

CASE AUTH/3550/7/21

HEALTH PROFESSIONAL V LUNDBECK

Concerns about the promotion of Vyepti at a virtual symposium

A contactable health professional complained that Vyepti (eptinezumab) had been promoted by Lundbeck prior to the grant of its marketing authorisation via the Migraine Trust which was a UK charity.

The complainant stated that Lundbeck partnered with and paid Migraine Trust UK for a session entitled 'Functional impact of migraine: an important consideration for preventive treatment'. One of the slides mentioned eptinezumab's mode of action, dosing, route of administration and EU approval status. Another slide discussed the Promise-2 study with clinical data presented for eptinezumab. The complainant alleged that Lundbeck had circumvented the Code and allowed UK health professionals to be invited to this symposium session considering eptinezumab did not have a marketing authorisation in the UK.

The complainant alleged that the same session was also available on demand on the Migraine Trust website with open access to the present date in 2021; it was also on Vimeo. The complainant alleged that this was disguised promotion of a pipeline product. Further, the declaration at the start of the video implied a hands-off agreement but it was evident Lundbeck had been much more involved. The complainant was concerned that Lundbeck UK compliance had not prevented this session from taking place and had allowed continued hosting on the Migraine Trust platform in 2021 with open access to anyone after the symposium had finished; this was allegedly not in line with self-regulation or industry standards.

The detailed response from Lundbeck is given below.

The Panel noted that the complainant made allegations in relation to three activities: the live Lundbeck symposium at the Migraine Trust international symposium (which comprised two pre-recorded presentations and a live Q&A), an on-demand video as published on the Migraine Trust website and a Vimeo video to which the complainant provided a link. It appeared that the content of the Lundbeck symposium and videos were identical and the Panel ruled on that basis.

The Panel noted that according to Lundbeck, the link provided by the complainant was to the private Vimeo account of the Migraine Trust technical team where videos were stored in a format ready to be uploaded to a platform; the Vimeo video and account it was stored on were private and not publicly searchable from search engines. The Panel considered that the complainant bore the burden of proof and that he/she had not established that the video on a private technical development platform, prior to its publication on the final platform, was accessible by either the intended or broader audience as alleged. The Panel therefore ruled no breaches of the Code in relation to the Vimeo video which was the subject of the link provided by the complainant.

The Panel noted Lundbeck's submission that Lundbeck Global, in Denmark, organised this meeting and that Lundbeck UK was not involved nor did it direct any UK health professionals to the symposium nor any associated materials; no UK speakers were engaged.

The Panel noted Lundbeck's submission that the Migraine Trust was a UK charity and that 18.2% of registered delegates were from the UK, the largest number from any country.

The Panel noted Lundbeck's submission that as part of the sponsorship between the Migraine Trust International Symposium (MTIS) and Lundbeck Global, the company sent invitation 'e-shots' to the Lundbeck symposium to all delegates including UK health professionals, headed 'Lundbeck welcomes you to the MTIS Virtual Symposium 2020' and containing the Lundbeck logo; the UK company was informed by Lundbeck Global about the e-shots but the signatory failed to appreciate that the e-shots would be sent to all registered delegates, including UK delegates. Lundbeck accepted that the symposium fell within the scope of the Code.

The Panel queried whether, regardless of the e-shots, given that the congress was organised by a UK organisation, originally due to take place in the UK, and the largest number of delegates from any single country was the UK, the UK nexus was such that the Lundbeck symposium fell within the scope of the Code.

In relation to Lundbeck's responsibility for the on demand content, the Panel noted Lundbeck's submission that Lundbeck Global and the charity MTIS had a signed agreement for the provision of a virtual pre-recorded symposium followed by a live moderated Q&A session but that Lundbeck did not agree to the provision of this pre-recorded symposium as on demand content on the MTIS congress website.

The Panel noted that it was a well-established principle that a company was responsible for the acts or omissions of its consultants, agents or third parties working on its behalf which came within the scope of the Code. If this were not the case, companies would be able to rely on such acts or omissions as a means of circumventing the requirements of the Code. The Panel noted that the contractual basis of the relationship between Lundbeck and the Migraine Trust International Symposium was not wholly dissimilar to the contractual basis of the relationship between companies and third parties etc in relation to hosting the company symposium. The Panel considered on balance that the same principles should apply in the particular circumstances of this case. In addition, the Panel noted that although the Lundbeck virtual symposium package referred to the pre-recorded element of the live symposium, the contract did not explicitly cover the storage or destruction of this digital asset; nor did Lundbeck provide a copy of any communications or briefing that covered this matter. In these circumstances, the Panel considered that Lundbeck was, on the balance of probabilities, responsible for the video published on the on demand page of the MTIS website and the Panel ruled on that basis.

The Panel noted that the complainant highlighted that one slide contained a table titled 'Anti-CRGP mAbs offer a new option for preventative treatment in adults' and mentioned the mode of action, dosing, route of administration and EU approval status, along with clinical data of eptinezumab. The Panel noted that Vyepti (eptinezumab) did not have a

marketing authorisation in the UK at the time of the meeting and considered that eptinezumab had been promoted prior to the grant of its marketing authorisation in breach of the Code, as acknowledged by Lundbeck, and in this regard high standards had not been maintained.

The Panel noted Lundbeck's submission that the symposium was organised by the global company. Lundbeck UK had not argued that it was not responsible for the content of the symposium. The Panel did not have a copy of the symposium or video in question, however, from a screenshot provided by Lundbeck, the opening slide of the symposia stated 'Lundbeck Industry Symposium: Functional Impact of Migraine: an important consideration for preventive treatment'. The Panel noted that those attending the live event would have had access to the MTIS agenda, provided by Lundbeck, where it was listed as an industry symposia adjacent to the Lundbeck logo. The first and third slide of the first presentation of the symposia included the statement 'Educational financial support provided by H. Lundbeck A/S'. In the Panel's view, reference to 'educational financial support' was ambiguous with regard to the extent of the company's involvement and influence over the material, some viewers might assume that Lundbeck's involvement was limited to the provision of funds and that was not so. The Panel noted that this potentially misleading implication was particularly compounded by the verbal repetition of the sponsorship declaration at issue by the presenter of each session within the symposium. In the Panel's view, whilst early references appeared to be clear that it was a Lundbeck meeting, such references were inconsistent with subsequent references which were the subject of complaint and the difference between the two might have caused confusion. Some viewers might have considered that Lundbeck's involvement with the individual clinical presentations was different to its involvement in hosting the overall symposium. Therefore, on the balance of probabilities, the Panel considered that the verbal and written references to 'educational financial support' were a misleading and ambiguous description of Lundbeck's involvement and the Panel therefore ruled a breach of the Code. This ruling applied to the live symposium and on demand video.

In relation to the allegation that it was disguised promotion as a UK health professional would 'not expect to have been presented on a pipeline product by the nature of the symposium title', the Panel noted that the title of the symposium was 'Functional Impact of Migraine: an important consideration for preventive treatment'. The Panel noted that the allegation appeared to be limited to the impression given at the outset, by the initial slide which referred to the title of the symposium and preventative treatment and ruled on that basis. In the Panel's view, the Lundbeck logo on the agenda and invitation e-shots, references to an industry symposium within the agenda, e-shots and the initial slide of the symposium and reference to treatment in the title of the symposium, meant that, on balance, viewers would not have initially expected anything other than a promotional meeting where a Lundbeck medicine would be discussed. The Panel considered therefore that at the very beginning of the symposium the promotional nature of the meeting, on balance, had not been disguised and on this narrow ground no breach of the Code was ruled, which applied to the live symposium and the on demand video. The Panel considered that the complainant's concerns in relation to the pipeline nature of the product was covered by its ruling above.

In relation to Clause 2, the Panel noted that an email from a MTIS agency referred to participants having had access to the Lundbeck symposium on the MTIS website and

that a section of the on demand page of the MTIS 2020 event platform did not require a registered user log-in and this had been updated. The Panel considered that in promoting a pipeline product at both the live symposium and on a platform that was found not to be restricted, Lundbeck had thus brought discredit upon, and reduced confidence in, the industry and a breach of Clause 2 was ruled.

A contactable health professional complained that Vyepti (eptinezumab) had been promoted by Lundbeck prior to the grant of its marketing authorisation via the Migraine Trust which was a UK charity.

COMPLAINT

The complainant stated that the Migraine Trust international symposium was due to take place in London in October 2020 but had switched to a virtual event due to Covid-19. The Migraine Trust Virtual Symposium was initiated by the Migraine Trust. The website for the virtual symposium read as follows:

‘View the scientific programme and Industry Symposia via the sessions page, add favourites to your schedule, visit the exhibition area to learn about the latest developments amongst our Industry partners and interact and engage with Industry and other registered delegates via chat message or 1on1 video meetings all offered through the platform. We suggest you update your profile as a starting point and then view the system generated recommendations and matchmaking suggestions also found within your profile settings. Your interests have been used to match you with other registered delegates, Industry partners, sessions, speakers and products.’

The complainant stated that Lundbeck partnered with and paid Migraine Trust UK for a session entitled ‘Functional impact of migraine: an important consideration for preventive treatment’. The two titles of the presentation for this event were ‘Capturing the functional impact of migraine’ and ‘Functional Impact versus headache frequency: defining the criteria for preventative treatment in migraine’. For the latter, session around 43 minutes 48 seconds into the talk, a table was presented entitled ‘Anti-CRGP mAbs offer a new option for preventive treatment in adults’. The slide mentioned eptinezumab’s mode of action, dosing, route of administration and EU approval status. The next slide discussed the Promise-2 study with clinical data presented for eptinezumab. The complainant alleged that Lundbeck had circumvented the Code and allowed UK health professionals to be invited to this symposium session considering eptinezumab did not have a marketing authorisation in the UK. The same session was also available on demand with open access to anyone to even the present date in 2021. The session was also available on Vimeo. This was blatant promotion of a pipeline product using a UK charity to UK health professionals. This was a breach of the following Clauses: 3.1 (multiple times as initial session, on demand for wider audience and Vimeo all had the same session pre-licence talk), 5.1 and 2. This was also disguised promotion as a UK health professional would not expect to have been presented on a pipeline product by the nature of the event title, in breach of Clauses 15.6 and 5.1. The declaration at the start of the video implied a hands-off agreement as it was said the talk was provided by an educational financial support from Lundbeck but it was evident Lundbeck had been much more involved considering the content of the session and slides. This was a breach of Clause 5.5 as the declaration of full involvement was not transparent. It was concerning that Lundbeck UK compliance had not prevented this session from taking place and had allowed continued hosting

on the Migraine Trust platform in 2021 with open access to anyone after the symposium had finished. This was not in line with the self-regulation or industry standards, in breach of Clause 2.

When writing to Lundbeck, the Authority asked it to consider the requirements of Clauses 2, 3.1, 5.1, 5.5 and 15.6 of the 2021 Code as cited by the complainant and also the requirements of Clause 11.1 of the 2021 Code. It seemed that the complaint was about the meeting in October 2020 and that materials were still available. The 2019 Code would apply to the meeting. The equivalent clauses in the 2019 Code were 2, 3.1, 9.1, 9.10 and 12.1.

RESPONSE

Lundbeck submitted that it took these allegations very seriously and had carried out a thorough and comprehensive internal investigation. In order to address this complaint in a clear and concise manner Lundbeck had divided its response into four sections:

A Background to The Migraine Trust & The Migraine Trust International Symposium (MTIS)

Lundbeck submitted that The Migraine Trust was a UK charity dedicated to helping people affected by Migraine and every two years it held an international symposium (MTIS) in order to bring together the world's leading experts on headache and migraine to share their latest research with their colleagues. In October 2020 this symposium was held virtually due to the COVID-19 pandemic and involved 1,732 registered delegates from over 90+ countries of which 18.2% of these registered delegates were from the UK, and therefore it was a truly international event with a diverse international audience.

Lundbeck Global supported this virtual meeting by sponsoring an industry satellite symposium held on Thursday, 8 October 2020, 13.30-15.00 (EST). Lundbeck UK was not involved in the organisation of the symposium and did not direct any UK health professionals to the symposium or any of its content or materials. Additionally, no UK health professionals were engaged as presenters or chairs at the virtual symposium.

B Allegations around declaration of sponsorship and disguised promotion

Lundbeck submitted that the complainant alleged that the declaration of Lundbeck's full involvement was not transparent as the 'declaration at the start of the video implied a hands-off agreement'.

The symposium in question was clear from the outset as to Lundbeck's involvement, with the video opening with the slide 'Lundbeck Industry Symposium: Functional Impact of Migraine: an important consideration for preventative treatment'. Therefore, it was immediately apparent that this was Lundbeck's symposium which would be discussing preventative treatment. This was further supported by the congress organiser's (MTIS) agenda for the event which made it clear that this session was a Lundbeck-sponsored satellite symposium and then again in the first and third slide of the first presentation of the symposia where it was reiterated, both on the slide and then verbally by the presenter, that this symposia had been sponsored by Lundbeck through 'Educational financial support'.

Lundbeck submitted that its declaration of sponsorship was sufficiently prominent from the outset and it was clear to all delegates the extent of the company's involvement and influence over the event/material. Therefore, Lundbeck refuted a breach of Clause 9.10 (2019 Code) as alleged by the complainant.

The complainant also alleged that the video amounted to disguised promotion 'as a UK HCP would not expect to have been presented on a pipeline product by the nature of the event title'.

Lundbeck submitted, as outlined above, that it was clear from the outset as to Lundbeck's involvement in this symposium. Additionally, the event title made it clear, again, that the symposium was sponsored by Lundbeck and would be discussing 'preventative treatment in migraine'. Therefore, in line with other PMCPA rulings (eg Case AUTH/3213/6/19), Lundbeck's involvement was clear and the symposium would have been considered as promotional to all attendees. As per the ruling in the case referenced above, 'promotional material does not need to be labelled as such, however, it must not be disguised, and the identity of the responsible pharmaceutical company or a pharmaceutical company's involvement must be obvious at the outset'. The Panel also ruled that given the company's 'role in the meeting, its commercial interest and the inclusion of logos on materials, on balance, the promotional nature of the meeting was not disguised'. Therefore, Lundbeck refuted a breach of Clause 12.1 (2019 Code) as alleged by the complainant, as promotion had not been disguised.

C Allegation around promotion prior to granting of the marketing authorisation

Lundbeck submitted that this satellite symposium was organised by Lundbeck Global (based in Denmark), at a virtual international congress and directed at a truly international audience.

During Lundbeck's internal investigation, it had established that as part of the global sponsorship with MTIS, Lundbeck Global were given the opportunity to develop e-shots about the Lundbeck symposium which were sent by MTIS to ALL registered delegates, including UK health professionals. Lundbeck therefore accepted that the inviting of UK health professionals brought the satellite symposium within the scope of the UK ABPI Code.

Subsequently, given the symposium included information on Eptinezumab (Vyepiti) and the broader medication class prior to the granting of the product's UK marketing authorisation, Lundbeck regrettably accepted a breach of Clause 3.1 (2019 Code).

Background to the breach

Lundbeck submitted that it was important for the Panel to note, however, that Lundbeck Global had followed the correct company process and had informed the UK affiliate about the virtual symposium they were sponsoring, as well as the e-shots. Additionally, the local UK Lundbeck team had also followed the correct process, seeking advice from an external signatory on the applicability of the ABPI Code to this activity.

During this period, Lundbeck UK had engaged an external provider to give signatory and compliance advice and Lundbeck submitted that it was disappointed to find during its investigation that, due to an oversight, the signatory failed to appreciate that the e-shots would be sent out to all registered attendees (including UK delegates) and therefore advised incorrectly on the applicability of the ABPI Code to this symposium.

D Allegation about high standards (Clauses 9.1 and 2)

Lundbeck submitted that the error fell below its expectation around healthcare compliance standards, therefore, it regrettably accepted a breach of Clause 9.1 (2019 Code).

The allegation of a breach of Clause 2 was a very serious matter, however, and Lundbeck refuted that the company's actions in this matter brought discredit to, or reduced confidence in, the industry for the following reasons:

- Company processes were followed by both Lundbeck Global and Lundbeck UK with regard to this symposium and the materials associated with it. The company deferred to an external provider and was let down by his/her oversight and incorrect Code advice.
- The company had subsequently accepted breaches of Clauses 3.1 and 9.1 and acted to end the relationship between Lundbeck and the external provider.
- The company now had in place experienced members of the medical and compliance team who, were experienced signatories (details of their activities since joining Lundbeck were provided). These positions were being recruited for at the time of this symposium and hence the company was using external signatory and compliance support.
- The virtual satellite symposium in question was viewed by over 100 delegates in total and less than a quarter of these were from the UK, of which a number were Lundbeck and other pharmaceutical industry representatives (Medical and Marketing) .
- Therefore, the reach of this symposia extended only to a very small number of UK healthcare professionals who were attending a truly international congress.
- Subsequently, on the balance of probabilities, the seriousness of a Clause 2 should be reserved for activities of particular censure that potentially harm the well-being of patients and the reputation of the industry. The breach of the Code in this instance was as a result of an oversight by a signatory which led to incorrect advice being given and therefore individual human error.

On the basis of these arguments, Lundbeck refuted a breach of Clause 2.

Summary

Lundbeck UK deeply regretted the error made by an external signatory that led to incorrect advice around the applicability of the UK Code with regard to this historical symposium. Lundbeck had ended this contract.

Lundbeck submitted that it was a very different organisation compared to October 2020 when this symposium took place, now employing two internal experienced signatories who were able to advise the business on all activities under the scope of the ABPI Code. Lundbeck also continued to invest significantly in the compliance training of its employees, so it ensured all relevant members of staff were well versed on the expectations and requirements of the ABPI

Code, and to ensure that they continued to seek advice when required, as they did correctly with regard to this global virtual symposia.

Therefore, Lundbeck would not let these complaints about historical matters distract it from the ongoing progress that it continued to make with regard to healthcare compliance in the UK in 2021 under the leadership of its Compliance Governance Committee.

Further information

In response to a request for further information from the Panel, Lundbeck responded as follows.

A. The written agreement between Lundbeck and the Migraine Trust: Virtual Symposium

Lundbeck submitted that in 2020, Lundbeck Global was given the opportunity to sponsor the annual international congress organised by the Migraine Trust which was to take place virtually due to the ongoing COVID-19 pandemic. In order to provide this sponsorship, Lundbeck Global drafted a written agreement with the charity which outlined, amongst other obligatory legal and compliance requirements, what would be included in the sponsorship 'package' in exchange for the funding provided. This agreement included an appendix which clearly outlined what was being agreed between the two parties in exchange for the sponsorship being provided by Lundbeck.

The virtual symposium in question was part of the sponsorship 'package' with Lundbeck, as highlighted in the written agreement and the 'Personal Package' slide provided to Lundbeck by The Migraine Trust following the signing of the agreement.

Lundbeck submitted that this clearly showed that the agreement between Lundbeck Global and the charity was for the provision of a virtual pre-recorded symposium followed by a live moderated Q&A session with the presenting faculty during a prime slot at the virtual international congress. Lundbeck submitted that the Panel should be aware that Lundbeck did not agree to the provision of this pre-recorded symposium as on demand content on their congress website, and as highlighted, this was subsequently not a part of the agreement signed by both parties.

Lundbeck submitted that the first time it became aware of the availability of this recorded symposium (the video), on The Migraine Trust congress 2020 website was when Lundbeck UK received the original complaint from the PMCPA in August 2021 and accessed the link provided by the complainant. On accessing the link, it was apparent that the Lundbeck Global pre-recorded symposium, as well as all the other sponsoring companies pre-recorded symposia, had been uploaded by the charity on to the Migraine Trust International Symposium 2020 website that they had created for the congress. This weblink has since been moved over to the 2022 website domain in preparation for the annual event being run in September 2022.

Lundbeck submitted that the Panel should be assured that as soon as Lundbeck became aware of the availability of this video, it acted swiftly to contact the Migraine Trust to explain that the provision of this Symposium as on demand content on their open access congress website had not been agreed and Lundbeck requested that it be taken down immediately. Lundbeck also recommended that the charity checked with the other sponsoring companies that they had agreed, and were happy, that their pre-recorded symposia were also available on the charity's 2020 congress website. On the 18 August 2021, the charity's technical team confirmed that all

sponsoring company's symposia content had been taken down from the website and could no longer be accessed. Lundbeck verified this on the same day by checking the website and the link provided by both the complainant and the Migraine Trust in their correspondence. The open access to these recorded industry symposia on this website was as a result of a mistake by the Migraine Trust technical team which they confirmed to Lundbeck .

Lundbeck submitted that it had never directed any UK health professionals to this open access international congress website, which hosted the recorded industry symposia of Lundbeck and other pharmaceutical companies.

The accessibility of the MTIS 2020 link highlighted by the complainant and its availability

Lundbeck submitted that, as outlined above, this link was to the dedicated Migraine Trust International Congress 2020 website, where the charity had hosted the pre-recorded industry symposia videos following the completion of the 'live' congress. Therefore, this symposium, as well as all the other companies' industry symposia were available on the charity congress website to any person who visited the dedicated platform from week commencing 12 October 2020 until 18 August 2021 when Lundbeck were made aware of their availability and were able to request and confirm their withdrawal with the Migraine Trust. Subsequently the video (and all other symposium material) had not been available since 18 August 2021.

The accessibility of the Vimeo link highlighted by the complainant and its availability

Lundbeck submitted that the Vimeo link to the pre-recorded symposium provided by the complainant was a link to the private Vimeo account of the Migraine Trust technical team, which they used in order to upload and 'suspend' videos so that they can then be embedded on the platform that they want to use the videos on. Lundbeck submitted that this was common practice so that videos can be stored in the format ready to be uploaded to the desired platform. The private Vimeo accounts/videos were not searchable publicly from search engines and the direct URL link to the video stored in the private Vimeo account was also private and not publicly searchable. However, as highlighted by the Migraine Trust technical team, the direct Vimeo URL is possible to obtain using the "Inspect" function of Google Chrome to uncover the embedded code links in the page's HTML. Lundbeck submitted that subsequently, the complainant was able to provide two links: the link to the Migraine Trust website page where the Lundbeck, and other industry, pre-recorded symposia videos were hosted, as well as the private dedicated URL link for the Lundbeck video specifically. Lundbeck submitted that in order to provide complete clarity for the Panel, it enclosed an email from the project lead from the Migraine Trust technical team which included a timeline and overview, how the video was hosted on Vimeo, and how the complainant was able to access it and subsequently provided the private Vimeo URL to the PMCPA.

Summary

In summary, Lundbeck submitted that the industry pre-recorded symposia for the Migraine Trust International Congress, were made available on a dedicated Migraine Trust 2020 Congress website following the completion of the congress in October 2020, thus allowing any visitors to the dedicated website to access and view all the pre-recorded industry symposia videos as on demand content.

This availability was unbeknown to Lundbeck and subsequently was not part of the written signed sponsorship agreement between Lundbeck Global and the Migraine Trust. As soon as becoming aware of the availability of the symposium, Lundbeck submitted it acted swiftly to contact the Migraine Trust and have this content removed from their website, which they confirmed in writing in August 2021.

Lundbeck submitted it would like to assure the Panel that the provision of this video was as a result of a mistake by the charity's technical team, which they had accepted and acted to fix as soon as they were made aware. Lundbeck did not agree to this video being hosted on this website and had never sought to distribute it or direct any healthcare professionals to this congress website or the specific pre-recorded video itself.

Lundbeck submitted that the Panel should be aware that this mistake did not only impact Lundbeck's symposium, but it meant all the other sponsoring companies symposia were also made available on the website as well; on being made aware of their mistake the Migraine Trust acted immediately to take down all the company's videos and content from the website.

Lundbeck submitted that on receiving this complaint, Lundbeck UK acted swiftly to enhance the digital component of the monitoring pillar of its compliance programme to broaden its search capabilities of any Lundbeck related web content that may be incorrectly available. This was an important part of its continued journey of identifying and mitigating compliance risk, particularly those posed by the challenges of operating in a more digital and 'virtual' industry environment.

Lundbeck submitted that the availability of this video was not at the bequest of Lundbeck nor known by the company. It accepted that mistakes were made with regard to this Lundbeck Global symposium which it had accepted in its original response and taken immediate and substantial measures to ensure it did not happen again, however, the open availability of the symposium as on demand content was outside of the company's knowledge and control and was not something it would ever have agreed to.

PANEL RULING

The Panel noted that the complainant made allegations in relation to three activities: the live Lundbeck symposium at the Migraine Trust international symposium (which comprised two pre-recorded presentations and a live Q&A), an on-demand video as published on the Migraine Trust website and a Vimeo video to which the complainant provided a link. The Panel noted that from the supplementary response and evidence submitted by Lundbeck, it appeared that the content of the Lundbeck symposium and videos were identical and the Panel ruled on this basis.

In relation to the Vimeo link provided by the complainant, the Panel noted that according to Lundbeck, the link was to the private Vimeo account of the Migraine Trust technical team where videos were stored in a format ready to be uploaded to a platform; the Vimeo video and account it was stored on were private and not publicly searchable from search engines. According to the agency, it appeared that the direct Vimeo link would have been potentially accessible if a user had found the embed Code links in the webpages HTML but this would not have been easily accessible to anyone who had not worked with HTML and web development. The Panel considered that the complainant bore the burden of proof and that he/she had not established that the video on a private technical development platform, prior to its publication on the final platform, was accessible by either the intended or broader audience as alleged. The Panel

therefore ruled no breach of Clauses 2, 3.1, 9.1, 9.10 and 12.1 of the 2019 Code in relation to the Vimeo video which was the subject of the link provided by the complainant.

The Panel noted that the live symposium had to comply with the 2019 Code. The Panel noted that the on demand video, which was embedded on the MTIS on-demand page, was still live at the time that the complaint was submitted and thus had to comply with the current Code (2021 Code) and relevant applicable 2019 Code at the time of its publication. Given there were no material differences between the 2019 and 2021 Code in relation to the clauses cited, the Panel considered and ruled on all aspects of the complaint under the 2019 Code.

The Panel noted Lundbeck's submission that Lundbeck Global, based in Denmark, organised this meeting and that Lundbeck UK was not involved in the organisation of the symposium. Lundbeck UK did not direct any UK health professionals to the symposium nor any associated materials; no UK speakers were engaged.

The Panel noted Lundbeck's submission that the Migraine Trust was a UK charity and that of the 1732 registered delegates from over 90 countries, 18.2% (315) were from the UK. The Panel noted that the UK had the largest number of delegates from any country; the second largest was the US with 262 delegates.

The Panel noted that the complainant stated that the meeting was due to take place in London but was switched to a virtual event due to the pandemic; it was not clear to the Panel when the decision to make MTIS a virtual event was made and if Lundbeck Global had agreed to 'sponsor' an industry symposium before or after this decision was made; Lundbeck made no submission in that regard.

The Panel noted Lundbeck's submission that as part of the sponsorship between MTIS and Lundbeck Global, the company was given the opportunity to develop invitation 'e-shots' to the Lundbeck symposium, which were sent out to all delegates including UK health professionals. The Panel noted that these e-shots were headed 'Lundbeck welcomes you to the MTIS Virtual Symposium 2020' and contained the Lundbeck logo. The Panel further noted Lundbeck's submission that the UK company were informed by Lundbeck Global about the e-shots but that the signatory failed to appreciate that the e-shots would be sent to all registered delegates, including UK delegates. Lundbeck accepted that the symposium fell within the scope of the Code.

The Panel queried whether, regardless of the e-shots, given that the congress was organised by a UK organisation, originally due to take place in the UK prior to being switched to a virtual event due to the pandemic, and the largest number of delegates from any single country was the UK, the UK nexus was such that the Lundbeck symposium fell within the scope of the Code.

In relation to Lundbeck's responsibility for the on demand content, the Panel noted Lundbeck's submission that Lundbeck Global and the charity MTIS had a signed agreement for the provision of a virtual pre-recorded symposium followed by a live moderated Q&A session but that Lundbeck did not agree to the provision of this pre-recorded symposium as on demand content on the MTIS congress website.

The Panel noted that it was a well-established principle that a company was responsible for the acts or omissions of its consultants, agents or third parties working on its behalf which came within the scope of the Code. If this were not the case, companies would be able to rely on

such acts or omissions as a means of circumventing the requirements of the Code. The Panel noted that the contractual basis of the relationship between Lundbeck and the Biennial Migraine Trust International Symposium was not wholly dissimilar to the contractual basis of the relationship between companies and third parties etc in relation to hosting the company symposium. The Panel considered on balance that the same principles should apply in the particular circumstances of this case. In addition, the Panel noted that although the Lundbeck virtual symposium package referred to the pre-recorded element of the live symposium, the contract did not explicitly cover the storage or destruction of this digital asset; nor did Lundbeck provide a copy of any communications or briefing that covered this matter. In these circumstances, the Panel considered that Lundbeck was, on the balance of probabilities, responsible for the video published on the on demand page of the MTIS website and the Panel ruled on that basis.

In relation to the allegation that there was promotion of a pipeline product to health professionals, the Panel noted Lundbeck's submission that at the time of the meeting, October 2020, Vyepti did not have EMA or MHRA approval, but it had been granted FDA approval. The Panel noted Lundbeck's submission that the symposium did include material on Eptinezumab (Vyepti) and that Lundbeck accepted that the meeting was promotional.

The Panel noted that Lundbeck made no submission nor provided relevant material in relation to the supplementary information to Clause 3 of the 2019 Code, Promotion at International Meetings and therefore the Panel did not consider the applicability of this provision to the event at issue.

The Panel noted that the complainant highlighted that one slide contained a table titled 'Anti-CRGP mAbs offer a new option for preventative treatment in adults' and mentioned the mode of action, dosing, route of administration and EU approval status, along with clinical data of Lundbeck's medicine eptinezumab. The Panel noted that Vyepti (eptinezumab) did not have a marketing authorisation in the UK at the time of the meeting (October 2020) and considered that eptinezumab had been promoted prior to the grant of its marketing authorisation in breach of Clause 3.1 of the 2019 Code and in this regard high standards had not been maintained. The Panel therefore ruled breaches of Clauses 3.1 and 9.1 of the 2019 Code in relation to both the live symposium and on-demand video on the congress website. Lundbeck had acknowledged a breach of Clause 3.1. The Panel noted that the complainant had also alleged a breach of Clause 2 on this point which the Panel considered as part of its overall Clause 2 ruling below.

The Panel noted the complainant's allegation that the declaration at the start of the video was not transparent and implied a hands-off agreement as it stated that Lundbeck provided educational financial support but it was evident that Lundbeck had been much more involved, the declaration of full involvement was not transparent.

The Panel noted that the supplementary information to Clause 9.10 of the 2019 Code, Declaration and Sponsorship, stated, *inter alia*, that the declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material were aware of it at the outset. The wording of the declaration must be unambiguous so that readers would immediately understand the extent of the company's involvement and influence over the material.

The Panel noted that Lundbeck stated that the symposium was organised by the global company. Lundbeck UK had not argued that it was not responsible for the content of the

symposium. The Panel did not have a copy of the symposium or video in question, however, from a screenshot provided by Lundbeck, the opening slide of the symposia stated 'Lundbeck Industry Symposium: Functional Impact of Migraine: an important consideration for preventive treatment'. The Panel noted that those attending the live event would have had access to the MTIS agenda, provided by Lundbeck, where it was listed as an industry symposia adjacent to the Lundbeck logo. It appeared, from the information provided by Lundbeck, that two further slides (first and third slide of the first presentation of the symposia) included the statement 'Educational financial support provided by H. Lundbeck A/S'. In the Panel's view, reference to 'educational financial support' was ambiguous with regard to the extent of the company's involvement and influence over the material, some viewers might thereby assume that Lundbeck's involvement was limited to the provision of funds and that was not so. The Panel noted that this potentially misleading implication was particularly compounded by the verbal repetition of the sponsorship declaration at issue by the presenter of each session within the symposium. In this regard the Panel noted the complainant's reference that 'it was **said** that the **talk** was provided by an educational financial support from Lundbeck (emphasis added)'. In the Panel's view, whilst early references to the nature of Lundbeck's involvement appeared to be clear that it was a Lundbeck meeting, such references were inconsistent with subsequent references which were the subject of complaint and the difference between the two might have caused confusion. Some viewers might have considered that Lundbeck's involvement with the individual clinical presentations was different to its involvement in hosting the overall symposium. Therefore, on the balance of probabilities, the Panel considered that the verbal and written references to 'educational financial support' were a misleading and ambiguous description of Lundbeck's involvement and the Panel therefore ruled a breach of Clause 9.10 of the Code. This ruling applied to the live symposium and on demand video.

In relation to the allegation that it was disguised promotion as a UK health professional would 'not expect to have been presented on a pipeline product by the nature of the symposium title', the Panel noted that the title of the symposium was 'Functional Impact of Migraine: an important consideration for preventive treatment'. The Panel noted that the allegation appeared to be limited to the impression given at the outset, by the initial slide which referred to the title of the symposium and preventative treatment and ruled on that basis. In the Panel's view, the Lundbeck logo on the agenda and invitation e-shots, references to an industry symposium within the agenda, e-shots and the initial slide of the symposium and reference to treatment in the title of the symposium, meant that, on balance, viewers would not have initially expected anything other than a promotional meeting where a Lundbeck medicine would be discussed. The Panel considered therefore that at the very beginning of the symposium the promotional nature of the meeting, on balance, had not been disguised and on this narrow ground no breach of Clause 12.1 of the 2019 Code was ruled. This ruling applied to the live symposium and the on demand video. The Panel considered that the complainant's concerns in relation to the pipeline nature of the product was covered by its ruling of Clause 3.1 above.

The Panel noted that the complainant had alleged a breach of Clause 2, but had not alleged a breach of Clause 9.1, for failing to maintain high standards, in relation to the overall case. The Panel noted that the supplementary information to Clause 2 included promotion prior to the grant of a marketing authorisation as an example of an activity that was likely to be in breach of that Clause. In relation to Clause 2, the Panel also noted the complainant's reference to the continued hosting on the MTIS website with open access to anyone after the symposium finished. In this regard, the Panel noted that an email from the MTIS agency to MTIS and Lundbeck, dated 18 August 2021, referred to participants having had access to the Lundbeck symposium on the MTIS website. The Panel noted that the agency had noticed that a section of

the on demand page of the MTIS 2020 event platform did not require a registered user log-in and this had been updated. The Panel considered that in promoting a pipeline product at both the live symposium and on a platform that was found not to be restricted, Lundbeck had thus brought discredit upon, and reduced confidence in, the industry and a breach of Clause 2 was ruled.

Complaint received **29 July 2021**

Case completed **26 July 2022**