

CASE AUTH/3450/1/21

COMPLAINANT v LUNDBECK

Promotion of Brintellix (vortioxetine)

An anonymous, contactable complainant who described him/herself as a health professional, complained about the promotion of Brintellix (vortioxetine) by Lundbeck Limited.

The complainant stated that a representative from Lundbeck provided him/her with a weblink to view on-demand content for Brintellix on a webpage was entitled 'Clinical experience of emotional blunting and data on the efficacy of vortioxetine on anhedonia'. The event registration page stated 'This webinar is organised and funded by Lundbeck' and there was a large Brintellix product logo. Below the logo it stated, 'Vortioxetine is indicated for the treatment of major depressive episodes in adults'. There was no prescribing information or adverse event reporting provided; it was stated that these would be available but they were not on the registration page to access.

The complainant noted that there was no disclaimer to make the page accessible for health professionals only, and that anyone, including members of the public, could have entered the registration page, where the product and indication were stated, and registered for and watched the webinars. The representative had said that access was not restricted as the webinar could be found through a search engine using the terms 'Brintellix UK webinar'.

The detailed response from Lundbeck is given below.

The Panel noted that the webinar was, according to Lundbeck, a promotional event organised by its global team based in Denmark and directed at health professionals across nine European countries, including the UK. The webinar was held as a 'live' event in May 2020 and was subsequently made available as 'on demand' recorded content; it was for local affiliates to distribute this information to health professionals in their respective countries.

The Panel noted that an invite to the live webinar was emailed by Lundbeck representatives to UK health professionals who had opted in to receive promotional materials. The email included an invitation and a biography of the speaker, both of which included embedded prescribing information. If a health professional accepted the invitation, they were sent a specific URL link to the registration page; this email included prescribing information as an attachment; information on accessing the 'on demand' content was only sent to those who had originally accepted the invitation to the live event.

The Panel noted that contrary to the complainant's statement, the screenshot of the registration page showed that the registration form contained numerous data entry fields including job title. According to Lundbeck, once health professionals had registered on

the platform, a due diligence process was followed to ensure that they were a health professional and their suitability to access the promotional webinar validated. The Panel further noted Lundbeck's submission that access to the registration page was through a closed email invitation to specific health professionals; neither the registration page nor the webinars were advertised to the public or hosted on any publicly available platform.

The Panel noted Lundbeck's submission that it was highly improbable that a member of public would search the three specific terms 'Brintellix', 'UK' and 'webinar', together, and thus access the registration page. Representatives were not instructed to provide this direction to access the webinar and Lundbeck was unable to identify any evidence that this occurred.

The Panel noted that the Lundbeck event should not have been searchable on Google. The platform providers explained how the event might have appeared in a Google search, despite not being requested by Lundbeck.

The Panel considered that it appeared measures were in place to ensure the registration page and webinar were only accessed by invited health professionals; the registration page was hosted on a closed platform with search optimisation disabled. It appeared to the Panel that the only way the registration page or webinar might be found via a search engine was using very specific search terms and only after a search engine had found the link by some other means and indexed it to make it searchable. The Panel noted that there was no evidence that specific search terms had been highlighted by the company or that the registration page or event was advertised to the public; no breach of the Code was ruled. The Panel did not consider that the complainant had discharged his/her burden of proof, that Lundbeck had promoted Brintellix to members of the public as alleged and no breaches of the Code were ruled.

The Panel noted that the information displayed on the registration webpage included the Brintellix product logo, its indication and the title of the webinar 'Clinical experience of emotional blunting and data on the efficacy of vortioxetine on anhedonia' and considered that the page was thus promotional. The Panel noted that the registration page did not include the prescribing information or adverse event reporting statement as alleged and breaches of the Code were ruled as acknowledged by Lundbeck.

The Panel noted Lundbeck's submission that whilst the event registration page was certified by Lundbeck and uploaded to the webpage, due to a misinterpretation of the Code, a global employee instructed the platform provider to change the UK job code on the registration page and main event page so that it aligned with the job code on the certified webinar slides. The job code of the final form of the registration page was thus amended after certification and the subsequent uncertified registration page was available.

The Panel considered that the final form of the registration page had been amended following certification, and therefore it ruled a breach of the Code as acknowledged by Lundbeck. The Panel noted that a robust certification procedure underpinned self-regulation and considered that high standards had not been maintained. It appeared to the Panel that Lundbeck had been let down by one of its global colleagues who had amended the job code but no other information following certification.

The Panel noted its comments and rulings above and did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2, which was a sign of particular censure and was reserved for such use, and no breach was ruled.

An anonymous, contactable complainant who described him/herself as a health professional, complained about the promotion of Brintellix (vortioxetine) by Lundbeck Limited.

Brintellix was indicated for the treatment of major depressive episodes in adults.

COMPLAINT

The complainant stated that a representative from Lundbeck provided him/her with a weblink to view on-demand content for Brintellix. The webpage was entitled 'Clinical experience of emotional blunting and data on the efficacy of vortioxetine on anhedonia'. On the event registration page (ref UK-BRIN-0875. Date of Preparation: May 2020) a disclaimer stated 'This webinar is organised and funded by Lundbeck' and there was a large Brintellix product logo. Below the logo it stated, 'Vortioxetine is indicated for the treatment of major depressive episodes in adults'. There was no prescribing information or adverse event reporting provided; it was stated that these would be available but they were not on the registration page to access.

The complainant noted that there was no disclaimer or firewall to make the page accessible for health professionals only, and that anyone, including members of the public, could have entered the registration page, where the product and indication were stated, and registered for and watched the webinars as professional registration numbers or job titles for attendees were not required on the registration form. The complainant noted that the representative had told him/her that access was not restricted as the webinar could be found through a search engine using the terms 'Brintellix UK webinar' if the weblink was a problem. The complainant stated that he/she had read the complaints process on the PMCPA website and alleged breaches of Clauses 4.1, 4.2, 4.9, 14.1, 28.1, 28.3, 26.1, 26.2, 9.1 and 2.

The complainant requested that his/her details be kept confidential. The complainant stated that he/she could provide screenshots of the webpage if required but noted that Lundbeck should provide them in view of the reference number (UK-BRIN-0875) and date of preparation provided. The complainant further named the presenter of the webinar whose picture was on the registration page.

When writing to Lundbeck, the Authority asked it to consider the requirements of Clauses 4.1, 4.2, 4.9, 14.1, 28.1, 28.3, 26.1, 26.2 and 9.1 of the Code as cited by the complainant.

RESPONSE

Lundbeck noted that the complaint related to an event registration page for a Lundbeck Global-organised promotional webinar entitled 'Clinical experience of emotional blunting and data on the efficacy of vortioxetine on anhedonia'; the complainant specifically highlighted concerns around:

- The provision of prescribing information and adverse event reporting on the registration page.
- The accessibility of the registration page.
- The certification of the registration page.

Consequently, Lundbeck had been asked to respond to Clauses 4.1, 4.2, 4.9, 14.1, 28.1, 28.3, 26.1, 26.2 and 9.1 of the Code. Lundbeck noted that although the letter from the PMCPA did not refer to Clause 2 it had addressed that clause as it was highlighted by the complainant.

Lundbeck explained that Brintellix was indicated for the treatment of major depressive episodes in adults. The marketing authorisation holder was H Lundbeck A/S, Denmark and the product was marketed and promoted in the UK.

Lundbeck stated that the event was a pan-European promotional webinar organised by the Lundbeck global team based in Copenhagen, Denmark to support affiliate countries in helping to reach customers and provide valuable education during the Covid-19 pandemic. The webinar took place on 14 May 2020 and was directed at health professionals across nine European countries, including the UK.

Lundbeck UK was asked to invite UK health professionals to the webinar and the company subsequently did so via its representatives. Therefore, the webinar content and all other associated materials were recognised clearly as being within the scope of the UK Code.

The webinar was about the data associated with vortioxetine and was held initially as a 'live' event but was also made available as 'on demand' recorded content to all nine European countries. Local Lundbeck affiliates chose how to pass this information on to health professionals in their respective countries.

In the UK, information on accessing the 'on demand' content was sent by Lundbeck UK to UK health professionals who had originally been invited to the 'live' event and had accepted that invite. However, in order to be able to access either the 'live' webinar or the subsequent 'on-demand' webinar, a UK health professional was required to have first completed registration on the registration page in question. Registration required health professionals to provide their details and job titles in order to validate their suitability to access such promotional material.

Lundbeck noted that the complainant alleged that there was no prescribing information or adverse event reporting provided on the registration page. The webinar registration page was to be accessed by health professionals invited by Lundbeck from the nine different European countries to register for the pan-European event.

Lundbeck explained that in order for its representatives to invite UK health professionals to the live webinar on the 14 May they were briefed on how to promote the webinar and provided with an email template along with the following attachments to be included in the email - a detailed PDF invitation with embedded prescribing information and a biography of the speaker with embedded prescribing information. The email invite and accompanying attachments were only sent to health professionals who had opted in to receive promotional content. It was only when health professionals replied to the representatives to accept the invite to attend the webinar that they were sent an email including the link to the certified registration page. That email also had the prescribing information attached.

Lundbeck noted that the subsequent link to the recorded 'on demand' version of the webinar was only provided to health professionals who had accepted the invitation to the initial 'live' event as instructed.

Lundbeck submitted that the above process demonstrated that it had considered the requirements of promotion and had ensured that invited UK health professionals had full access to prescribing information before accessing the registration page and registering for the live or recorded on-demand events where prescribing information and the adverse event reporting statement would also be available to them. Additionally, the prescribing information was also embedded in the certificate that was provided to those health professionals who attended the webinar.

Lundbeck stated that it had, however, identified an omission from the registration page itself whereby the prescribing information and adverse event reporting statement had not been embedded or provided via a single clickable link. Instead, a prominent statement informing health professionals that prescribing information and the adverse event reporting statement would be available on the main event page was provided. Although this was an oversight, Lundbeck did not consider that it would have jeopardised patient safety as health professionals would have received the prescribing information and adverse event reporting statement three times (the invitation, speaker biographies and the email which include the link to the registration page) before accessing the registration page. They would then have received access to it again during the webinar on the main event page and then finally they would have received it again when they received their certificates for attending the event.

To summarise, in practical terms, all invited and attending UK health professionals would have had sufficient access to the prescribing information and adverse event reporting statement associated with the international webinar (five times) before, during and after the event. Lundbeck thus did not consider that it had jeopardised patient safety. In technical terms, Lundbeck accepted that the registration page was promotional and as such, the link to the prescribing information and adverse event reporting information was missing. For this oversight, Lundbeck accepted breaches of Clauses 4.1 and 4.9.

Lundbeck stated that it was not clear why the complainant cited Clause 4.2 because there was no allegation about the content of the prescribing information for vortioxetine - the content complied with the requirements of the clause.

With regard to the complainant's allegations that the registration page was accessible to anyone, including members of the public, Lundbeck noted that the webinar was only for health professionals and was only to be accessed following the receipt and acceptance of an invitation to attend sent from a Lundbeck representative. Once a health professional accepted the invitation, the representative would then provide access to the webinar event via a specific URL link embedded in an email so that the health professional could register via the registration page. Therefore, access to the registration page was through a closed email invitation to specific health professionals who had given prior permission to receive promotional emails. The representatives received a clear briefing and subsequent communication on this point. The webinar and subsequent registration page were therefore not advertised to the public, nor hosted on any publicly available platform. The webinar was hosted on a closed platform with a unique URL link which was not advertised to the public by Lundbeck at any point.

Lundbeck noted the complainant's allegation that the webinar could be found using the search terms 'Brintellix', 'UK' and 'webinar'. Lundbeck did not request or pay to have any search optimisation associated with this registration page or event and this had been confirmed by the platform providers who had provided an alternative rationale as to how this might appear on a search engine trawl. While a member of the public might search for reference information using

the term 'Brintellix', it was highly improbable that he/she would use the three specific search terms 'Brintellix', 'UK' and 'webinar' and thus access the registration page.

Lundbeck noted that the complainant had additionally alleged that the job title for attendees was not required in order to register on the registration page, but Lundbeck confirmed that this was a requirement as evidenced on the registration page. Once health professionals had registered on the platform, a due diligence process was followed to ensure that they were bona fide health professionals; a final registration list was created and the representatives were asked to put their initials next to their customers.

Therefore, as the information on the registration site was neither advertised nor made available to members of the public by Lundbeck, Lundbeck denied breaches of Clauses 26.1, 26.2 and 28.3.

Lundbeck submitted that it was unable to identify any evidence to support the complainant's allegation that a representative had told him/her that 'the webinar was accessible from a search engine by typing in "Brintellix UK Webinar" if the weblink was a problem'. The representatives were not instructed to provide this direction to access the webinar and so the company would not expect any of its field force to give that instruction. Lundbeck stated that it had spoken to all of its representatives and reviewed their call notes on its customer relationship management (CRM) system for the respective period; there was no evidence that representatives had provided written or verbal communication to support the complainant's allegation. The internal investigation supported the instructions the representatives were given for inviting health professionals to the webinar.

Lundbeck submitted that the registration page complied with Clauses 26.1 and 26.2 and access to the registration platform was through a closed email-only invitation and the registration webpage was hosted on a closed platform and restricted to health professionals who had expressed an interest to attend the webinar. The registration page was not advertised or accessible to the public. Since technically, the registration page was promotional and access to that content had not been restricted only to health professionals, Lundbeck accepted the breach of Clause 28.1. Lundbeck noted that there was no deliberate or malicious intent – the failure to have additional restrictive measures was a genuine mistake.

Lundbeck noted that the complainant had referred to the event registration page and in doing so had quoted the job code (UK- BRIN-0875). That job code actually corresponded to the certified webinar slides. The event registration page was certified by UK medical signatories on the 12 May, before the representatives invited their health professionals – that item had the job code UK-BRIN-0883. Lundbeck stated that it was therefore disappointed that the job code of the final form of the registration page was amended after certification and accepted a breach of Clause 14.1 on that point.

The platform provider confirmed that the certified registration page was the webpage uploaded and used for the event from 12 May onwards. Therefore, when the representatives started to send the event URL link to their health professionals so that they could register for the webinar, that link directed them to the correct certified event registration page with job code UK-BRIN-0883.

Lundbeck submitted that on further investigation with its global colleagues who organised this event, it had established that the webinar was scheduled to go live on 14 May at 3pm (GMT).

On the afternoon of the 14 May when the global team was doing its final checks on the webinar content prior to the 'live' event, one global employee instructed the platform provider to change the UK job code on the registration page and main event page so that it aligned with the code on the certified webinar slides ie UK-BRIN-0875. Lundbeck submitted that that action was unacceptable and in breach of the UK Company Approval Standard Operating Procedure (SOP) with regard the certification of promotional items and meant that changes were made to a certified item post certification. The subsequent uncertified registration page item was therefore available to any invited UK health professional who accessed the page from 1pm on the 14 May 2020 until the page was deactivated and withdrawn in December 2020.

Lundbeck accepted that that was a very disappointing finding which came about due to a misinterpretation of the Code by one global colleague based outside the UK. On interview it was apparent that he/she had become confused while carrying out the final checks on the materials associated with the webinar and thought that the code for the registration page should align with the code for the webinar slides. He/she had forgotten that the registration page had been certified in the UK as it was the only affiliate which had required the registration page to be certified.

Reassuringly, Lundbeck established that that was the only change that occurred and the content remained as per the certified final form. Lundbeck submitted that the data analytics associated with the page showed that from around 1pm on 14 May when the page was changed, and thus became uncertified, there were 35 interactions by invited health professionals prior to the live event at 3pm on the 14 May and 22 interactions with the page following the completion of the 'live' event and the availability of the 'on demand' content until the event was withdrawn in December 2020, with the last registration taking place on the 14 August 2020. Therefore, the uncertified page was potentially seen by fifty seven health professionals in the UK.

To summarise, Lundbeck was extremely disappointed to have been badly let down by the actions of a global employee. Lundbeck stated that it took the matter very seriously and accepted a breach of Clause 14.1. The finding had highlighted a training need amongst its global colleagues with regard to the Code if they were to continue to conduct compliant activities that would involve the UK. Subsequently Lundbeck would put in place a number of corrective measures to ensure the error did not happen again (see below).

Lundbeck reiterated that it took the allegations outlined in the complaint extremely seriously as reflected in the thoroughness of its investigation. Lundbeck was extremely disappointed to find that mistakes by individual employees who had not followed company processes had led to a number of breaches of the Code. Lundbeck fully accepted these in the spirit of self-regulation and learning from its mistakes.

Lundbeck submitted that whilst it was no excuse, some of the mistakes might have been made because the company and the industry as a whole was very busy at the time trying to adapt to the constraints posed by the COVID-19 pandemic and the move to a remote way of working while still trying to support health professionals with increased digital activity. In addition to that, the pan-European event in question was organised by Lundbeck's global colleagues across nine European countries, which could often lead to more challenges due to inconsistencies between different country codes and processes. In addition to that the UK did not have full control of the event and therefore did not have full oversight or relationships with the third party platform providers, which made things more challenging.

To summarise, Lundbeck accepted that mistakes had been made and subsequently high standards had not been maintained at all times and therefore it accepted a breach of Clause 9.1. However, given the overall number of times prescribing information and adverse event reporting was provided to attendees, Lundbeck did not believe that the activity in question or the breaches associated with it had jeopardised patient safety or were such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry and therefore Lundbeck denied a breach of Clause 2.

Lundbeck stated that its investigation identified a number of issues related to the approval of webinar materials. Two Lundbeck employees (one UK and one Global) failed to follow clear approval processes - mistakes which had subsequently led to clear breaches of the Code. This had therefore highlighted a need for immediate corrective and preventative actions which had started to be implemented and include the following:

- The registration page was not available to be searched for via search engines.
- Lundbeck had suspended all similar activities with its global colleagues as well as in the UK, while it undertook a thorough review of the company's processes for the approval of promotional activities. Actions from these findings would be implemented and communicated out to the business in a timely manner.
- A refresher Code training and SOP training would be organised for all relevant staff, including the colleagues involved in the above Code breaches.
- Processes for digital materials and meetings would be reviewed to ensure even more was done to restrict their access to only the targeted audience.

Lundbeck considered healthcare compliance of the utmost importance and had already initiated a number of corrective and preventative actions (CAPAs) as outlined above. Through 2020 Lundbeck was in the process of recruiting an experienced senior medical manager and a regional compliance manager. These employees would manage the implementation of the CAPAs and champion the importance of Code adherence, fully supported by the UK country manager as the company looked to make greater improvements in the area of healthcare compliance.

Lundbeck deeply regretted the mistakes that had been made and was extremely disappointed to have received a complaint, however it was committed to learning from that as a business. Lundbeck was fully confident that with its new recruits onboard and with the company's full support, it could drive improvements across all the areas of the business.

Following a request from the Panel for further information, Lundbeck stated that whilst it did not feel that its response contradicted itself, the company appreciated that the technicalities and reach of Google indexing (autonomously searching, collecting, storing and publishing of data) made this a complex case to unravel. Lundbeck stated that through its investigation in response to this complaint, it became apparent that the registration page could be found on an internet search engine (Google) by searching for three specific terms, 'Brintellix', 'UK' and 'Webinar', in combination with each other. However, this was unknown to Lundbeck and it was not intended for the registration page link to be available to access via a search engine. The pages associated with this event were hosted on a closed platform, not publicly advertised with search optimisation disabled for the event, and therefore, as confirmed by the platform providers (email provided), the registration page should not have been able to have been found on any internet search engine.

Lundbeck submitted that the intention was for the registration page to have been restricted only to those UK health professionals invited by Lundbeck whom had been provided with the direct link to the registration page. Therefore, the accessibility of the link to this page through a specific Google search of the terms 'Brintellix UK webinar' was a surprise to Lundbeck. Lundbeck submitted that having sought expert advice from the platform providers, it was informed that this had occurred through Google finding the link in some other way (possibly through an invited delegate pasting the personal link into the Google search), which allowed Google to index it (make it searchable). Lundbeck submitted that this was outside their knowledge, control or intention, and provided the potential access to the registration page when these specific terms were searched for together.

Lundbeck stated that in its original response it accepted that, whilst the access to this link through a very specific Google search was not intended nor known by Lundbeck, there was no check in place once a user clicked on the link to ensure that he/she was not a member of the public before reaching the page. Therefore, whilst the page was never intended for an external audience (wider than the invited health professionals) and it was 'highly improbable that a member of public would search for the three specific search terms together and therefore access the registration page' as the event was not advertised, Lundbeck accepted that best practice would have been to have a 'check' in place anyway when clicking on the link, before reaching the page, and subsequently it accepted a breach of Clause 28.1. On reflection however, and in light of the publishing of the recent Case AUTH/3369/8/20 by the PMCPA, Lundbeck noted the Panel's comments, particularly those highlighted below:

'The Panel considered that the complainant's submission that there was no check to ensure that he/she was not a member of the public suggested that when he/she had accessed the leavepieces he/she was not on the live Pfizerpro website. It seemed reasonable in this case to consider the leavepieces as material on an internal company site. On balance, the Panel decided that the two leavepieces, which Pfizer had removed from its website but which had unintentionally, and unknown to Pfizer, remained directly accessible by Google, did not amount to promotion of Ecalta to the public. No breach of the Code was ruled.'

Lundbeck submitted that it felt that a case precedent had since been established, and whilst a check would be advised, it seemed reasonable in this instance not to have built this functionality as the registration page was being held on a closed platform for a private invited audience of health professionals only and was not intended for an external audience. Subsequently, Lundbeck submitted that the unknown and unintentional accessibility of the page through a very specific Google search, due to Google finding and giving access to the closed private link, should not amount to a breach of the Code and in this instance specifically Clause 28.1. Lundbeck requested that the Panel considered this recent case ruling when reviewing its case, as there appeared to be a lot of similarities.

Lundbeck reiterated that in its original response it highlighted that 'access to the registration platform was through a closed email-only invitation and the registration webpage was hosted on a closed platform and restricted to health professionals who had expressed an interest to attend the webinar. The registration page was not advertised in the public domain nor accessible to the public'. Lundbeck stated that this related to its intention, direction and remit when it came to this event and subsequent registration page. As outlined above, Lundbeck stated that it did not advertise the registration page nor make it accessible to the public, it became apparent during its investigation that Google had found and indexed the private link by some other means and

subsequently enabled access when a combination of some very specific search terms were searched for. This was unknown to Lundbeck and out with the company's intention and control having taken measures to host this on a closed platform accessible through a closed email-only invitation. On being made aware of this issue, Lundbeck contacted Google to remove this indexing which provided access to this previously unpublished page and Google confirmed that they removed the access.

Therefore, Lundbeck considered that whilst it was technically possible for someone other than those health professionals who had received the invite to have found the registration page, this was unintentional and unknown to Lundbeck. In addition to this, it was highly improbable and unlikely that anyone not invited would search for the three specific terms together ('Brintellix', 'UK' and 'Webinar'), and therefore reasonably have found the registration page, considering that the event was not advertised.

In summary, Lundbeck submitted that it was possible for an individual to access the registration page by typing in very specific search terms into a search engine, specifically Google. However, this was as a result of Google finding and indexing this private link and despite the fact that the registration page was hosted on a closed platform with search optimisation disabled. Therefore, it was not the intention of Lundbeck, nor known by the company that this had occurred as evidenced by the platform providers. Lundbeck submitted that on reflection, it would have been prudent to include a 'check' on the link to ensure that the individual accessing it was a health professional and not a member of the public, however this functionality was not included in this instance as the link, and subsequent registration page, was never intended for an external audience and a number of measures had been taken to ensure this. Lundbeck submitted that the accessibility unknowingly provided by Google was very similar to Case AUTH/3369/8/20 and asked the Panel to apply the recent case precedent established in that ruling when considering this case.

PANEL RULING

The Panel noted that the complainant referred to being provided with a weblink to view an 'on-demand' Brintellix webinar by a Lundbeck representative. The webinar titled 'Clinical experience of emotional blunting and data on the efficacy of vortioxetine on anhedonia' was, according to Lundbeck, a promotional event organised by its global team based in Denmark and directed at health professionals across nine European countries, including the UK. The webinar was held as a 'live' event on 14 May and was subsequently made available as 'on demand' recorded content; it was for local affiliates to choose how to distribute this information to health professionals in their respective countries.

The Panel noted that an initial invite to the live webinar was emailed by Lundbeck representatives to UK health professionals who had opted in to receive promotional materials. Attached to the email was a detailed PDF invitation and a biography of the speaker, both of which included embedded prescribing information. If a health professional accepted the invitation, only then were they sent an email including the specific URL link to the certified registration page; this email included prescribing information as an attachment. The Panel further noted Lundbeck's submission that information on accessing the 'on demand' content was only sent to those health professionals who had originally accepted the invitation to the live event. It appeared from the instructions to UK staff, following the live webinar, that the on demand link was only to be sent to those who had accepted the invitation to attend the live webinar but could not make it at the last minute.

Access

The Panel noted the complainant's allegation that there was no disclaimer or firewall to make the registration page accessible to health professionals only and anyone including members of the public could enter the registration page where the product and indication were stated as well as register and watch the webinars as professional registration numbers or job titles for attendees were not required on the registration form. Further, the complainant alleged that he/she was told by the representative that access was not restricted and the webinar could be found through a search engine using the terms 'Brintellix UK webinar' if the weblink was a problem.

Clause 28.1 required that promotional material about prescription only medicines directed to a UK audience which is provided on the Internet must comply with all relevant requirements of the Code. The supplementary information stated that unless access to promotional material about prescription only medicines was limited to health professionals and other relevant decision makers, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified. This was to avoid the public needing to access material for health professionals unless they chose to.

The Panel noted that contrary to the complainant's statement, the screenshot of the registration page in question, provided by Lundbeck, showed that the registration form contained numerous data entry fields including job title. According to Lundbeck, once health professionals had registered on the platform, a due diligence process was followed to ensure that they were a bona fide health professional and their suitability to access the promotional webinar validated. The Panel further noted Lundbeck's submission that access to the registration page was through a closed email invitation to specific health professionals; neither the registration page nor the webinars were advertised to the public or hosted on any publicly available platform.

The Panel noted Lundbeck's submission that whilst a member of the public might search for reference information using the term 'Brintellix', it was highly improbable that he/she would use the three specific search terms 'Brintellix', 'UK' and 'webinar', together, and thus access the registration page. Representatives were not instructed to provide this direction to access the webinar and Lundbeck was unable to identify any evidence to support the complainant's allegation that a representative had told him/her that the webinar was accessible from a search engine by typing in 'Brintellix UK Webinar'.

The Panel noted Lundbeck's submission that it did not request or pay to have any search optimisation associated with this registration page or event which was confirmed by the platform providers. The platform providers had, however, provided an alternative rationale as to how the information might appear on a search engine trawl. In this regard, the Panel noted that following receipt of this complaint in response to a request from Lundbeck, the platform providers confirmed that the platform was closed and Lundbeck's events should not have been searchable on Google. The platform providers explained that it did not list items on Google and did not provide Google the ability to query its catalogue of events; Google would have had to have found the link in other ways which were endless. The platform providers explained that the event might have appeared in a Google search, despite not being requested by Lundbeck, if a user that was attending the event allowed Google to find the link (ie shared it or similar) which was usually through a user sharing it publicly or privately on social media or other; it was

possible that Google could have indexed the page (made it searchable) if an invited delegate had pasted their personal link into a Google search.

The Panel noted Lundbeck's submission that it would have been prudent to have included a 'check' on the registration page link to ensure that the individual accessing it was a health professional and not a member of the public. The Panel considered, however, that based on the evidence provided, it appeared that measures were in place to ensure the registration page and webinar were only accessed by invited health professionals; the registration page was hosted on a closed platform with search optimisation disabled. It appeared to the Panel that the only way the registration page or webinar might be found via a search engine was using very specific search terms and only after a search engine had found the link by some other means and indexed it to make it searchable. The Panel noted that there was no evidence that specific search terms had been highlighted by the company or that the registration page or event was advertised to the public. The Panel noted its comments above and ruled no breach of Clause 28.1. The Panel did not consider that the complainant had discharged his/her burden of proof, that Lundbeck had promoted Brintellix to members of the public as alleged. No breach of Clauses 26.1 and 26.2 were ruled. The Panel noted its comments and rulings above and subsequently ruled no breach of Clause 28.3.

Obligatory Information

The Panel noted the complainant's allegation that whilst the event's registration page (ref UK-BRIN-0875. Date of Preparation: May 2020) stated that prescribing information and adverse event reporting would be available on the main event page, they were not available to access on the registration page itself. The Panel noted that the information displayed on the registration webpage provided by Lundbeck (ref UK-BRIN-0883) included the Brintellix product logo, its indication and the title of the webinar 'Clinical experience of emotional blunting and data on the efficacy of vortioxetine on anhedonia' and considered that the page was thus promotional.

Clause 4.2 listed the content of prescribing information which was required by Clause 4.1 to be provided with all promotional material except for abbreviated advertisements. In the Panel's view, failure to provide the required information would be a breach of Clause 4.1. The Panel thus made no ruling in relation to Clause 4.2. Whilst the Panel noted Lundbeck's submission that all invited and attending UK health professionals would have had sufficient access to the prescribing information and adverse event reporting statement associated with the webinar (five times) before, during and after the event, the supplementary information to Clause 4.1 stated, inter alia, that each promotional item for a medicine must be able to stand alone and include the prescribing information. The Panel noted that the registration page did not include the prescribing information as listed in Clause 4.2 and a breach of Clause 4.1 was ruled as acknowledged by Lundbeck. Similarly, the page did not include an adverse event reporting statement as required by Clause 4.9 and a breach of that Clause was ruled as acknowledged by Lundbeck.

Certification

The Panel noted that the complainant had raised Clause 14.1 but had provided no reasons as to why in his/her view Lundbeck was in breach of that Clause.

The Panel, however, noted Lundbeck's submission that whilst the event registration page (ref UK-BRIN-0883) was certified by Lundbeck on 12 May 2020 and was uploaded to the webpage

on that date prior to the UK representatives distributing invitations to health professionals to access it, on 14 May, due to a misinterpretation of the Code, a global employee instructed the platform provider to change the UK job code on the registration page and main event page so that it aligned with the job code on the certified webinar slides (ref UK- BRIN-0875). The job code of the final form of the registration page was thus amended after certification and the subsequent uncertified registration page was available to any invited UK health professional who accessed the page from 1pm on the 14 May 2020 until the page was deactivated and withdrawn in December 2020 and was potentially seen by fifty-seven health professionals in the UK. The Panel noted Lundbeck's submission that that was the only change that occurred, and the content remained as per the certified final form.

The Panel noted that Clause 14.1 required that, inter alia, promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified by one person on behalf of the company in the manner provided for by this clause. The Panel noted that whilst not a requirement within the Clauses of the Code, the 'Guidelines on Company Procedures relating to the Code of Practice' stated that each certificate should bear a reference number with the same reference number appearing on the promotional material in question so that there can be no doubt as to what had been certified. A particular reference number should relate to only one item of promotional material.

The Panel considered that the final form of the registration page had been amended following certification, and therefore it ruled a breach of Clause 14.1 as acknowledged by Lundbeck.

The Panel noted that a robust certification procedure underpinned self-regulation. The Panel noted its comments and ruling of Clause 14.1 above and considered that high standards had not been maintained and a breach of Clause 9.1 was ruled as acknowledged by Lundbeck. The Panel noted, however, that it appeared that Lundbeck had been let down by one of its global colleagues who had amended the job code but no other information following certification. The Panel noted its comments and rulings above and did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2, which was a sign of particular censure and was reserved for such use, and no breach was ruled.

Complaint received **4 January 2021**

Case completed **5 August 2021**