the UK (.com) or Global (.info) version.

The global video was clearly hosted on the Leo Pharma Global YouTube channel page and opened with the Leo logo. The video ended by displaying the Leo logo and the Leo Global address in Denmark. As the video was not limited to any type of audience (eg health professionals only) it was clearly intended for a general public audience. The video did not name or identify a specific product and so it was not promotion to the public or promotion to health professionals. The video was not created in partnership with a patient organisation.

Leo therefore denied all breaches:

- Clause 14 – this global material was not required to be certified for a UK audience
- Clause 28.1 – as the content was intended for the general public, it did not need to be limited to health professionals
- Clause 26.1 - there was no mention of, or hint about, a specific product therefore there was no promotion to the public
- Clause 26.2 - there was no mention of, or hint about, a specific product therefore there was no encouragement for the public to ask for a specific medicine by name

- Clause 26.3 – as no product was identified, there was no need to include the adverse event reporting statement
- Clause 12.1 - as no product was identified or hinted at, there could be no disguised promotion
- Clauses 4.1; 4.2; 4.3; 4.4; 4.5; 4.6; 4.8; 4.9 – as no product was identified the content was not promotional and the mandatory information associated with promotional material was not required, indeed it would be wholly inappropriate
- Clause 27.9 – as there were no payments or partnerships with a patient organisation in association with this video
- Clause 9.10 – as Leo’s responsibility for the video is patently evident, bearing the Leo logo prominently at the beginning and end of the video and by virtue of being hosted on the Leo YouTube website
- Clause 9.10 – although the video referred to the CancerClot website, there was no suggestion that it was not a Leo information source and it was highlighted from within a Leo video on a Leo YouTube channel. As stated below, this patient website bore clear indications of Leo’s ownership of the website.

#### A6 ‘I want to help create awareness about blood clots and cancer’

Leo noted that this video, hosted on the Leo Global YouTube channel, lasted one minute and 7 seconds. It was also used on a Leo UK website [www.cancerclot.com](http://www.cancerclot.com), [CATHrombosis.com](http://CATHrombosis.com), and the Leo UK YouTube channel. Parts of the video appeared in two video assets individually certified by the UK. Copies of the UK certificates were provided [UK/IE/MAT-27608v.1 certified on 9/9/2019 and UK/IE/MAT-27606v.1; certified on 18/9/2019].

The words spoken by the featured individual were displayed in text in the video thus the written transcript was an inherent part of the video. The individual was from the UK and Leo UK sourced the patient on behalf of the global team.

The global video was clearly hosted on the Leo YouTube channel page and opened with the Leo logo. The video ended by displaying the Leo logo and the Leo Global address in Denmark. As the video was not limited to any type of audience (eg health professionals only) it was clearly intended for a general public audience. The video did not name or identify a specific product and so it was not promotion to the public or promotion to health professionals. The video was not created in partnership with a patient organisation.

Leo therefore denied all breaches:

- Clause 14 – this global material was not required to be certified for a UK audience
- Clause 28.1 – as the content was intended for the general public, it did not need to be limited to health professionals
- Clause 26.1 - there was no mention of, or hint about, a specific product therefore there was no promotion to the public
- Clause 26.2 - there was no mention of, or hint about, a specific product therefore there was no encouragement for the public to ask for a specific medicine by name
- Clause 26.3 – as no product was identified there was no need to include the adverse event reporting statement
- Clause 12.1 - as no product was identified or hinted at, there could be no disguised promotion

- Clauses 4.1; 4.2; 4.3; 4.4; 4.5; 4.6; 4.8; 4.9 – as no product was identified the content was not promotional and so the mandatory information associated with promotional material was not required, indeed it would be wholly inappropriate
- Clause 27.9 – as there were no payments or partnerships with a patient organisation in association with this video
- Clause 9.10 – as Leo's responsibility for the video is patently evident, bearing the Leo logo prominently at the beginning and end of the video and by virtue of being hosted on the Leo Pharma Global YouTube website.

#### A7 'I do not recall being told about blood clots'

Leo noted that this video, hosted on the Leo Global YouTube channel, lasted 35 seconds. The video was also used on a Leo UK website [www.cancerclot.com](http://www.cancerclot.com), [CATHrombosis.com](http://CATHrombosis.com), and the Leo UK YouTube channel. A small part of this video appeared in a video certified by the UK. A copy of the UK certificate for the video was provided [UK/IE/MAT-27610v.1 certified on 30/9/2019].

The words spoken by the featured individual were displayed in text in the video and so the written transcript was an inherent part of the video. The individual was from the UK and Leo UK sourced the patient on behalf of the global team.

Leo noted that the global video was clearly hosted on the Leo Pharma Global YouTube channel page and opened with the Leo logo. The video ended by displaying the Leo logo and the Leo Global address in Denmark. As the video was not limited to any type of audience (eg health professionals only) it was clearly intended for a general public audience. The video did not name or identify a specific product and so it was not promotion to the public or promotion to health professionals. The video was not created in partnership with a patient organisation.

Leo therefore denied all breaches:

- Clause 14 – this global material was not required to be certified for a UK audience
- Clause 28.1 – as the content was intended for the general public, it did not need to be limited to health professionals
- Clause 26.1 - there was no mention of, or hint about, a specific product therefore there was no promotion to the public
- Clause 26.2 - there was no mention of, or hint about, a specific product therefore there was no encouragement for the public to ask for a specific medicine by name
- Clause 26.3 – as no product was identified there was no need to include the adverse event reporting statement
- Clause 12.1 - as no product was identified or hinted at, there could be no disguised promotion
- Clauses 4.1; 4.2; 4.3; 4.4; 4.5; 4.6; 4.8; 4.9 – as no product was identified the content was not promotional and so the mandatory information associated with promotional material was not required, indeed it would be wholly inappropriate
- Clause 27.9 – as there were no payments or partnerships with a patient organisation in association with this video
- Clause 9.10 – as Leo's responsibility for the video was patently evident, bearing the Leo logo prominently at the beginning and end of the video and by virtue of being hosted on the Leo Pharma Global YouTube website.

#### A8 'Emphasise the prevalence of thrombosis to cancer patients and their families'

Leo noted that this 32 second video was hosted on the Leo Global YouTube channel. This short video appeared as part of a longer video certified by the UK/ Ireland team for compliance with the UK and IPHA Codes and used on a Leo UK website [www.cancerclot.com](http://www.cancerclot.com), [CATHrombosis.com](http://CATHrombosis.com), and the Leo Pharma UK YouTube channel. A copy of the UK/IE certificate was provided [UK/IE/MAT-27955v.1 certified on 12/9/2019].

The words spoken by the featured individual (an Irish patient's daughter) were displayed in text in the video and thus the written transcript was an inherent part of the video. The individual was from Ireland and Leo UK/Ireland sourced the patient via Thrombosis Ireland, an Irish patient organisation, on behalf of the global team. Although the patient was sourced via a patient organisation, the video was not created in partnership with a patient organisation.

Leo submitted that the Global video was clearly hosted on the Leo YouTube channel page and opened with the Leo logo. The video ended by displaying the Leo logo and the Leo Global address in Denmark. As the video was not limited to any type of audience (eg health professionals only) it was clearly intended for a general public audience. The video did not name or identify a specific product and so it was not promotion to the public or promotion to health professionals.

Leo therefore denied all breaches:

- Clause 14 – this global material was not required to be certified for a UK audience
- Clause 28.1 – as the content was intended for the general public, it did not need to be limited to health professionals
- Clause 26.1 - there was no mention of, or hint about, a specific product therefore there was no promotion to the public
- Clause 26.2 - there was no mention of, or hint about, a specific product therefore there was no encouragement for the public to ask for a specific medicine by name
- Clause 26.3 – as no product was identified there was no need to include the adverse event reporting statement
- Clause 12.1 - as no product was identified or hinted at, there could be no disguised promotion
- Clauses 4.1; 4.2; 4.3; 4.4; 4.5; 4.6; 4.8; 4.9 – as no product was identified the content was not promotional and so the mandatory information associated with promotional material was not required, indeed it would be wholly inappropriate
- Clause 27.9 – although the patient was sourced via a non-UK patient organisation, there were no payments or partnerships with the organisation in association with this video or its production
- Clause 9.10 – as Leo's responsibility for the video was patently evident, bearing the Leo logo prominently at the beginning and end of the video and by virtue of being hosted on the Leo Pharma Global YouTube website

#### A9 'We never suspected a link between cancer and blood clots'

Leo noted that this 56 second video was hosted on the Leo Global YouTube channel. The video was also used on the Leo UK Twitter channel. A copy of the UK/IE certificate was

provided. Part of the video also appeared in a longer video certified by the UK/ Ireland team for compliance with the UK and IPHA Codes and present on the Leo Pharma UK YouTube channel and cancerclot.com. Copies of the relevant approval certificates were provided [UK/IE/MAT-38041v.1 certified on 21/9/2019 and UK/IE/MAT-27954v.1 certified on 12/09/2019].

The words spoken by the featured individual (an Irish patient's daughter) were displayed as text in the video and so the written transcript was an inherent part of the video. The individual was from Ireland and Leo UK/Ireland sourced the patient via Thrombosis Ireland, an Irish patient organisation, on behalf of the global team. Although the patient was sourced via a patient organisation, the video was not created in partnership with a patient organization .

Leo submitted that the global video was clearly hosted on the Leo Pharma Global YouTube channel page and opened with the LEO logo. The video ended by displaying the Leo logo and the Leo Global address in Denmark. As the video was not limited to any type of audience (eg health professionals only) it was clearly intended for a general public audience. The video did not name or identify a specific product and so it was not promotion to the public or promotion to health professionals.

Leo therefore denied all breaches:

- Clause 14 – this global material was not required to be certified for a UK audience
- Clause 28.1 – as the content was intended for the general public, it did not need to be limited to health professionals
- Clause 26.1 - there was no mention of, or hint about, a specific product therefore there was no promotion to the public
- Clause 26.2 - there was no mention of, or hint about, a specific product therefore there was no encouragement for the public to ask for a specific medicine by name
- Clause 26.3 – as no product was identified there was no need to include the adverse event reporting statement
- Clause 12.1 - as no product was identified or hinted at, there could be no disguised promotion
- Clauses 4.1; 4.2; 4.3; 4.4; 4.5; 4.6; 4.8; 4.9 – as no product was identified the content was not promotional and the mandatory information associated with promotional material was not required, indeed it would be wholly inappropriate
- Clause 27.9 – although the patient was sourced via a non-UK patient organisation, there were no payments or partnerships with the patient organisation in association with this video or its production
- Clause 9.10 – as Leo's responsibility for the video was patently evident, bearing the Leo logo prominently at the beginning and end of the video and by virtue of being hosted on the Leo Pharma Global YouTube website

#### A10 'We were shocked when my mother developed a blood clot'

Leo noted that this 56 second video was hosted on the Leo Global YouTube channel. The video was certified by the UK/ Ireland team for compliance with the UK and IPHA Codes and was also used on a Leo UK website [www.cancerclot.com](http://www.cancerclot.com), [CATHrombosis.com](http://CATHrombosis.com), and the Leo UK YouTube channel. A copy of the certificate was provided [UK/IE/MAT-27959v.1 certified on 18/9/2019].



The words spoken by the featured individual (an Irish patient's daughter) were displayed as text in the video and so the written transcript was an inherent part of the video. The individual was from Ireland and Leo UK/Ireland sourced the patient via Thrombosis Ireland, an Irish patient organisation, on behalf of the global team. Although the patient was sourced via a patient organisation, the video was not created in partnership with a patient organisation.

Leo submitted that the global video was clearly hosted on the Leo YouTube channel page and opened with the Leo logo. The video ended by displaying the Leo logo and the Leo Global address in Denmark. As the video was not limited to any type of audience (eg health professionals only) it was clearly intended for a general public audience. The video did not name or identify a specific product and so it was not promotion to the public or promotion to health professionals.

Leo therefore denied all breaches:

- Clause 14 – this global material was not required to be certified for a UK audience
- Clause 28.1 – as the content was intended for the general public, it did not need to be limited to health professionals
- Clause 26.1 - there was no mention of, or hint about, a specific product therefore there was no promotion to the public
- Clause 26.2 - there was no mention of, or hint about, a specific product therefore there was no encouragement for the public to ask for a specific medicine by name
- Clause 26.3 – as no product was identified there was no need to include the adverse event reporting statement
- Clause 12.1 - as no product was identified or hinted at, there could be no disguised promotion
- Clauses 4.1; 4.2; 4.3; 4.4; 4.5; 4.6; 4.8; 4.9 – as no product was identified the content was not promotional and the mandatory information associated with promotional material was not required, indeed it would be wholly inappropriate
- Clause 27.9 – although the patient was sourced via a non-UK patient organisation, there were no payments or partnerships with that organisation in association with this video or its production
- Clause 9.10 – as Leo's responsibility for the video is patently evident, bearing the Leo logo prominently at the beginning and end of the video and by virtue of being hosted on the Leo YouTube website

#### A11 'Cancer patients should be aware of blood clots'

Leo noted that video lasted two minutes and 9 seconds and was hosted on the Leo Global YouTube channel. The video was certified by the UK/ Ireland team for compliance with the UK and IPHA Codes and was also used on a Leo UK website [www.cancerclot.com](http://www.cancerclot.com), [CATHrombosis.com](http://CATHrombosis.com), and the Leo UK YouTube channel.

Approximately 75% of the video was also used in another UK/IE certified video used on a Leo UK website [www.cancerclot.com](http://www.cancerclot.com), [CATHrombosis.com](http://CATHrombosis.com), and the Leo UK YouTube channel. Copies of the relevant certificates were provided [UK/IE/MAT-27958v.1 certified on 12/9/2019 and UK/IE/MAT-27957V.1 certified on 12/9/2019].

The words spoken by the featured individual (an Irish patient's daughter) were displayed as text in the video and so the written transcript was an inherent part of the video. The individual was from Ireland and Leo UK/Ireland sourced the patient via Thrombosis Ireland, an Irish patient organisation, on behalf of the global team. Although the patient was sourced via a patient organisation, the video was not created in partnership with a patient organization.

Leo submitted that the global video was clearly hosted on the Leo YouTube channel page and opened with the Leo logo. The video ended by displaying the Leo logo and the Leo Global address in Denmark. As the video was not limited to any type of audience (eg health professionals only) it was clearly intended for a general public audience. The video did not name or identify a specific product and so it was not promotion to the public or promotion to health professionals.

Leo therefore denied all breaches:

- Clause 14 – this global material was not required to be certified for a UK audience
- Clause 28.1 – as the content was intended for the general public, it did not need to be limited to health professionals
- Clause 26.1 - there was no mention of, or hint about, a specific product therefore there was no promotion to the public
- Clause 26.2 - there was no mention of, or hint about, a specific product therefore there was no encouragement for the public to ask for a specific medicine by name
- Clause 26.3 – as no product was identified there was no need to include the adverse event reporting statement
- Clause 12.1 - as no product was identified or hinted at there could be no disguised promotion
- Clauses 4.1; 4.2; 4.3; 4.4; 4.5; 4.6; 4.8; 4.9 – as no product was identified the content was not promotional and the mandatory information associated with promotional material was not required, indeed it would be wholly inappropriate
- Clause 27.9 – although the patient was sourced via a patient organisation, there were no payments or partnerships with that organisation in association with this video or its production
- Clause 9.10 – as Leo's responsibility for the video is patently evident, bearing the Leo logo prominently at the beginning and end of the video and by virtue of being hosted on the Leo YouTube website

#### A15 'How blood clots affected my life'

Leo noted that this 2 minute and 7 second video was hosted on the Leo Global YouTube channel. The video was certified by the UK/ Ireland team for compliance with the UK Code and was also used on a Leo UK website [www.cancerclot.com](http://www.cancerclot.com), [CATHrombosis.com](http://CATHrombosis.com), and the Leo UK YouTube channel. A copy of the UK/IE certificate was provided. *[UK/IE/MAT-27610v.1 certified on 30/9/201]*

The words spoken by the featured individual were displayed as text in the video and so the written transcript was an inherent part of the video. The individual was from the UK and Leo UK sourced the patient on behalf of the global team.

The text beneath the video specifically informed readers about a patient site, cancerclot.info on the Global YouTube Channel. It did not specifically indicate that the website was a Leo site, however the link was immediately beneath the Leo logo and the top banner of the landing page displayed the same Leo logo. Additionally, the patient cited CancerClot as a source of information but did not specify the UK (.com) or global (.info) version. Screenshots provided.

Leo submitted that the global video was clearly hosted on the Leo YouTube channel page and opened with the Leo logo. The video ended by displaying the Leo logo and the Leo Global address in Denmark. As the video was not limited to any type of audience (eg health professionals only) it was clearly intended for a general public audience. The video did not name or identify a specific product and so it was not promotion to the public or promotion to health professionals. The video was not created in partnership with a patient organisation.

Leo therefore denied all breaches:

- Clause 14 – this global material was not required to be certified for a UK audience
- Clause 28.1 – as the content was intended for the general public it did not need to be limited to health professionals
- Clause 26.1 - there was no mention of, or hint about, a specific product therefore there was no promotion to the public
- Clause 26.2 - there was no mention of, or hint about, a specific product therefore there was no encouragement for the public to ask for a specific medicine by name
- Clause 26.3 – as no product was identified there was no need to include the adverse event reporting statement
- Clause 12.1 - as no product was identified there could be no disguised promotion
- Clauses 4.1; 4.2; 4.3; 4.4; 4.5; 4.6; 4.8; 4.9 – as no product was identified the content was not promotional and the mandatory information associated with promotional material was not required, indeed it would be wholly inappropriate
- Clause 27.9 – as there were no payments or partnerships with a patient organisation in association with this video
- Clause 9.10 – as Leo's responsibility for the video was patently evident, bearing the Leo logo prominently at the beginning and end of the video and by virtue of being hosted on the Leo YouTube website
- Clause 9.10 – although the video referred to 'CancerClot', there was no suggestion that it was not a Leo information source and it was highlighted from within a Leo video on a Leo YouTube channel. As stated below, the website did bear clear indications of Leo's ownership of the website.

#### A18 'You need to regularly hear about the risk'

Leo noted that this video lasted one minute and 20 seconds and was hosted on the Leo Global YouTube channel.

The video was certified by the UK/ Ireland team for compliance with the UK Code and was also used on a Leo UK website [www.cancerclot.com](http://www.cancerclot.com), [CATHrombosis.com](http://CATHrombosis.com), and the Leo UK YouTube channel. A copy of the UK/IE certificate was provided [UK/IE/MAT-27605v.1 certified on 12/9/2019].

The words spoken by the featured individual were displayed as text in the video and so the written transcript was an inherent part of the video. The individual was from the UK and Leo UK sourced the patient on behalf of the global team.

The text beneath the video specifically informed readers about cancerclot.info on the global YouTube Channel. It did not specifically indicate that the website was a Leo site, however the link was immediately beneath the Leo logo and the top banner of the landing page displayed the same Leo logo .

Leo submitted that the global video was clearly hosted on the Leo YouTube channel page and opened with the Leo logo. The video ended by displaying the Leo logo and the Leo Global address in Denmark. As the video was not limited to any type of audience (eg health professionals only) it was clearly intended for a general public audience. The video did not name or identify a specific product and so it was not promotion to the public or promotion to health professionals. The video was not created in partnership with a patient organisation.

Leo therefore denied all breaches:

- Clause 14 – this global material was not required to be certified for a UK audience
- Clause 28.1 – as the content was intended for the general public it did not need to be limited to health professionals
- Clause 26.1 - there was no mention of, or hint about, a specific product therefore there was no promotion to the public
- Clause 26.2 - there was no mention of, or hint about, a specific product therefore there was no encouragement for the public to ask for a specific medicine by name
- Clause 26.3 – as no product was identified there was no need to include the adverse event reporting statement
- Clause 12.1 - as no product was identified or hinted at, there could be no disguised promotion
- Clauses 4.1; 4.2; 4.3; 4.4; 4.5; 4.6; 4.8; 4.9 – as no product was identified the content was not promotional and the mandatory information associated with promotional material was not required, indeed it would be wholly inappropriate to do so
- Clause 27.9 – as there were no payments or partnerships with a patient organisation in association with this video
- Clause 9.10 – as Leo’s responsibility for the video was patently evident, bearing the Leo logo prominently at the beginning and end of the video and by virtue of being hosted on the Leo Pharma Global YouTube website
- Clause 9.10 – as while the text beneath the video referred to cancerclot.info, there was no suggestion that it was not a Leo information source and it was highlighted from a page bearing a Leo video within a Leo YouTube channel. As stated below, the website did bear clear indications of Leo’s ownership of the website.

#### A19 ‘Cancer patients must know risk of blood clots’

Leo noted that this one minute and 7 seconds video was hosted on the Leo Global YouTube channel.

The video was certified by the UK/ Ireland team for compliance with the UK Code and was also used on a Leo UK website [www.cancerclot.com](http://www.cancerclot.com), [CATHrombosis.com](http://CATHrombosis.com), and the Leo UK YouTube

channel. A copy of the UK/IE certificate was provided [UK/IE/MAT-27604v.1 certified on 18/9/2019].

The words spoken by the featured individual were displayed as text in the video and so the written transcript was an inherent part of the video. The individual was from the UK and Leo UK sourced the patient on behalf of the global team.

The text beneath the video specifically informed readers about cancerclot.info on the global YouTube Channel. It did not specifically indicate that the website was a Leo site, however the link was immediately beneath the Leo logo and the top banner of the landing page displayed the same Leo logo.

Leo noted that the global video was clearly hosted on the Leo YouTube channel page and opened with the Leo logo. The video ended by displaying the Leo logo and the Leo Global address in Denmark. As the video was not limited to any type of audience (eg health professionals only) it was clearly intended for a general public audience. the video did not name or identify a specific product and so it was not promotion to the public or promotion to health professionals. The video was not created in partnership with a patient organisation.

Leo therefore denied all breaches:

- Clause 14 – this global material was not required to be certified for a UK audience
- Clause 28.1 – as the content was intended for the general public, it did not need to be limited to health professionals
- Clause 26.1 - as there was no mention of, or hint about, a specific product there was no promotion to the public
- Clause 26.2 - there was no mention of, or hint about, a specific product therefore there was no encouragement for the public to ask for a specific medicine by name
- Clause 26.3 – as no product was identified there was no need to include the adverse event reporting statement
- Clause 12.1 - as no product was identified or hinted at, there could be no disguised promotion
- Clauses 4.1; 4.2; 4.3; 4.4; 4.5; 4.6; 4.8; 4.9 – as no product was identified the content was not promotional and the mandatory information associated with promotional material was not required, indeed it would be wholly inappropriate to do so
- Clause 27.9 – as there were no payments or partnerships with a patient organisation in association with this video
- Clause 9.10 – as Leo’s responsibility for the video was patently evident, bearing the Leo logo prominently at the beginning and end of the video and by virtue of being hosted on the Leo Pharma Global YouTube website
- Clause 9.10 – as while the text beneath the video referred to cancerclot.info, there was no suggestion that it was not a Leo information source and it was highlighted from a page bearing a Leo video within a Leo YouTube channel. As stated below, the website did bear clear indications of Leo’s ownership of the website.

#### V60 ‘Leo Pharma’

Leo noted that this video lasted six minutes and 5 seconds and was hosted on the named YouTube channel, which was described on YouTube as:

'[Name] is the online broadcast platform for the National Health Channel and its two subsidiary channels -- Health Sector TV and Public Sector TV. Our programmes can also be viewed via television on Sky Channel 231 and BBC/ITV Freesat Channel 402'

Leo noted that the channel appeared to be inactive and the most recent video added to the platform was 6 years ago in 2014. The National Health Channel had its own YouTube channel but also appeared to be inactive; its most recent posting was 5 years ago. It might (or might not) be associated with National Health Channel TV - another YouTube channel that had not posted since 2016. Google searches did not identify any active company/entity with that title.

Leo stated that although one of its ex-employees could remember the creation of this video, no current employees did. There was no knowledge of how or why the video was on the named YouTube channel. The video appeared to have been uploaded onto the channel in 2012. The video displayed the Leo logo prominently at the outset and end of the film, as well as a statement at the beginning that 'Leo Pharma had provided funding and editorial input into this film' and so it was clear that Leo was originally involved in its creation. The video opened with an interview of a Leo UK senior executive. The video additionally featured two named UK health professionals.

Leo submitted that it was possible that the video was originally created as a corporate video and uploaded to YouTube by the agency that created it, however that was mere hypothesis on Leo's part. It was also possible for YouTube videos to be downloaded by a third party and used for its own purposes, and a pharmaceutical company would have no control over this; again this was speculative on Leo's part. No record of the video or its certification could be identified. The current Leo senior executive had been in post since 2013 and so therefore the video, featuring the previous incumbent, would not have been used since the beginning of 2013.

Leo noted that the video mentioned several dermatological conditions and featured on actinic keratosis. It mentioned treatment options, including 'cryotherapy' and 'cream-based treatments' but did not name or identify a medicine.

Leo submitted that the video was not hosted on any website or channel page. There was no evidence that Leo was responsible for the upload of the video onto a public channel or its continuing presence. The video did not name or identify a specific product and was theoretically suitable for any type of audience and was not therefore promotion to the public or promotion to health professionals. At no point was a Leo product named, discussed or promoted. It was unlikely that the video had been created in partnership with a patient organisation.

Leo stated that it had been unable to contact the named YouTube channel user.

Leo therefore denied all alleged breaches:

- Clause 14 – Leo had no evidence of the original creation of this historic video. Moreover, Leo did not believe it sanctioned its upload to the named YouTube channel, which was an unknown company to Leo, therefore there was no requirement, or indeed scope for Leo to certify its presence on the YouTube channel
- Clause 26.3 – a statement that Leo's aim was 'helping people achieve healthy skin' did not promote a product. In fact, as a dermatology focused company, Leo Pharma's Global mission statement was to 'help people achieve healthy skin'. That did not imply promotion of a particular product or products, nor did it imply product or

treatment claims. Rather it was a simple statement of fact of the basic mission of any pharmaceutical company, which was to improve quality of life for patients within the disease areas in which it was active

- Clause 28.1 – as the content was intended for the general public, it did not need to be limited to health professionals
- Clause 26.1 - a statement that Leo's aim was to achieve healthy skin did not promote a product
- Clause 26.2 - a statement that Leo's aim was to achieve healthy skin was not encouragement for the public to ask for a specific medicine by name
- Clause 26.3 – as no product was identified there was no need to include the adverse event reporting statement
- Clauses 4.1; 4.2; 4.3; 4.4; 4.5; 4.6; 4.8; 4.9 – as no product was identified the content was not promotional and the mandatory information associated with promotional material was not required, indeed it would be wholly inappropriate.

### **CancerClot websites**

Leo noted that there were two CancerClot websites:

- Cancerclot.info run by Leo Global and mentioned in the text of some group A videos
- Cancerclot.com run by Leo UK

### **Cancerclot.info (Leo Global website)**

Leo stated that a number of videos that were at issue in this complaint specifically referred to cancerclot.info. In that regard, Leo noted the complainant's concerns about:

- whether the website was appropriately labelled as being from Leo (Clause 9.10)
- whether an appropriate gateway existed (Clause 28)
- patient mandatory information (Clause 26.3)
- failure to certify (Clause 14)

Leo stated that the website landing page clearly identified Leo via a logo at the top of the page and also in the prominent footer bar and in addition the website clearly identified Leo via a logo at the top of every video page and also in the prominent footer bar (screenshots provided).

Leo stated that as the website itself was managed by Leo Global based in Denmark, and was not targeted at the UK, UK certification did not apply. While the website referred generally to cancer and deep vein thrombosis and pulmonary embolism etc, no individual treatments were identified. Therefore, there was no need for the patient-specific mandatory information to be applied.

Leo denied all associated breaches of the Code:

- Clause 9.10 – Leo's involvement was clear and obvious
- Clause 28.1 – the website did not contain promotional content and did not require a gateway

- Clause 28.2 – this was not information or promotional material about medicines, nor placed by the UK or the UK's authority
- Clause 26.3 – mandatory information was not required because individual treatments were not mentioned
- Clauses 14.1 and 14.3 - this was not a UK website and did not require UK certification

### **Cancerclot.com (LEO UK website)**

Leo stated that this website was created for audiences in the UK and Ireland and was clearly and prominently labelled as such at the outset on the cookie warning and on the landing page. It clearly stated at the top of the webpage that the site had been created by Leo and the Leo logo was also at the top of the page. The job bag number and date of prep were clearly visible in the footer . A copy of the UK/IE certificate for the website was provided [UK/IE/MAT-09943, certified on 23/8/2020].

For clarity, Leo noted that the website was not signposted from any of the thrombosis videos currently hosted on the Leo UK YouTube channel.

Leo denied all associated breaches of the Code:

- Clause 9.10 – Leo UK's involvement was clear and obvious
- Clause 28.1 – the website did not contain promotional content and did not require a gateway
- Clause 26.3 – mandatory information was not required because individual treatments were not mentioned
- Clauses 14.1 and 14.3 - the website had been certified as being intended for members of the UK and Ireland public.

### **Leo UK YouTube channel**

For completeness, Leo included a small selection of screenshots from the Leo Pharma UK YouTube channel. Leo noted that the target audience, job bag numbers date of prep, etc., could be clearly seen. For clarity Leo submitted that none of the thrombosis videos currently hosted on the Leo Pharma UK YouTube channel redirected readers to cancerclot.com. There were two clusters of thrombosis videos hosted on the Leo UK YouTube channel that were intended for the general public. Both featured the same patients used in the global videos and as already indicated, with much of the same content. Leo provided sample screen shots of the opening to each video that clearly indicated the UK approach to material.

### **Conclusion**

In conclusion, Leo welcomed legitimate scrutiny and was pleased to confirm that it did not believe it had breached the Code on any of the numerous allegations raised by the complainant.

### **Further information**

Leo submitted further information to the above, noting that in its original response it discussed those videos, mainly hosted by the Leo Pharma Global YouTube channel which were the focus of the complaint, and considered that the global videos which were also hosted on a Leo UK



website or channel to be potentially within scope of the complaint. On further review of its websites, Leo realised that there were four more videos, which fell within that scope ie videos B30 - B33. Leo sincerely apologised for the initial oversight, and for any inconvenience caused.

Although the complaint was about content hosted by Leo Global rather than Leo UK, in recognition of the fact that Leo UK also hosted the videos on its own website, [www.CAThrombosis.com](http://www.CAThrombosis.com), Leo would comment on the individual videos and allegations accordingly, as per the original response. Leo reiterated that it did not consider these videos on the Leo Global YouTube channel, run out of Denmark, with no reference to the availability of medicines in the UK, were within scope of the UK Code.

These additional four videos referred to a website indicated by the complainant. Comments on the website were included below.

Leo noted that the complainant had essentially made the same allegations for each video. Leo stated that it would address his/her concerns directly.

The complaints included:

- failure to certify (Clauses 14.1 and 14.3)
- failure to certify transcript (14.1)
- failure to exclude the public from HCP promotional material (Clause 28.1)
- patient mandatory information (Clause 26.3)
- health professional mandatory information (Clauses 4.1; 4.2; 4.3; 4.4; 4.5; 4.6; 4.8; 4.9)
- disguised link to [cancerclot.info](http://cancerclot.info) as being Leo's (Clauses 9.10).

Leo noted that the UK was not involved in the production or content of the four videos which were produced by a Canadian patient organisation, Thrombosis Canada, with an educational grant from Leo Canada. The videos were made as part of a country speaker tour by a named UK health professional for Leo Canada during which Thrombosis Canada partnered with this health professional. The UK's only involvement was to ascertain the health professional's availability and willingness to conduct the speaker tour for Leo Canada.

Of the 13 group B videos, none of which Leo originally believed to be used by the UK, four of them, B30 - 33, had been used on the Leo UK/IE non-promotional website, [www.CAThrombosis.com](http://www.CAThrombosis.com). This was a non-promotional website for health professionals, with a branch for patients and the public on the homepage. Furthermore, the content was restricted to registered users of the website, that was, behind an email address and password.

With regards to the content of the videos themselves, and whether they breached the Code, this was discussed below. The videos in question, hosted on the Leo Global YouTube channel were:

B30 'Which clot symptoms should I watch for?' – 1 minute, 32 seconds

B31 'Which cancer patients get blood clots?' – 1 minute, 51 seconds

B32 'What do patients really need?' – 3 minutes, 14 seconds

B33 'Meet [named health professional]' – 1 minute, 18 seconds

As stated above, the videos were also used on a Leo UK/IE non-promotional website for health professionals [www.CAThrombosis.com](http://www.CAThrombosis.com), behind account registration and password protection. They were hosted in a section called Patient Support, with the text 'These materials are intended to support your communication with your patients who might be experiencing symptoms or are at risk of CAT'. The videos were not downloadable and were included on the website for the health professional to watch in order to support their patient discussions on this topic. The videos did not name or identify a specific product and were related to the disease area of cancer-associated thrombosis. It was not therefore promotion to the public or promotion to health professionals. Clause 14.3 required disease educational material for the public or patients to be certified. However, as these videos were hosted on a UK health professional website and not hosted on a UK patient website or channel, they were not therefore directed at the public or patients, and so there was no requirement for them to be certified.

These videos were clearly hosted on the Leo Global YouTube channel page and they all opened with the Leo logo and Thrombosis Canada logo. The videos all ended by displaying the Thrombosis Canada and Leo logos and the Leo Global address in Denmark, as well as a declaration of funding.

Leo submitted that with regard to the presence of the videos on the Leo Pharma Global YouTube channel, as they were not limited to any type of audience (eg health professionals only) they were clearly intended for a general public audience, but not directed to a UK audience. In so far as their inclusion on the Leo UK [www.CAThrombosis.com](http://www.CAThrombosis.com) website was concerned, although the videos were created for a patient audience, they were provided on a password protected health professional website and intended to be viewed by a UK health professional. The videos were not used on Leo Pharma UK patient websites or Leo UK YouTube channel.

The videos did not name or identify a specific product and so they were not promotion to the public or promotion to health professionals.

Near the end of the videos was the text 'Need more information? Contact your doctor!' and 'You could also find more information on the website [www.cancerclot.info](http://www.cancerclot.info)'. This text also appeared on the videos as used on the UK [www.CAThrombosis.com](http://www.CAThrombosis.com) website. This website was the global variant of a patient website. The UK approved version of the website was hosted at [www.cancerclot.com](http://www.cancerclot.com). There were no clickable links to that website. With regards the presence of the videos on the UK website [www.CAThrombosis.com](http://www.CAThrombosis.com), the inclusion of the URL text was incidental, as the video had been produced with non-UK support, hence the global variant of the patient website on the video. Again, the inclusion of the video on the website was intended for health professionals to watch, in order to support their discussions with patients – they were not downloadable or intended for UK patients to watch. Indeed, Leo did not use these videos on the UK patient website [www.cancerclot.com](http://www.cancerclot.com).

Therefore, to summarise, Leo Pharma denied all breaches:

- Clause 14 – this global material was not required to be certified for a UK audience in so far as its inclusion on the Leo Pharma Global YouTube channel was concerned. With regards the use of the videos on a UK health professional website, as these were disease education videos with the intent of helping guide and inform health

professional discussions with patients, but not directed specifically at patients or the public, there was no requirement for these to be certified

- Clause 28.1 – this content was limited to health professionals, and was non-promotional material, therefore out of scope of this clause
- Clause 28.2 – the global patient website [www.cancerclot.info](http://www.cancerclot.info) was not a UK website, not created with UK authority, and did not refer to the availability or use of medicine in the UK. The inclusion of the text of this URL on the video as used on a UK health professional website [www.CAThrombosis.com](http://www.CAThrombosis.com) did not change that fact
- Clause 26.3 – as no product was identified there was no need to include the adverse event reporting statement. With regards the global website [www.cancerclot.info](http://www.cancerclot.info), that was a global website, not directed to a UK audience, with no products identified
- Clauses 4.1; 4.2; 4.3; 4.4; 4.5; 4.6; 4.8; 4.9 – as no product was identified the content was not promotional and the mandatory information associated with promotional material was not required, indeed it would be wholly inappropriate
- Clause 9.10 – as Leo's responsibility for the video was patently evident, bearing the Leo logo prominently at the beginning and end of the video and by virtue of being hosted on the Leo Pharma Global YouTube website
- Clause 9.10 – while the videos referred to the [www.cancerclot.info](http://www.cancerclot.info) website, there was no suggestion that it was not a Leo information source and it was highlighted from within a Leo funded video on a Leo YouTube channel. This patient website bore clear indications of Leo's ownership of the website at the outset.

In conclusion, Leo Pharma UK welcomed legitimate scrutiny, but again refuted breaches of the Code with regards to this case. Leo regretted any inconvenience caused to the Panel in its assessment of this case as a result of this late addition, and sincerely apologised for that.

### **Further correspondence and response from Leo and complainant**

The complainant did not accept the Case Preparation Manager's decision that there was no *prima facie* case to answer with regard to videos T58 and U59 and so the complaint regarding those would be considered by the Panel. In accordance with Paragraph 5.5 of the Constitution and Procedure Leo was invited to comment on the further evidence.

### **Comments from complainant**

The complainant stated that he/she was confused as to why videos U59 and T58 were described as 'unlisted'; he/she did not have any specific links – all videos were clearly available on the YouTube channel. T58 was still on the YouTube channel under a 'Playlist' called 'EAHP presentation on cancer-associated thrombosis' – if one clicked on the playlist a number of videos, including the video in question, could be seen. U59 was still on the Leo Global YouTube channel under the 'Playlist' called 'ICTHIC'. No special links or knowledge were needed to access the videos. Both videos featured UK health professionals discussing specific medicines in the UK.

In T58, the named health professional discussed the results of an audit in his/her hospital in Wales in terms of medication usage, low molecular medicine and specifically mentioned the Leo medicine tinzaparin stating 'with tinzaparin usage or heparin usage the most common side effect that we find is bruising'.

In U59, the named health professional firstly described that he/she worked in England and then discussed his/her experience of treating cancer surgery patients for 4-6 weeks as there was 'good data with LMWH'. The complainant stated that Leo marketed a low molecular weight heparin.

The health professional mentioned 'some good data' with LMWH for ambulatory cancer patients and recommended LMWH in some circumstances. He/she discussed several international guidelines which recommended LMWH and were followed by health professionals in the UK. He/she also went through the study design for 'PROVE' which included a large population of lung cancer patients using tinzaparin.

### **Further comments from the complainant**

The complainant reiterated that the videos were available online to the public and were not hidden. The complainant explained that if one launched the YouTube site and searched for 'Leo Pharma', then the 'Leo Pharma Global' channel would be found and if one clicked on this channel icon, a list of 'Created Playlists' would be available. Within that section were playlists entitled 'ICTHIC' and 'EAHP Presentation on Cancer-Associated Thrombosis' - the videos U59 and T58 were within those playlists. The complainant stated that Leo must not be aware that these videos were available online to the public if it maintained that they were only searchable by a specific link or address.

### **Response to the above from Leo**

Leo submitted that when the complaint was received in October 2020, the Authority provided links to most of the videos but links to T58 and U59 were not provided, presumably because they could not be located.

In its original response, Leo had stated that it was initially also unable to locate videos T58 and U59. However, on making enquiries with Leo Global, it appeared that those videos were 'unlisted' ie invisible and could not be found or accessed anywhere by searching. An individual would have to have known the actual YouTube link in order to be able to view the video. Upon clicking the link, the videos opened within the Leo Pharma Global YouTube channel. Therefore, Leo understood that only individuals in possession of the link could view the videos. These videos, which featured UK health professionals, and which were targeted at health professionals, were not currently hosted by Leo UK, and the company therefore considered that they were outside the scope of the Code.

On receipt of the information from the complainant as noted above, Leo stated that it was indeed the case that the videos could be accessed via the 'Playlists' tab on the Leo Pharma Global YouTube channel. The videos were not present under the more general 'Videos' tab. Neither Leo Pharma UK nor its colleagues in Global who looked after this digital channel were aware of that discrepancy. It was usually the case that videos stored under a 'Playlists' tab represented a smaller subset. However, that did not appear to be the case in this instance. The videos were still not searchable via the YouTube search box, and they were still described as 'Unlisted' when accessed via the 'Playlists' tab.

Leo submitted that whilst it regretted that it was not aware of the videos being accessible via the Playlists tab, it believed that underlined the challenges posed by an unusually lengthy complaint

such as this regarding 60 videos, particularly as it pertained to cross-border digital access and archiving.

Video T58 was a presentation made by a UK Pharmacist at the 2018 European Association of Hospital Pharmacists congress, in a Leo Pharma sponsored symposium; it was a Leo Global organised event, including the production of the video. The video ran for just over 27 minutes and was almost exclusively on the topic of patient counselling in managing cancer-associated thrombosis. Within this context of patient counselling, the pharmacist mentioned that in his/her hospital in Wales, tinzaparin was used. Tinzaparin was a Leo Pharma low molecular weight heparin. That was the only context in which the product was mentioned. The video was not currently used by Leo Pharma UK.

Video U59 was a presentation made by a UK health professional at the 2018 International Conference on Thrombosis and Hemostasis Issues in Cancer, in a Leo Pharma sponsored symposium; it was a Leo Global organised event, including the production of the video. The video ran for just over 14 minutes and was a more general presentation on the topic of thromboprophylaxis in active cancer. During the presentation, all forms of relevant anticoagulation were discussed, including low molecular weight heparins (LMWH) and direct oral anti-coagulants (DOACS). Tinzaparin, a Leo Pharma LMWH, was mentioned by name once, in the context of a single study-design slide in patients with lung cancer, towards the end of the presentation. The video was not currently used by Leo Pharma UK.

Leo submitted that Clause 28.2 of the 2019 Code, stated that:

‘Information or promotional material about medicines covered by Clause 28.1 which is placed on the Internet outside the UK will be regarded as coming within the scope of the Code, if:

- it was placed there by a UK company/with a UK company’s authority, or
- it was placed there by an affiliate of a UK company, or with the authority of such a company **and** it makes specific reference to the availability or use of the medicine in the UK’ (emphasis added).

Leo acknowledged that video T58 referred to the availability or use of tinzaparin in the UK. Video U59 did not reference the availability or use of tinzaparin in the UK. The fact that the presenter, a global key-opinion leader, worked at a UK hospital, did not in itself mean that every medicine or class of medicine mentioned in his/her presentation could be assumed to be available or used in the UK, particularly where that presentation or symposium has been arranged by a non-UK organisation.

Leo Pharma was headquartered in Denmark, therefore, regardless of whether the videos did or did not reference availability of a Leo medicine in the UK, as this video was not placed on the Leo Pharma Global YouTube channel by an affiliate of a UK company, nor with the authority of Leo Pharma UK, the company considered that these videos were outside the scope of the Code.

Leo referred to Paragraph 5.3 of the PMCPA Constitution and Procedure and stated that no direct outreach from the complainant or his/her company had been received to its knowledge, and Leo questioned whether this complaint (and other complaints received from the complainant) should proceed until inter-company dialogue had happened and proved

unsuccessful. Furthermore, such unauthorised activity, on behalf of the company the complainant worked for, might also place him/her in breach of his/her employment contract. Leo stated that it welcomed any such outreach from the complainant or his/her company, and welcomed the opportunity to correct and improve its company processes, operations and procedures.

## **PANEL RULING**

The Panel noted that the complainant's allegations were all, bar one, in relation to videos hosted on the Leo Global (based in Denmark) YouTube Channel; one video (V60) which appeared to have been commissioned by Leo was hosted on a non-Leo YouTube channel.

The Panel noted that most of the videos hosted on the Leo Global channel referred to by the complainant made no reference to the availability or use of a Leo medicine in the UK and were therefore not within the scope of the Code. Nonetheless, the Panel noted the company's submission that Leo UK also hosted some of these videos, or parts of these videos, on its own UK sites and channels (A1-A11, A15-A19 and, B30-B33) and the company acknowledged that those videos which were on Leo UK websites and channels would be within the scope of the Code. Although the complaint appeared to be in relation to the videos on the Leo Global YouTube channel, the Panel noted Leo's submission in relation to its own UK sites and channels and considered the complaint in that regard where applicable.

### **Group A videos (A1-A11, A15-A19)**

The Panel noted Leo's submission that A1 and A16 were the same video as were A2 and A17. The Panel therefore considered that there were fourteen videos within group A which were subject to this complaint.

The Panel noted that all fourteen videos were hosted on the Leo Global YouTube channel and featured either a patient (A1-A7, A15, A18, A19) or a carer (A8 -A11) discussing their experience of cancer-associated thrombosis. The Panel noted that neither the patient nor the carer specifically referred to the availability or use of a Leo medicine in the UK in any of the videos.

The Panel noted Leo's submissions that the carer was from Ireland and Leo UK/Ireland had sourced him/her from an Irish patient organisation on behalf of the global team and that the patient was from the UK and Leo UK had sourced him/her on behalf of the global team. In the Panel's view, these factors were not such as to automatically bring the videos within the scope of the Code.

The Panel considered that the fourteen videos or parts of them which were also hosted on Leo UK websites and/or the Leo UK YouTube channel were within the scope of the Code and considered the videos under the Code in that regard.

The Panel noted that the Leo Pharma logo appeared at the beginning and end of each Group A video hosted on the Leo Global YouTube channel. The Panel noted Leo's submission that all or parts of these videos were also hosted on Leo UK sites/channels. The Panel did not have copies of the videos which were hosted on the Leo UK sites/channels before it. Based on the copies of the videos before it, and Leo's submission that they or parts of them were hosted on Leo UK sites/channels, the Panel considered that the material was clearly owned by Leo and

was not material sponsored by the company. In that regard, in the Panel's view, Clause 9.10, which related to sponsored material, was not relevant and no breach was ruled in relation to each of the fourteen Group A videos.

The Panel noted that there was no direct or indirect reference to a specific medicine in any of the fourteen videos. One video (A1/16) referred to injecting a medicine, however, the Panel noted that there were a number of anticoagulants which might be self-injected from different companies. In the Panel's view, the Group A videos were non-promotional disease awareness videos aimed at the public and thus the requirements of Clauses 4 and 28.1 did not apply. The Panel therefore ruled no breach of Clauses 4.1, 4.3, 4.5, 4.6, 4.8, 4.9 and 28.1 in relation to each Group A video. Given that no breach of Clause 4.1 was ruled, the requirements of Clause 4.2 were not relevant and so the Panel also ruled no breach of that clause.

The Panel considered the videos were non-promotional and thus did not need to be certified as promotional material. No breach of Clause 14.1 was ruled.

As noted above, the Panel considered the Group A videos to be disease awareness videos aimed at the public. The Panel noted Leo's submission that where all or part of the videos were hosted on a Leo UK site/channel they had been certified for such use. The words spoken by the featured individuals were displayed as text within the video and so the written transcript was an inherent part of the video and did not need to be separately certified. The Panel therefore ruled no breach of Clause 14.3 in relation to each of the videos in Group A.

The Panel did not consider that the videos were directed at patients taking a particular medicine and therefore they did not require the inclusion of the reporting of side effects statement as described in Clause 26.3; the Panel therefore ruled no breach of Clause 26.3 in relation to each Group A video.

The Panel noted Leo's submission that there was no association with a patient organisation in relation to videos A1-A7, A15, A18, A19 and therefore the Panel ruled no breach of Clause 27.9 in relation to each of those videos.

In relation to videos A8-A11, the Panel noted Leo's submission that although the carer was sourced via a patient organisation, the video was not created in partnership with a patient organisation and therefore Leo had not sponsored patient organisation material. The Panel ruled no breach of Clause 27.9 in relation to each video in that regard.

### **B30, B31, B32 and B33**

The Panel noted Leo's submission that Leo UK had no involvement in the production of these four Group B videos; they were produced by a Canadian patient organisation with an educational grant from Leo Canada as part of a country speaker tour for Leo Canada, during which the patient organisation partnered with a UK health professional. Each video recorded a conversation between a patient ambassador from the patient organisation and the health professional. Leo UK's only involvement was to ascertain the health professional's availability and willingness to conduct the speaker tour for Leo Canada. In the Panel's view, use of a UK health professional sourced by Leo UK in Leo Canada material hosted on the Leo Global YouTube channel would not *de facto* bring the videos within the scope of the Code. However, the Panel noted Leo's submission that the four videos were also used on the Leo UK/Ireland website, CAThrombosis.com. The Panel considered that the videos hosted on

CAThrombosis.com were within the scope of the Code and considered the videos under the Code in that regard.

The Panel noted Leo's submission that the videos were on a Leo UK/IE non-promotional website for health professionals [www.CAThrombosis.com](http://www.CAThrombosis.com), behind account registration and password protection; they were not directed at the public or patients.

The Panel noted Leo's submission that the videos were not downloadable, and were for health professionals to watch, in order to support discussions with patients on the topic of cancer-associated thrombosis. The videos were hosted in a section called 'Patient Support' with the text 'These materials are intended to support your communication with your patients who may be experiencing symptoms or are at risk of CAT [Cancer- Associated Thrombosis]'. Neither speaker in the videos referred directly or indirectly to a specific medicine.

The Panel did not consider that the complainant had discharged his/her burden of proof that the videos were promotional and therefore no breach of Clauses 4.1, 4.3, 4.5, 4.6, 4.8, 4.9, 14.1 and 28.1 was ruled in relation to each Group B video. Given that a no breach of Clause 4.1 was ruled, the requirements of Clause 4.2 were not relevant and so the Panel also ruled no breach of that clause.

The Panel noted that a screen within each video stated, *inter alia*, 'Need more information? Contact your doctor!'. However, the Panel noted Leo's submission that the videos were restricted to registered users of the website and were intended for health professionals to view. It appeared to the Panel that the Leo Canada material had not been appropriately edited for specific use on a UK website for health professionals. Nonetheless, the Panel considered that the complainant had not shown, on the balance of probabilities, that the videos on CAThrombosis.com were available to the public or patients and no breach of Clause 14.3 was ruled in relation to each Group B video.

The Panel did not consider that the videos were directed at patients taking a particular medicine and therefore they did not require the inclusion of the reporting of side effects statement as described in Clause 26.3; the Panel therefore ruled no breach of Clause 26.3 in relation to each Group B video.

The Panel noted the complainant's allegation that in each video, a slide advised viewers to visit [cancerclot.info](http://cancerclot.info) for more information without making clear that they were being directed to a Leo owned website. The Panel noted that a screen within each video stated, *inter alia*, 'You can also find more information on the website [www.CancerClot.info](http://www.CancerClot.info)'. The Panel noted Leo's submission that this text also appeared on the videos as used on the Leo UK website, CAThrombosis.com. In that regard, the Panel noted that the videos already appeared on a Leo website (CAThrombosis.com) and there was no implication that the website they were being referred to ([cancerclot.info](http://cancerclot.info)) was not also a Leo website. Furthermore, it was clear on visiting [cancerclot.info](http://cancerclot.info) that it was a Leo website. The Panel noted that Clause 9.10 covered material sponsored by a company and noted that the video in question appeared on a Leo website and that the CancerClot websites were also Leo websites and not sponsored material. In that regard, in the Panel's view, Clause 9.10 was not relevant and no breach was ruled.

The Panel noted that a UK website for health professionals (CAThrombosis.com), within a section about patient support, contained videos referring to a Leo Global website ([cancerclot.info](http://cancerclot.info)), which was aimed at patients. The Panel noted Leo's submission that it had a



UK version of this patient website (cancerclot.com) which was certified. The Panel queried why Leo had not edited the Group B videos in question to refer to cancerclot.com rather than cancerclot.info. The Panel noted that the Group B videos directed health professionals to refer their patients to look at cancerclot.info, which had not been certified as per Clause 14.3, and the Panel therefore ruled a breach of Clause 14.3 in relation to cancerclot.info.

The Panel did not consider that the complainant had established that cancerclot.info was intended for patients taking a particular medicine and therefore it ruled no breach of Clause 26.3 in that regard.

### **T58**

The Panel noted Leo's submission that this video was of a presentation given by a UK pharmacist at the 2018 European Association of Hospital Pharmacists congress, in a Leo Global symposium. Leo Global produced the 27-minute video which was mostly about patient counselling in managing cancer-associated thrombosis. Within the video the pharmacist briefly mentioned that tinzaparin (a Leo low molecular weight heparin) was used in his/her hospital.

The Panel noted Leo's submission that video T58 was aimed at health professionals and was an 'unlisted' video and that Leo had therefore assumed that only health professionals in possession of the link could view it. The Panel further noted, on receipt of additional information from the complainant, that Leo had acknowledged that this video was publicly accessible via the 'playlists' tab on the Leo Global YouTube channel but that the video was not currently used by Leo UK on any of its sites or channels.

The Panel noted that Clause 28.2 stated that 'Information or promotional material about medicines covered by Clause 28.1 [prescription only medicines] which is placed on the Internet outside the UK will be regarded as coming within the scope of the Code, if:

- it was placed there by a UK company/with a UK company's authority, or
- it was placed there by an affiliate of a UK company, or with the authority of such a company and it makes specific reference to the availability or use of the medicine in the UK.'

The Panel disagreed with Leo's interpretation of Clause 28.2. The Panel noted that Leo Global was affiliated to Leo UK and therefore promotional videos hosted on the Leo Global channel would be within scope of the Code if they specifically referred to the availability or the use of a Leo prescription only medicine in the UK, which video T58 did.

The Panel noted that T58 was a video of a Leo symposium which referred to the use of a Leo medicine, tinzaparin (brand name Innohep), in thrombosis and it was therefore promotional material. The video was not certified and therefore a breach of Clause 14.1 was ruled.

The Panel noted that there was no prescribing information or adverse event reporting statement for tinzaparin either within the video itself or signposted on the YouTube channel. There was no statement as to where the prescribing information could be found. The Panel therefore ruled a breach of Clauses 4.1, 4.5, 4.6 and 4.9.

The Panel noted that the material was dated in that it was clear it was added to the YouTube channel on 15 June 2018. The Panel therefore ruled no breach of Clause 4.8.

Clause 4.3 stated that the non-proprietary name must appear immediately adjacent to the most prominent display of the brand name. The Panel noted that the video did not display the brand name, Innohep, and therefore no breach of Clause 4.3 was ruled.

With regard to the allegation about the quiz, the Panel considered that the three questions posed at the end of the presentation (which appeared to be the same three questions asked at the beginning of the symposium) were intended to gauge the audience's knowledge/opinion before and after viewing the symposium to see if it had changed. The Panel noted that the supplementary information to Clause 18.1 stated that the use of competitions, quizzes and suchlike, and the giving of prizes, were unacceptable methods of promotion. That did not preclude the use at promotional meetings of quizzes which were intended to gauge attendees' knowledge of the subject matter of the meetings, provided that such quizzes were non-promotional in nature and were *bona fide* tests of skill that recognised the professional standing of the audience and no prizes were offered. To be acceptable a quiz must form part of the meeting's formal proceedings. The Panel noted that the questions asked members of the audience what they thought was the optimal class of medicine for the treatment of cancer-associated thrombosis in the first six months, what medicines could interact with direct oral anticoagulants and could pharmacists play a role in the management of patients with cancer-associated thrombosis? The Panel did not consider that the questions asked in the quiz in question promoted a Leo medicine or that the complainant had made out why in his/her view they were inappropriate and no breach of Clause 18.1 was ruled in that regard.

With regard to the allegation that the presentation referred to the cancerclot website but there was no mention that this was a Leo website, the Panel noted that the slide at 16.10 which referred to websites and patient empowerment stated 'The CancerClot website is a resource we look forward to sharing with our patients' and to the right of that text was a large image of material which featured an NHS logo. In the Panel's view, whilst it was a Leo symposium, given the content and layout of the slide in question and the overall look of the presentation it was not wholly clear that the speaker was referring viewers to another Leo information resource. However, the Panel noted that Clause 9.10 covered material sponsored by a company and noted that the video in question appeared on a clearly signposted Leo YouTube channel and that the cancerclot websites were Leo owned websites and not sponsored material. In that regard, in the Panel's view, Clause 9.10 was not relevant and no breach was ruled.

The Panel noted its comments and rulings of breaches of the Code above and further ruled a breach of Clause 28.1.

### **U59**

The Panel considered that as the video made no specific reference to the availability or use of tinzaparin in the UK, was hosted on the Leo Global YouTube channel and the video was not currently used by Leo UK, it was not within the scope of the Code. The Panel therefore ruled no breach of the Code in relation to this video as it was not within the scope of the Code.

### **V60**

The Panel noted Leo's submission that the video appeared to have been uploaded onto the YouTube channel (a non-Leo channel) in 2012. It displayed the Leo logo at the beginning and

end of the film, as well as a statement at the beginning that 'LEO Pharma has provided funding and editorial input into this film.'

The 6-minute video included interviews with two UK health professionals and a Leo UK senior executive who stated that Leo was the leading dermatological company in the prescription market in the UK and that the company hoped to partner with the NHS on raising disease awareness. It appeared to the Panel that the video was commissioned by Leo for a UK audience but it was unclear as to how it came to be uploaded to YouTube.

The uploader of the video was stated and the Panel noted Leo's submission that this user was described on YouTube as '...the online broadcast platform for the National Health Channel and its two subsidiary channels - Health Sector TV and Public Sector TV. Our programmes can also be viewed via television on Sky Channel 231 and BBC/ITV Freesat Channel 402'.

The Panel noted Leo's submission that an ex-employee could remember the video being created but that Leo could find no record of the video or its certification. The Panel further noted Leo's submission that it had no knowledge of how or why the video was on this YouTube channel and that it might have originally been created as a corporate video and uploaded to YouTube by the agency that created it although the company had no evidence in that regard.

The Panel noted that the text in YouTube below the video stated:

'LEO Pharma is the leading dermatological company in the prescription medicine market in the UK. We have a large medical department which carries out clinical studies in order to provide competitive drugs to the benefit of patients and society. A major focus for LEO Pharma is Dermatology and we would like to think we can positively increase the quality of life for patients suffering from Psoriasis, Eczema, Skin infections and Skin Cancers.'

The Panel noted that the video mentioned several dermatological conditions, predominantly actinic keratosis. The two health professionals referred to treatment options, including cryotherapy, photodynamic therapy, emollients and creams but did not name a specific medicine. The Panel noted the complainant's assertion that the commentary in the video positioned cream based treatments above the other types of treatment mentioned, and as Leo was the marketing authorisation holder for Picato (ingenol mebutate), a gel used in the treatment of actinic keratosis, the complainant alleged that Leo had positively positioned its medicine over the other medicines mentioned.

The Panel noted that Picato was first authorised in the UK on 15 November 2012 and that the video in question was uploaded to YouTube on 27 February 2012.

The Panel considered that, on the balance of probabilities, Leo commissioned the video in the pre-licence period for Picato. The Panel queried whether the video was setting the scene for the forthcoming authorisation of Leo's new medicine, Picato, in 2012. The Panel had no information before it regarding how many medicines were available to treat actinic keratosis either at the time the material was posted on YouTube or when it was viewed by the complainant; neither party made any submission in that regard.

The Panel noted Leo's submission that the video was not hosted on any Leo website or channel page and that there was no evidence that Leo was responsible for the upload of the video onto YouTube.

The Panel noted that companies were responsible under the Code for the acts and omissions of their third parties which came within the scope of the Code, even if they acted contrary to the instructions which they had been given. However, the Panel had no information before it that a relationship had existed between Leo and the named YouTube channel and considered that the complainant had not discharged his/her burden of proof that Leo, or a third party acting on its behalf, had uploaded the material to YouTube. In that regard, the Panel considered that the complainant had not shown that Leo was accountable under the Code for the presence of the material on YouTube. The Panel therefore ruled no breach of Clauses 28.1, 28.3, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 26.1, 26.2, 26.3, 14.1, 14.3 and 3.1 of the Code.

### **Overall**

The Panel noted that the complainant raised Clause 16.1 but provided no evidence that relevant personnel had not been adequately trained or were not conversant with the Code. A breach of the Code was not in itself evidence in that regard. The Panel considered that the complainant had not discharged his/her burden of proof and therefore no breach of Clause 16.1 was ruled.

The Panel noted its comments and rulings above and considered that the rulings of breaches of the Code in relation to video T58 and in relation to directing a UK audience to cancerclot.info in the Group B videos meant that Leo had failed to maintain high standards and a breach of Clause 9.1 was ruled.

Clause 2 was a sign of particular censure and was reserved for such use. Given its comments and rulings above, overall, the Panel did not consider that Leo had brought discredit upon or reduced confidence in the pharmaceutical industry and no breach of Clause 2 was ruled.

**Complaint received**      **25 October 2020**

**Case completed**        **10 September 2021**