**CASE AUTH/3463/1/21**

# COMPLAINANT v LUNDBECK

## Lundbeck website

**An anonymous contactable complainant, who described him/herself as a health professional, complained about the home page/research and development (R&D) page of Lundbeck Limited's corporate website .**

**The complainant noted that the home page incorporated a video on mental health and it was more than 2 years since the webpage was last approved.**

**On the same page, there was a Research and Development tab which stated that Lundbeck's R&D efforts were dedicated to creating new and innovative pharmaceuticals for the treatment of psychiatric and neurological disorders and a tab to read more. The complainant alleged that it was not appropriate information for the public or patients; referring to statements such as: 'Lundbeck is devoted to the treatment of psychiatric and neurological disorders' and 'We dedicate our entire R&D efforts to develop innovative drugs for treatment of a number of psychiatric and neurological disorders'. Following a pipeline tab led to a page showing medicines Lundbeck had in development along with indications. Another tab labelled 'products' listed Lundbeck products (brand and generic names) alongside the indications for each.**

**The complainant alleged that it was inappropriate for Lundbeck UK to direct readers onto a global site where information on products and pipeline was readily available. On the Lundbeck UK site there was no warning to prevent either health professionals, patients or members of the public transferring to the global page from the UK R&D page. The complainant alleged that Lundbeck was responsible for the content to which it directed readers and alleged breaches of the Code including with regard to the promotion of pipeline products to the public, patients and health professionals. Members of the public would speak to their health professional about those prescription only medicines and adverse event reporting for patients was not provided and the page was not approved for patients or members of the public. The complainant alleged that medicines had been promoted to health professionals without the provision of prescribing information or adverse event reporting. The complainant alleged that promotional content had not been approved for a UK audience and it was disguised promotion as the UK R&D page directed to a webpage where information on pipeline and products was available without prior warning on the UK page.**

**The detailed response from Lundbeck is given below.**

**The Panel noted Lundbeck's submission that whilst both the homepage of the Lundbeck UK website and the video were certified under the Code in December 2018 and therefore the Panel ruled no breach of the Code.**

**The Panel noted Lundbeck's submission that whilst material which required examination did not need to be re-certified, the entire website was certified as one job bag and certain content which was live on the website did require re-certification. The Panel noted that at the time of the complaint, more than two years had lapsed since the website had been certified and the Panel therefore ruled a breach of the Code as acknowledged by Lundbeck.**

**The Panel did not consider that the complainant had established that the information on the research and development page was inappropriate as alleged, and therefore ruled no breach of the Code in that regard.**

**The Panel noted that near the bottom of the Lundbeck UK research and development webpage was a link to find more information about Lundbeck's publications which took visitors to a webpage on the Lundbeck global website. The Panel noted that the top of the webpage which the user was taken to stated 'GLOBAL' and was titled 'Disclosure of clinical trial information'; it detailed the company's policy for scientific publications and clinical trial data sharing.**

**The Panel noted Lundbeck's submission that a user would have to navigate the global website in order to find the information on products and pipeline; visitors were not taken directly from the UK research and development page to the separate global pipeline and products pages. The Panel further noted Lundbeck's submission that the Lundbeck UK website was approved with a 'pop-up' informing the reader that they were being redirected to a non-UK website for which Lundbeck UK had no responsibility and every page of the global website stated "GLOBAL" at the top.**

**The Panel noted that the complainant bore the burden of proof and did not consider that he/she had established that the link from the research and development webpage on the Lundbeck UK website to the disclosure of clinical trial information on the global website was inappropriate as alleged. Nor did the Panel consider that there was evidence that directing readers from the research and development webpage on the Lundbeck UK website to the disclosure of clinical trial information on the global website constituted disguised promotion as alleged. The Panel therefore ruled no breaches of the Code, including no breach of Clause 2, in relation to the allegations about pipeline and product information.**

An anonymous contactable complainant, who described him/herself as a health professional, complained about the home page/research and development (R&D) page of Lundbeck Limited's corporate website.

**COMPLAINT**

The complainant noted that the home page incorporated a 1 minute 53 second educational video (entitled: our corporate movie) on mental health disease (ref UK-NOTPR-0020) with wording underneath 'Page last modified 24 June 2020'. However, the complainant noted that at the bottom of the page it stated, 'Date of preparation: December 2018 Job number: UK-NOTPR-0031'. The page had not been re-approved in 2 years. The complainant alleged a breach of Clause 14.3, as the page was educational material for the public or patients issued by a company which related to diseases or medicines. The complainant also alleged a breach of Clause 14.5 as material which was still in use must be recertified at intervals of no more than

two years to ensure that it continued to conform with the relevant regulations relating to advertising and the Code. The complainant noted that it had been more than 2 years since last approval for the page as it was updated in June 2020 but the last modified date at bottom was 2018.

The complainant noted that on the same page, there was a Research and Development tab which stated that Lundbeck's R&D efforts were dedicated to creating new and innovative pharmaceuticals for the treatment of psychiatric and neurological disorders. There was a tab to read more. It did not seem to be appropriate information for general members of the public or patients to read about. Clicking on the 'read more' tab sent the reader to another page (https://lundbeck.com/uk/about-us/research-and-development) with a date of preparation of December 2018 (ref UK-NOTPR-0031). The complainant noted that there was a lot of information on that page which would not be suitable for members of the public or patients. There were statements such as: 'Lundbeck is devoted to the treatment of psychiatric and neurological disorders' and 'We dedicate our entire R&D efforts to develop innovative drugs for treatment of a number of psychiatric and neurological disorders'. At the bottom of that page was a section titled 'Publications and clinical trials'. At the end of that particular section, it was stated, for more information on Lundbeck's publications click here. The complainant provided a link for the subsequent global webpage and noted that one of the tabs on that page was 'pipeline' . The pipeline page showed all the medicines Lundbeck had in development along with indications. There were 14 projects and areas listed along with indications. Another tab was labelled 'products' and on that global page all of Lundbeck products (brand and generic names) were listed alongside the indications for each. It was stated at the top of the products page that Lundbeck had a broad range of products within brain diseases. The complainant noted that Lundbeck's main products treated depression, schizophrenia and Alzheimer's and Parkinson's diseases.

The complainant submitted that it was inappropriate for Lundbeck UK to direct readers onto a global site where information on products and pipeline was readily available and accessible to anyone. On the Lundbeck UK site there was no warning (eg a disclaimer) to prevent either health professionals, patients or members of the public transferring onto this global page from the UK R&D page . In fact, the Lundbeck UK page provided a click through and direction for individuals from the Lundbeck UK site to the global page with pipeline and products tabs on which meant anyone could look at them. The complainant submitted that Lundbeck was responsible for the content to which it directed readers, especially as it was a Lundbeck global webpage. The complainant alleged several breaches of the Code as the UK audience was directed to inappropriate content on the global Lundbeck website providing accessibility to products and pipeline.

The complainant stated that pipeline products were promoted to members of the public, patients and health professionals, in breach of Clauses 3.1, 9.1 and 2 (repeated breach); a full list of several products was provided and promoted (with indication shown) to members of public, patients and health professionals in breach of Clauses 26.1, 26.2, 9.1, 14.3 and 2 as members of the public would speak to their health professional about those prescription only medicines and adverse event reporting for patients was not provided and the page was not approved for patients or members of the public. The complainant alleged that medicines had been promoted to health professionals without the provision of prescribing information in breach of Clauses 4.1 (multiple times) as no prescribing information was provided, and 4.9 as no adverse event reporting was provided on the page either. The complainant alleged that promotional content had not been approved for a UK audience in breach of Clause 14.1. The complainant also

alleged disguised promotion in breach of Clause 12.1 as the UK R&D page directed to a webpage where information on pipeline and products was available without prior warning on the UK page.

In summary, the complainant submitted that the Lundbeck UK R&D page should not have provided an option to direct health professionals/patients/members of the public to a global page where information on pipeline and products was available so readily and easily. In that regard the complainant further alleged a breach of Clause 28.1 as the Code stated that 'Unless access to promotional material about prescription only medicines is 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 is to avoid the public needing to access material for health professionals unless they choose to. The MHRA Blue Guide states that the public should not be encouraged to access material which is not intended for them'.

The complainant was very concerned that the Lundbeck UK website had not segregated the website off for the public resulting in pipeline and product promotion to patients - in breach of Clauses 9.1 and 2 on repeated occasions.

When writing to Lundbeck, the Authority asked it to consider the requirements of Clauses 2, 3.1, 4.1, 4.9, 9.1, 12.1, 14.1, 14.3, 14.5, 26.1, 26.2, and 28.1 of the Code.

**RESPONSE**

Lundbeck stated that it took complaints very seriously and had carried out a thorough and comprehensive internal investigation with regard to the allegations made. Supporting documents were provided.

Lundbeck noted that the complaint related to the Lundbeck UK website, specifically the following two allegations:

1. The date of preparation on the home page of the website (ref UK-NOTPR-0031) was December 2018. The home page contained a video on mental health disease (ref UK-NOTPR-0020) with 'Page last modified June 2020'. The complainant alleged breaches of Clauses 14.3 and 14.5.

2. Information on the Lundbeck Global website, accessed via a link from the Lundbeck UK website (R&D page which had a publications and clinical trials link) , was not appropriate for the public or patients, specifically:

    a. The pipeline webpage contained information on medicines in development and indications, promoting them to the public, patients and health professionals. The complainant alleged breaches of Clauses 3.1, 9.1 and 2.
    b. The products webpage contained indications and products promoting them to the public, patients and health professionals, with no prescribing information or adverse events reporting information. The complainant alleged breaches of Clauses 4.1, 4.9, 26.1, 26.2, 9.1, 14.1, 14.3 and 2.
    c. The Lundbeck UK R&D page directed visitors to a global Lundbeck webpage where information on pipeline and products was available without prior warning thereby

disguising promotion while not segregating the website off from the public. The complainant alleged breaches of Clause 12.1, 28.1, 9.1 and 2.

Lundbeck submitted that in order to respond to the numerous allegations made by the complainant in Cases AUTH/3463/1/21 and AUTH/3466/2/21, it had carried out a thorough internal investigation. The website in question (Lundbeck.com/UK) was a microsite of the global Lundbeck domain Lundbeck.com. The address Lundbeck.co.uk directed visitors to the site.

Lundbeck explained that in January 2021, it had intended to take down the UK website in its entirety in order to determine whether it required reapproval. The home page was 'unpublished' but due to human error, the other webpages of the website unfortunately remained live. As soon as Lundbeck knew about that error, all of the remaining pages were taken down on the 1 February 2021 before it received the complaint in Case AUTH/3466/2/21.

**1 The Lundbeck home page and the video on mental health disease**

Lundbeck stated that both the home page of the corporate website and the video itself constituted appropriate corporate awareness. Under Clause 14.3, both were certified as the same job bag had contained reference information on Lundbeck's medicines for members of the public. Lundbeck therefore refuted a breach of Clause 14.3 (certificates provided). Lundbeck stated that as the site contained no promotional information, Clause 14.1 was not relevant. Whilst material for examination did not need re-certification, unfortunately there was only a single job bag for the whole UK website and as certain content was still live and did require re-certification after 2 years, under Clause 14.5, Lundbeck accepted that breach. However, Lundbeck noted that both the content of the webpage and video in question were still suitable for a general UK audience.

**2 Information on the Lundbeck Global website was accessed by UK members of the public, patients and health professionals**

Lundbeck submitted that the approval of the Lundbeck UK website and archival of screenshots showed clearly that the website was approved with a 'pop-up' which informed the reader that they were being redirected to a non-UK website for which Lundbeck UK had no responsibility.

During its investigation, Lundbeck discovered that certain webpages in the job bag for the website (UK-NOTPR – 0031) had been certified under a different job bag code (UK-NOTPR-0021).

Lundbeck noted that under Clause 28.6 (which was not alleged by the complainant), the Code did not require a 'pop-up', only that it was made clear to users when they were leaving any of the company's sites, or sites sponsored by the company, or were being directed to a site which was not that of the company.

Lundbeck noted that in Case AUTH/3162/2/19, the Panel ruled that AstraZeneca in its retweet, made it clear that the cited website link was to a non-company website – therefore reinforcing across the industry that a 'pop up' alone was not a Code requirement.

Even if the complainant had provided any evidence to support their allegation that there was no 'pop-up', in line with the learning from Case AUTH/3162/2/19, should any visitor choose to

access the Global website, it was clear on many levels (content, layout and functionality) that this was the Lundbeck Global website. For example:

- Every page stated 'GLOBAL' at the top – for the pipeline ('GLOBAL') and products ('Global') page this was clearly in the same line of sight as the webpage content
    - the UK page stated 'UK'
- The address stated throughout was the Global Danish office
    - the UK page included only the UK address
- The Privacy Policy included the Global Danish office address
    - the UK Privacy Policy included the UK address
- The social media icons represented the Lundbeck Global social media accounts
    - the UK page had none
- The footer address was clearly Denmark
    - the UK footer included the UK address
- The Global website included 7 tabs in the wireframe
    - the UK website only had 5
- The product webpage on the Global website (screenshot provided) stated *'Due to regulatory restrictions we are not able to provide further details on our products on this website, more information may be available on our* local websites*'* clearly informing readers how to access local websites.
- The content on the Global website did not relate to the specific availability of any medicine in the UK.

Furthermore, Lundbeck stated:

- The publications and clinical trials link on the UK website took the reader to the disclosure of clinical trial information on the Global website, which stated 'GLOBAL' clearly at the top. The reader <u>was not</u> taken directly to the separate pipeline and products pages, which would have required a visitor to browse the website for additional content. It was improbable that any visitor browsing in such a manner would have entirely missed all the points above.
- No UK company employee or agency employee had directed any customer to this non-UK company website.

Therefore, Lundbeck submitted that the pipeline webpage and the products webpage on this Global website were not under the scope of the ABPI Code and it refuted all alleged breaches relating to Point 2.

**<u>Summary</u>**

Lundbeck was committed to improving compliance across its organisation, as outlined in detail in its recent response to Case AUTH/3450/1/21. Lundbeck therefore believed complaints from a suspected disgruntled ex-employee about historical matters that were not brought up by him/her during his/her employment demonstrated a deliberate attempt to bypass the company's whistle-blowing procedures and abuse the Authority's limited time and resources.

Lundbeck submitted that the UK company was a very different organisation to when the complainant was employed. The company had now recruited and onboarded an experienced medical and compliance staff. This had enabled the company to continue to implement substantial corrective actions (CAPAs) to ensure that it dealt with any specific historical issues

as part of a broader overarching Compliance Programme implementation. This would ensure Lundbeck had robust Governance and Oversight across the business with compliance being a key pillar of its company culture.

Lundbeck stated that it was determined to implement the right checks and balances, and whilst it investigated all allegations of non-compliance, it had initiated a moratorium on a number of key promotional activities and had instructed a company-wide internal audit. That audit would serve to highlight any other issues so Lundbeck could address and correct them within its new compliance framework. In addition, Lundbeck had invested 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 Code. It was therefore dismaying that the suspected complainant continued to lodge similar complaints that served only to distract Lundbeck from its significant ongoing progress.

To summarise, Lundbeck's position with regard to Case AUTH/3463/1/21, it accepted breaches of Clause 14.5 and therefore Clause 9.1 but it denied breaches of Clauses 14.1, 14.3, 3.1, 4.1, 4.9, 12.1, 26.1, 26.2 and therefore 9.1 and 2.

**PANEL RULING**

The Panel noted Lundbeck's submission that whilst both the homepage of the Lundbeck UK website and the video hosted on it constituted corporate awareness, they were certified under Clause 14.3 as the website also contained reference information on Lundbeck's medicines for members of the public and the entire website had been certified as one job bag (ref UK-NOTPR-0031).

The Panel noted that the website, including the homepage and video in question, had been certified in December 2018 and therefore the Panel ruled no breach of Clause 14.3.

Clause 14.5 stated, *inter alia*, that material which was still in use must be recertified at intervals of no more than two years to ensure that it continued to conform with the relevant regulations relating to advertising and the Code.

The Panel noted Lundbeck's submission that whilst material which required examination did not need to be re-certified, the entire website was certified as one job bag and certain content which was live on the website did require re-certification. The Panel noted that at the time of the complaint, more than two years had lapsed since the website had been certified and the Panel therefore ruled a breach of Clause 14.5 as acknowledged by Lundbeck.

The complainant was further concerned that the research and development page, which could be accessed from a tab on the homepage, included information that was not suitable for members of the public or patients. In that regard, the complainant specifically referred to the statement 'Lundbeck is devoted to the treatment of psychiatric and neurological disorders. We dedicate our entire R&D efforts to develop innovative drugs for treatment of a number of psychiatric and neurological disorders'. However, he/she did not state why in his/her view such information was not suitable for the public or patients and had not raised any specific clauses in that regard. The Panel therefore considered the allegation under Clause 9.1. However, it was not for the Panel to infer detailed reasons to support the allegation on behalf of the complainant; it was for the complainant to establish his/her case on the balance of probabilities. The Panel did not consider that the complainant had established that the information on the research and

development page was inappropriate as alleged, and the Panel therefore ruled no breach of Clause 9.1 in that regard.

The Panel noted that near the bottom of the Lundbeck UK research and development webpage was a link to find more information about Lundbeck's publications which took visitors to a webpage on the Lundbeck global website. The Panel noted that the top of the webpage which the user was taken to stated 'GLOBAL' and was titled 'Disclosure of clinical trial information'; it detailed the company's policy for scientific publications and clinical trial data sharing.

The Panel noted Lundbeck's submission that a user would have to navigate the global website in order to find the information on products and pipeline; visitors were not taken directly from the UK research and development page to the separate global pipeline and products pages. The Panel further noted Lundbeck's submission that the Lundbeck UK website was approved with a 'pop-up' informing the reader that they were being redirected to a non-UK website for which Lundbeck UK had no responsibility and every page of the global website stated "GLOBAL" at the top.

The Panel noted that the complainant bore the burden of proof and did not consider that he/she had established that the link from the research and development webpage on the Lundbeck UK website to the disclosure of clinical trial information on the global website was inappropriate as alleged. Nor did the Panel consider that there was evidence that directing readers from the research and development webpage on the Lundbeck UK website to the disclosure of clinical trial information on the global website constituted disguised promotion as alleged and no breach of Clause 12.1 was ruled. The Panel noted its comments above regarding the pop-up box, the content of the global webpage that users were directed to and that they would have to further navigate the global website to read the separate product and pipeline pages. The Panel therefore ruled no breach of Clauses 3.1, 9.1 and 2 in relation to the allegations about pipeline information and no breach of Clauses 26.1, 26.2, 28.1, 14.1, 14.3, 4.1, 4.9, 9.1 and 2 in relation to the allegations about product information.

**Complaint received** **25 January 2021**

**Case completed** **27 September 2021**