

CASE AUTH/3452/1/21

COMPLAINANT v LUNDBECK

Promotion of Abilify

An anonymous, contactable complainant who described him/herself as a health professional, complained about the promotion of Abilify Maintena (aripiprazole) prolonged-release suspension for injection by Lundbeck and in that regard provided a link to a particular webpage on the Lundbeck UK Progress in Mind Psychiatry and Neurology resource centre website.

Abilify Maintena was an atypical antipsychotic indicated for the treatment of schizophrenia in adult patients stabilised with oral aripiprazole.

The complainant stated that a Lundbeck medical science liaison (MSL) had provided him/her with information about a non-promotional educational resource website/hub where Lundbeck had written non-promotional articles for UK health professionals. Although the website was designed to provide non-promotional articles, there was disguised promotion of Abilify in an article entitled 'Towards new treatment options for MDD [major depressive disorder] and schizophrenia: a role for D2 receptor partial agonists'. The bottom of the article stated 'This Symposia was conducted with educational financial support provided by H. Lundbeck A/S'.

The complainant stated that Abilify was a well-established and well-known dopamine D2 receptor partial agonist and atypical antipsychotic. The article had deliberately over emphasised the mechanism of action and medicine class to mask the product name. The complainant was also concerned that the article recommended off-label usage as Abilify was licensed for maintenance treatment of schizophrenia and the article promoted it for use in depression. The complainant was concerned that a promotional article was placed onto what was described as an educational hub for health professionals. The complainant alleged that Lundbeck had deliberately avoided the name of the medicine as it was off-label but by repeated reference to mechanism of action and atypical antipsychotics it was clear that the article was promotional for Abilify instead of being an educational article. The complainant was also concerned that the article suggested there were fewer undesirable side effects with Abilify which was not so. The article was based on a symposium that took place in Mexico which was then used to construct an inappropriate promotional article for UK health professionals including off-label recommendations.

The detailed response from Lundbeck is given below.

The Panel noted that Lundbeck accepted the article was promotional, however it never intended for it to be placed on the Lundbeck UK Progress in Mind website or to be provided to any UK health professional. The Panel noted Lundbeck's submission that

Lundbeck UK had no involvement in supporting the Lundbeck global symposia or in the development of the article following it.

The Panel noted Lundbeck's submission regarding the activities of former members of staff and was concerned to note that according to Lundbeck, a senior medical member of Lundbeck staff had created and certified the job bag for the Progress in Mind website and that the article in question was not in the job bag but was a part of the cloned global content that then appeared on the UK website. The company submitted that the website had been taken down before it had received the complaint. It appeared from the metrics provided by the company that only one person accessed the article.

The Panel considered that the article promoted Abilify Maintena and omitted mandatory information such as the prescribing information, and where it could be found as well as the adverse events reporting statement. The Panel ruled breaches of the Code in that regard as acknowledged by Lundbeck.

The Panel considered that whilst it was clear that it was a Lundbeck UK website and it was stated at the bottom of the article 'This Symposia was conducted with educational financial support provided by H. Lundbeck A/S', those reading the content of the article would not necessarily be clear from the outset that the article at issue was a report from a Lundbeck meeting which was promotional for a product co-promoted by Lundbeck. The Panel considered that the promotional nature of the article was thus disguised and ruled a breach of the Code. This ruling was upheld on appeal from Lundbeck.

The Panel noted Lundbeck's submission that if the article had been properly certified for UK use, its content would have been robustly checked to ensure all claims on Abilify's efficacy and safety were in line with the licensed indications, accurate and capable of substantiation. However, incorrect and inappropriate information was included in this regard. The Panel therefore ruled breaches of the Code as acknowledged by Lundbeck. The Panel considered that the article by referring to the class of atypical antipsychotics, the dopamine D2 receptor partial agonists as offering new treatment options both in acute and maintenance schizophrenia and in the adjunctive treatment of major depressive disorder, promoted Lundbeck's product, Abilify Maintena, in a manner which was not in accordance with its marketing authorisation. The Panel ruled a breach of the Code as acknowledged by Lundbeck. High standards had not been maintained and a further breach of was ruled as acknowledged by Lundbeck.

Whilst the Panel noted Lundbeck's submissions and that a robust certification procedure underpinned self-regulation. That signatories and senior staff had not followed established Code and SOP principles in this regard resulting in an article which promoted an unlicensed indication, omitted important obligatory information and contained incorrect and inappropriate information in relation to efficacy and safety claims as acknowledged by Lundbeck brought discredit to and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

An anonymous, contactable complainant who described him/herself as a health professional, complained about the promotion of Abilify Maintena (aripiprazole) prolonged-release suspension for injection by Lundbeck Limited and in that regard provided a link to a particular webpage on the Lundbeck UK Progress in Mind Psychiatry and Neurology resource centre website.

Abilify Maintena was an atypical antipsychotic indicated for the treatment of schizophrenia in adult patients stabilised with oral aripiprazole.

COMPLAINT

The complainant stated that a Lundbeck medical science liaison (MSL) had provided him/her with information about a non-promotional educational resource website/hub where Lundbeck had written non-promotional articles for UK health professionals. The complainant was surprised to see that although the website was designed to provide non-promotional articles, there was disguised promotion of Abilify in an article entitled 'Towards new treatment options for MDD [major depressive disorder] and schizophrenia: a role for D2 receptor partial agonists' (link provided).

The complainant noted that the article mentioned the following in a disguised manner: Dopamine D2 receptor partial agonists, developed with both efficacy and tolerability in mind, were reported to offer new treatment options both in schizophrenia and in the adjunctive treatment of MDD. Despite the availability of effective antidepressants, about half of patients with MDD did not achieve an adequate clinical response – as defined by a 50% or greater reduction in depression. One effective option in such patients – and an alternative to switching or adding another antidepressant - was to augment treatment with an atypical antipsychotic. Such adjunctive therapy was supported by high quality evidence. Atypical antipsychotics had been developed with the aim of adding to existing treatment options in both MDD and schizophrenia. One such class was the dopamine D2 receptor partial agonists, thought to modulate the dopamine neurotransmission system - pending the level of endogenous dopamine - and leading to efficacy with fewer undesirable side effects, one of the presenters said. That said, the diversity in receptor profiling of the several antipsychotics approved – both from a binding affinity and intrinsic activity standpoint - offered a meaningful treatment choice to patients. Although efficacy was broadly comparable across agents, the tolerability profile was not, with D2 receptor partial agonists resulting in a lower side-effect burden in relevant domains. For each of these groups, and even when comorbidities overlapped, the D2 receptor partial agonist approach might offer valuable option in the acute and maintenance treatment of schizophrenia, he concluded. At the bottom of the article, it stated 'This Symposium was conducted with educational financial support provided by H. Lundbeck A/S'.

The complainant stated that Abilify was a well-established and well-known dopamine D2 receptor partial agonist and atypical antipsychotic promoted by Lundbeck. The article had deliberately over emphasised the mechanism of action and medicine class to mask the product name. The complainant was also concerned that the article recommended off-label usage as Abilify was licensed for maintenance treatment of schizophrenia and the article promoted it for use in depression. On the side of the page, there was also tags, with one of them listed as Dopamine D2 receptor agonists and another as treatment. The complainant was concerned that a promotional article was placed onto what was described as an educational hub for health professionals. The complainant alleged that Lundbeck had deliberately avoided the name of the medicine as it was off-label but by repeated reference to mechanism of action and atypical antipsychotics it was clear that the article was promotional for Abilify instead of being an educational article. The complainant was also concerned that the article suggested there were fewer undesirable side effects with Abilify which was not so. The article was based on a symposium that took place in Mexico which was then used to construct an inappropriate promotional article for UK health professionals including off-label recommendations.

The complainant alleged breaches of Clauses 2, 3.1, 3.2, 4.1, 4.2, 4.6, 4.9, 7.2, 7.4, 7.9, 9.1 and 12.1.

When writing to Lundbeck, the Authority asked it to consider the requirements of Clauses 2, 3.2, 4.1, 4.6, 4.9, 7.2, 7.4, 7.9, 9.1 and 12.1 of the Code as the complainant had decided not to raise Clauses 3.1 and 4.2.

RESPONSE

Lundbeck noted that the complaint related to an article provided on the Lundbeck UK Progress in Mind website which discussed a class of medicines that included aripiprazole. The complainant referred to Abilify but the marketing authorisation holder (MAH) of that medicine was Otsuka. The injection formulation of aripiprazole, Abilify Maintena, was co-promoted by Lundbeck and Otsuka. Otsuka was also the MAH for Abilify Maintena. Abilify Maintena was an atypical antipsychotic indicated for maintenance treatment of schizophrenia in adult patients stabilised with oral aripiprazole.

With regard to the staff involved, Lundbeck noted that two senior medical department employees were no longer employed by the organisation. It had therefore been difficult to understand what had happened. Both were signatories and their status and position therefore meant that their decisions on compliance matters were unchallenged by more junior and/or less experienced staff.

Lundbeck explained that the Lundbeck UK Progress in Mind website was launched in June 2019 for UK health professionals to access via a log-in. The educational website was under the governance of the medical department which was responsible for the compliance oversight of content and functionality. As was customary, the content for the UK affiliate website was created by the website developers using cloned content from the Lundbeck Global website. The Lundbeck UK Approval Standard Operating Procedure (SOP) required such content to be appropriately reviewed and approved in the company's approval system before use, to ensure its acceptability under the Code. One of the employees created a job bag for the website which he/she also certified – Lundbeck did not know why as this was expressly prohibited in the Approval SOP. The certificate for the job bag was provided.

Lundbeck explained that the article in question was developed by Lundbeck Global, for the Lundbeck Global Progress in Mind website, following a globally supported symposium held in Mexico. Lundbeck UK had no involvement in supporting that symposia or in the development of the article and the article was not intended to sit on the UK Progress in Mind website or to be provided to any UK health professional. The article made claims in relation to a class of medicines - one of which Lundbeck co-promoted, Abilify Maintena, thereby rendering the article promotional. When the Lundbeck UK website job bag was created by the employee, for reasons that were unknown to Lundbeck, it did not contain the article but, the article was a part of the cloned Global content that then appeared on the UK website. Lundbeck stated that its investigation had uncovered several discrepancies with the approval of the website. For example, there were two instances where process was not followed, as he/she had originated and approved the website job bag in June 2019 and then again in January 2020 without the article. Unfortunately, the approval and publishing of the promotional article subsequently took place without the requisite checks on content and obligatory information. Lundbeck emphasised that it did not know why the employee considered that that was acceptable and the company was unable to investigate further.

With regard to the reach of the website and article in question, Lundbeck stated that data analytics (from June 2019 to January 2021) showed that only 10 of the 90 UK health professionals who ever registered for the Progress in Mind website re-accessed the website following the day they registered. Out of those 10 registrants who revisited the website Lundbeck was confident that only one of them actually accessed the article in question, doing this on multiple occasions on the days leading up to, and on the day, that this complaint was made. In terms of finding the article following log-in, registrants would have a number of options available to them when they arrived on the website home page. In order for a health professional to find the article in question (without specifically utilising a targeted search) they would have to click through 4 pages and navigate past multiple other articles (44 in total across the 4 pages) before finding and choosing to access the article in question at the bottom of the last page. The only other way someone could arrive at the article was if a registrant copied the direct URL link in respect to the article and shared it. This would be the journey the Authority's case preparation manager would have taken, however Lundbeck noted that in following that pathway readers would still have had to accept and confirm that they were entering a site for UK health professionals, and they would still have found the article in question gated behind a registration/log-in request pop up. Lundbeck stated that in summary, the analytics were able to highlight that the reach of the article was extremely low and based on the data that Lundbeck had been able to access, only one registrant ever accessed the article in question, and consequently that health professional must therefore be the complainant.

Lundbeck stated that it suspected that the complainant was an ex-employee who had lodged several complaints in a short space of time and further details were provided. Lundbeck did not know why he/she chose to bypass the company's escalation or whistle-blowing procedures. Lundbeck stated that its investigation into these other complaints had uncovered a number of potential compliance concerns. Therefore, the website in question had already been unpublished before the company had received this complaint; the company had already decided to review everything over which the previous two employees had ownership and governance.

With regard to the alleged breaches of the Code, Lundbeck stated that the educational website was only directed at UK health professionals who needed to register their details in order to access the website content. As it was advertised as a Lundbeck educational hub, UK health professionals would therefore expect to see educational content. The article was educational, and it was also clearly promotional material for Abilify Maintena. Lundbeck noted that in the ruling for Case AUTH/3112/11/18, it was made clear that the Code did not require promotional material to be labelled as such, however, it must not be disguised, and the identity of the responsible pharmaceutical company must be obvious from the outset. As there was no disguising of the article's promotional nature nor of Lundbeck's involvement, Lundbeck refuted any breach of Clause 12.1.

Lundbeck accepted that the article constituted indirect promotion of Abilify Maintena. It was unsuitable for, and clearly never intended to be provided to, a UK audience but through the actions of an employee who certified it and allowed it to be placed on a UK website, mandatory information such as the prescribing information and adverse events reporting statement were omitted. Lundbeck regrettably accepted breaches of Clauses 4.1, 4.6, 4.9 in that regard.

Lundbeck noted that the promotional article contained indirect claims for Abilify Maintena. If it had been properly certified for UK use, its content would have been robustly checked to ensure all claims on Abilify's efficacy and safety were in line with the licensed indications, accurate and

capable of substantiation. Through the actions of the senior medical manager during the approval process, which allowed it to be placed on a UK website, incorrect and inappropriate information was included. Lundbeck regrettably accepted breaches of Clauses 3.2, 7.2, 7.4, 7.9 in that regard.

Lundbeck acknowledged that the approval standards related to the eventual placement of the article on a UK website fell short of the expectations set out in the Approval SOP. Lundbeck accepted a breach of Clause 9.1 because of the actions of the senior medical employee and the lack of oversight by a senior director.

Lundbeck stated that alleged breach of Clause 2 was a very serious matter. Whilst it accepted full liability for previous mistakes, the company was conducting a full internal audit to identify, correct and prevent risk associated with its current activities and materials. Lundbeck categorically refuted that its actions in the matter brought the industry into disrepute because the intent to publish the Global article on a UK website was disguised by the employee within the job bag. Lundbeck emphasised that publishing process and systems had immediately changed as a result of receiving this complaint, so that accidental or deliberate publishing of inappropriate content could not occur. Lundbeck further noted that the second employee had previously missed or allowed issues to occur and in that regard website oversight by a newly formed Compliance Committee would ensure issues could be identified before they constituted a breach of the Code. Lundbeck added that it had robust procedures that were not followed and it was not clear why experienced signatories and senior staff did not follow established Code and SOP principles. Finally, Lundbeck submitted that the reach of the article in question extended only to the complainant and it was very unlikely anyone else could have accessed it. Overall, Lundbeck submitted that on the balance of probabilities, the seriousness of a Clause 2 should be associated with activities that potentially harmed the well-being of patients and the reputation of the industry. On the basis of the arguments above, Lundbeck refuted a breach of Clause 2.

In summary, Lundbeck stated that it was committed to improving compliance across the organisation, as outlined in detail in its recent responses to Cases AUTH/3450/1/21, AUTH/3463/1/21 and AUTH/3466/1/21. Lundbeck considered that complaints from a disgruntled ex-employee about historical matters that had not been brought up by him/her during his/her employment demonstrated a deliberate attempt to bypass the company's whistle-blowing procedures and abuse the Panel's limited time and resources. Lundbeck was a very different organisation to when the complainant was employed. Lundbeck stated that it had recently recruited an experienced staff who had put in place a substantial corrective action plan across the company to ensure that compliance was part of the company culture. Lundbeck was determined to implement the right checks and balances, and whilst the company investigated all allegations of non-compliance, it had initiated a moratorium on a number of key promotional activities and a company-wide internal audit to ensure it identified, corrected and prevented risk associated with its current activities and materials. In addition, Lundbeck had invested significantly in the compliance training of its employees to ensure that all relevant members of staff were well versed on the expectations and requirements of the Code. It was therefore dismaying that the suspected complainant had lodged several similar complaints that served only to distract the company from its ongoing progress.

PANEL RULING

The Panel noted that Lundbeck accepted the article was promotional, however it never intended for it to be placed on the Lundbeck UK Progress in Mind website or to be provided to any UK health professional. The Panel noted Lundbeck's submission that Lundbeck UK had no involvement in supporting the Lundbeck global symposia or in the development of the article following it.

The Panel noted Lundbeck's submission regarding the activities of two former members of staff and was concerned to note that according to Lundbeck, one employee had created and certified the job bag for the Progress in Mind website and that the article in question was not in the job bag but was a part of the cloned global content that then appeared on the UK website. The company submitted that the website had been taken down before it had received the complaint. It appeared from the metrics provided by the company that only one person accessed the article.

The Panel considered that the article promoted Abilify Maintena and omitted mandatory information such as the prescribing information, and where it could be found as well as the adverse events reporting statement. The Panel ruled a breach of Clauses 4.1, 4.6 and 4.9 in that regard as acknowledged by Lundbeck.

The Panel noted that the complainant was surprised to see that although the website was designed to provide non-promotional articles he/she alleged that there was disguised promotion of Abilify in the article at issue. The Panel noted Lundbeck's submission that as the website was advertised as a Lundbeck educational hub, UK health professionals would therefore expect to see educational content such as the article which was also clearly promotional material for Abilify Maintena. The Panel further noted Lundbeck's submission that there was no disguising of the article's promotional nature nor of Lundbeck's involvement.

The Panel considered that whilst it was clear that it was a Lundbeck UK website and it was stated at the bottom of the article 'This Symposia was conducted with educational financial support provided by H. Lundbeck A/S', those reading the content of the article would not necessarily be clear from the outset that the article at issue was a report from a Lundbeck meeting which was promotional for a product co-promoted by Lundbeck. The Panel considered that the promotional nature of the article was thus disguised and ruled a breach of Clause 12.1. This ruling was appealed by Lundbeck.

The Panel noted Lundbeck's submission that if the article had been properly certified for UK use, its content would have been robustly checked to ensure all claims on Abilify's efficacy and safety were in line with the licensed indications, accurate and capable of substantiation. However, incorrect and inappropriate information was included in this regard. The Panel thus noted Lundbeck's acceptance that the material was not accurate nor capable of substantiation in relation to the efficacy and safety claims and that incorrect and inappropriate information was included. The Panel therefore ruled breaches of Clauses 7.2, 7.4 and 7.9 of the Code as acknowledged by Lundbeck. The Panel considered that the article by referring to the class of atypical antipsychotics, the dopamine D2 receptor partial agonists as offering new treatment options both in acute and maintenance schizophrenia and in the adjunctive treatment of major depressive disorder, promoted Lundbeck's product, Abilify Maintena, in a manner which was not in accordance with its marketing authorisation. The Panel ruled a breach of Clause 3.2 as acknowledged by Lundbeck.

The Panel noted its rulings above and considered that the failure to certify the material and the content of the material meant that high standards had not been maintained. The Panel therefore ruled a breach of Clause 9.1 as acknowledged by Lundbeck.

The Panel noted Lundbeck's submission with regard to the identity of the complainant and that its investigations into other complaints (thought to be from the same complainant) had uncovered a number of potential compliance concerns which resulted in the website in question being unpublished before the company had received this complaint.

Whilst the Panel noted Lundbeck's submission regarding the reach of the article in question, it noted that it was available to all health professionals registered on the website. The Panel noted that a robust certification procedure underpinned self-regulation. That experienced signatories and senior staff had not followed established Code and SOP principles in this regard resulting in an article which promoted an unlicensed indication, omitted important obligatory information and contained incorrect and inappropriate information in relation to efficacy and safety claims as acknowledged by Lundbeck brought discredit to and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

APPEAL FROM LUNDBECK

Lundbeck appealed the Panel's ruling of a breach of Clause 12.1.

Lundbeck stated that it was committed to improving compliance across its organisation and deeply regretted the mistakes that had been made. It was committed to learning from this as a business and submitted that the company was a very different organisation to when the suspected complainant was employed with responsibility for overseeing compliance and made decisions to bypass the company's processes and circumvent Code requirements.

Lundbeck submitted that the company had recruited experienced staff who had embarked on developing and implementing an all-encompassing compliance programme which included, but was not limited to:

- Formation of a Compliance Governance Committee made up of senior management
- Putting in place a corrective and preventative action plan across the company
- Substantial Code compliance training for all company employees
- Initiating a company-wide internal audit
- Reviewing and updating all company SOPs to ensure they were clear and fit for purpose
- Providing refresher training on company processes and SOPs
- Highlighting the company's whistleblowing process at all business updates and Townhall meetings

Lundbeck stated that it had also initiated a moratorium on a number of key promotional activities and had expanded its medical compliance resource (details provided).

Lundbeck hoped this reassured the Appeal Board as to the importance the company placed on its healthcare compliance responsibilities under the Code.

Lundbeck submitted that it fully appreciated previous historical issues with two ex-employees, as outlined in its original response to this case, and subsequently had accepted breaches as the article was promotional and that aspects of the article were not appropriate for a UK audience.

Therefore, Lundbeck wanted to make it clear that the reasons for this appeal was not to limit the number of breaches or to distance itself from its obligations, but to understand the Panel's ruling in relation to Clause 12.1, specifically which Lundbeck saw as a Panel mistake, that would have an impact on the whole industry's understanding.

Lundbeck submitted that it was a very different organisation that had invested significantly in its healthcare compliance programme over the last seven months and therefore as a responsible company it wanted to fully understand, and where necessary challenge, each ruling so that Lundbeck could ensure that it could fully adhere to any undertakings moving forward.

Lundbeck submitted that it would like clarification from the Appeal Board on how the ruling in this case aligned with previous Panel rulings. The Panel's ruling in this case considered that whilst it was clear that it was a Lundbeck UK website and it was stated at the bottom of the article 'This Symposia was conducted with educational financial support provided by H. Lundbeck A/S', those reading the content of the article would not necessarily be clear from the outset that the article at issue was a report from a Lundbeck meeting which was promotional for a product co-promoted by Lundbeck. The Panel therefore considered that the promotional nature of the article was disguised and ruled a breach of Clause 12.1.

Lundbeck submitted that the Panel made its decisions on a case-by-case basis. When previous rulings were ignored, this task was made even more challenging. The Code was based on both EU and UK law which relied heavily on case precedent when considering matters; it should be the same in the self-regulatory environment. Of relevance, in this case, was Lundbeck's understanding of the Panel's previous rulings below:

- 1 In Case AUTH/3213/6/19, the complainant alleged that information at a Janssen meeting was indirectly promotional and therefore not appropriate for a medical educational event and was in breach of Clause 12.1.

The Panel noted that promotional material did 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 stated that given Janssen'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.

- 2 In Case AUTH/3321/3/20, the complainant alleged material hosted on the Guidelines in Practice website and produced by A Menarini, was disguised promotion for Ranexa, citing a breach of Clause 12.1.

The Panel considered health professionals visiting the webpage would be immediately aware that the material was developed by A Menarini and would be likely to assume that it would include information on A Menarini's medicines and therefore be promotional. Therefore, the online promotional material was not disguised.

- 3 In Case AUTH/3112/11/18, the complainant alleged the Eli Lilly rheumatology website was unclear whether it was promotional or not.

The Panel noted that the Code did not require promotional material to be labelled as such, however, it must not be disguised, and the identity of the responsible pharmaceutical company must be obvious from the outset. Context was important. The Panel considered

it would be sufficiently clear to health professionals who accessed this website that it was a Lilly website and that it was promotional, and no breach of the Code was ruled.

- 4 In Case AUTH/3438/12/20, a complainant who described him/herself as a concerned member of the general public, complained about the use of LinkedIn by Pfizer UK Ltd to promote its Covid-19 vaccine.

The Panel considered that the LinkedIn post was clearly promotional; it was a positive message about a Pfizer medicine being shared by a senior employee. The Panel did not consider that the promotional nature of the material was disguised and so no breach of the Code was ruled.

Lundbeck submitted that the identity of the pharmaceutical company was clear on all the materials used to advertise the Progress in Mind website to health professionals with the presence of the Lundbeck logo and/or the disclaimer 'This website had been developed by Lundbeck for UK health professionals only'. The presence of the Lundbeck logo was on the web pages of the PiM website including the website landing page, with the strap line 'BROUGHT TO YOU BY...*Lundbeck logo*' which had to be navigated, following clinician registration, in order to access the article in question. This company involvement was then further reinforced by the disclaimer at the bottom of the article 'This Symposia was conducted with educational financial support provided by H. Lundbeck A/S'.

Lundbeck submitted that in full alignment with previous Panel rulings, on the balance of probabilities, it was apparent that Lundbeck's involvement was obvious at the outset, which was supported by the Panel's own submission in the case report that 'it was clear that it was a Lundbeck UK website'. Lundbeck submitted that it therefore respectfully urged the Appeal Board to consider the Panel's own historical submissions that 'promotional material did not need to be labelled as such as long as the identity of the responsible pharmaceutical company or a pharmaceutical company's involvement must be obvious at the outset' and overturn this breach.

Lundbeck submitted that the complainant made it clear that the article was obviously promotional to them and reiterated this on several occasions. The Panel, and Lundbeck, agreed that it was obviously promotional and subsequently all breaches in relation to the provision of obligatory information for promotional materials were sanctioned and accepted respectively. As such, on the balance of probabilities, the article hosted on a Lundbeck website, with a Lundbeck disclaimer and Lundbeck logos was clearly promotional to health professionals, confirmed by the complainant, who described themselves as such.

Lundbeck submitted that it was very confusing that the Panel also stated that it 'would not necessarily be clear from the outset that the article at issue was a report from a Lundbeck meeting which was promotional for a product co-promoted by Lundbeck.' In Lundbeck's opinion, an article was either obviously promotional or disguised promotion, but it could not be ruled to be both. A breach of Clause 12.1 would contradict other rulings and had an impact on the wider industry in terms of understanding and adherence. In terms of Lundbeck's own adherence to such an undertaking, examples were given below of the difficulties in practical implementation:

- Promotional Webpages/Websites: Would they require declaration of company involvement at the top of the first page or each page so that it was clear from the outset that the content will be promotional? Would this be needed even though company

involvement was made clear to a visitor when they access the website and confirmed they were a health professional, and then again through a declaration on embedded content/ articles?

- What was considered as 'at the outset' particularly with promotional digital assets appearing on pharmaceutical company's own websites? If every webpage was considered 'standalone' then did this ruling now mean that a declaration was needed at the top of each page, even though it was clear that the page was on a pharmaceutical company website.

In summary, Lundbeck fully accepted that mistakes were made in relation to this website which resulted in the appearance of this inappropriate promotional article and as such Lundbeck had accepted all the relevant breaches of the Code ruled by the Panel. However, as the company had outlined above, it submitted that there was no disguised promotion as Lundbeck, the complainant and the Panel agreed it was obviously a promotional article hosted on a Lundbeck website, which was clear from the outset.

Lundbeck submitted that it had strived to understand and adhere to previous Panel rulings and submitted that the consequential inconsistency through upholding this breach would only serve to add to the industry's confusion on how best to comply with the Code.

As highlighted in Lundbeck's original response and at the outset of this letter, Lundbeck was a very different organisation now having invested significantly in healthcare compliance in order to develop a wide-reaching compliance programme which enabled increased oversight and governance of all its activities. Therefore, as a responsible company Lundbeck wanted to understand each of the rulings and the practical implications of any subsequent undertakings. Lundbeck asked the Appeal Board to consider its appeal and the implications of the Panel's ruling with regard to disguised promotion in this case and utilise its powers to overturn this breach.

COMMENTS FROM COMPLAINANT

The complainant provided no comments on the appeal.

APPEAL BOARD RULING

The Appeal Board noted that pharmaceutical company websites were not always promotional for the company's medicines. In addition to the content of a website or webpages, context was an important consideration. For example, often a landing page would identify which sections of a website were for which audience.

The Appeal Board did not consider that the nature of the circumstances in the cases cited by Lundbeck (Case AUTH/3213/6/19, 3321/3/20, 3112/11/18 and 3438/12/20), in which no breach of Clause 12.1 was ruled, were similar to this case. Further, each case was considered based on its own particular merits.

The Appeal Board noted Lundbeck's submission that the website was advertised by the company's MSLs as a Lundbeck educational hub; the objective of the website was to support clinicians with resources. Whilst the material used to advertise the website referred to the website as a resource centre and it was clear from both the material and the website that it was

a Lundbeck website for health professionals only, there was no mention that the website would include discussion of the company's products.

The Appeal Board considered that in the circumstances UK health professionals would not necessarily expect the content of the website to be promotional. The Appeal Board noted Lundbeck's submission that the promotional article should not have appeared on the website in question and that the website was certified as non-promotional. The Appeal Board further noted the description of Lundbeck's involvement at the bottom of the article in question that 'This Symposia was conducted with educational financial support provided by H. Lundbeck A/S' rather than at the outset. In the Appeal Board's view, this added to the impression that the material was not promotional. Given the context in which the article appeared and the explanation of the company's involvement, the Appeal Board considered that those reading the article would not be clear from the outset that the article was based on a report from a Lundbeck meeting regarding a product co-promoted by Lundbeck or that it was promotional. The Appeal Board considered that the promotional nature of the article was thus disguised and upheld the Panel's ruling of a breach of Clause 12.1. The appeal was unsuccessful.

Complaint received 14 January 2021

Case completed 10 November 2021