CASE AUTH/3723/1/23 ***NO BREACH OF THE CODE***

COMPLAINANT v LUNDBECK

Allegations about market research

CASE SUMMARY

This case was in relation to market research commissioned by Lundbeck A/S (Lundbeck Global) and Otsuka Europe Ltd that took place annually between 2018 and 2021. The case in relation to Otsuka was proceeded with under Case AUTH/3722/1/23.

The complainant's allegations concerned the content of the market research, which they alleged had a promotional purpose.

The outcome was:

No Breach of Clause 9.1 (2016 Code)	**Requirement that high standards must be maintained at all times**
No Breach of Clause 12.2 (2016 Code)	**Requirement that market research activities must not be disguised promotion**
No Breach of Clause 9.1 (2019 Code) (x2)	**Requirement that high standards must be maintained at all times**
No Breach of Clause 12.2 (2019 Code) (x2)	**Requirement that market research activities must not be disguised promotion**
No Breach of Clause 5.1 (2021 Code)	**Requirement that high standards must be maintained at all times**
No Breach of Clause 25.4 (2021 Code)	**Requirement that market research activities must not be disguised promotion**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

A complaint was received from an anonymous, contactable complainant about market research commissioned by Lundbeck A/S (Lundbeck Global) and Otsuka Europe Ltd. The case in relation to Otsuka was proceeded with under Case AUTH/3722/1/23. The complainant stated that they were representing a group of employees and former employees of Otsuka EU and Lundbeck.

COMPLAINT

The complainant stated:

> '*I would like to point out that from 2018 until this year* [2022]*, repetitive and similar market research* [(MR)] *has been manaide* [sic] *by Otsuka Europe Ltd and then carried out in the various EU countries. It has been brought to the attention of Otsuka Europe Ltd on many occasions that in the market research questionnaire*

was repeatedly naming the product brand name (Abilify Maintena) and that this was obviously an activity [with] *promotional purposes. Furthermore, in the questionnaires, each year, they asked to the HCP* [(health professional)] *basically to transcribe data from the patient's clinical records in the MR's patient form, diagnosis, treatment, management, reactions, efficacy, etc... many times it has been reported by colleagues of the medical departments that they seemed Clinical study's question instead of MRs questions. Moreover, the internal procedure of Otsuka Europe Ltd does not provide for any filter by European compliance, on the European minimum requirements for MRs materials and questionnaire, EU Compliance review the purpose or the design of the MR, but they do not review the questionnaire* [and] *several time the comments received from affiliate on compliance topics are not considered and Otsuka Ltd do not apply any change. Please find below an example, that is a part of one of the questionnaires of these years, in 2022 the questions were slightly modified in grammatical terms but the meaning is the same. Trying to hide the real purpose, the investigation of patient clinical records and HCPs prescription habits they arrived at absurd questions such as "please* [now] *think of the last 3 hypothetical patients you have seen in the last month".*'

The complainant provided the following example:

'*Patient Record Form section. For statistical reasons, it is important that you think not about the patients you might consider most interesting or significant, but EXACTLY THE LAST 3 PATIENTS YOU VISITED. Now concentrate and look at the patient records of the last 3 schizophrenia patients you personally saw who are treated with atypical LAI antipsychotics. Enter the patient's year of birth: _____ When were you diagnosed with schizophrenia? Select the month and year. _____ _____ (month) (year) Which symptoms of schizophrenia are predominant for this patient? How many schizophrenia-related relapses has this patient experienced? What is this patient's level of functioning? Which healthcare facility referred this patient to your attention? What atypical LAIs is the patient taking? 1. monthly aripiprazole 2. olanzapine pamoate extended release 3. risperidone LAI 4. monthly paliperidone palmitate 5. Paliperidone palmitate administered quarterly. In which healthcare facility was the patient initiated? When did the patient start taking the current atypical LAI antipsychotic (<Scripter: Placeholder for current drug name>)? Select the month and year. _____ _____ (month) (year) Patient received a different antipsychotic (oral or injectable) prior to current atypical LAI antipsychotic. What antipsychotic did the patient receive prior to the current atypical LAI antipsychotic? List of LAI and oral antipsychotics follows. Overall, how many different types of LAI antipsychotics (typical or atypical) has this patient received over time? Which of the following best describes what happened during your last visit to this patient? Now complete the patient record form of the second patient of the last 3 suffering from schizophrenia that you see personally and who are receiving atypical LAI antipsychotics. Now complete the patient record form of the third patient of the last 3 suffering from schizophrenia that you see personally and who are receiving atypical LAI antipsychotics.*'

FURTHER INFORMATION FROM THE COMPLAINANT

The complainant stated that Otsuka Europe Ltd was the marketing authorisation holder of Abilify Maintena and the EU Otsuka headquarters, this meant that they would be legally and ethically responsible for EU affiliates and for the co-promoter companies.

The complainant stated that, in this case, Otsuka Europe Ltd and Lundbeck were contract owners for the market research. They selected and engaged the market research agency that managed the market research and the review, approval and distribution of the material in the European countries, including the UK.

The complainant stated that the agency interviewed at least 100 UK health professionals each year from 2017 to 2022 and 100 more health professionals from each other country (Spain, Germany, Italy and so on). Each year, the same questionnaire was used (repetitive market research) and every time they asked the health professional to transcribe the clinical data of the last three patients they saw into a specific patient record form. In some cases, the health professional was asked to think about the last three virtual or hypothetical patients they saw and to transcribe the clinical data into this virtual patient data form. The complainant alleged that the clinical data of the patient would be used just in a clinical study and not in market research.

The complainant stated that Otsuka Europe should have the certification of all the materials and should be able to review and check UK and EU requirements.

When writing to Lundbeck, the PMCPA asked it to consider the requirements of Clauses 12.2 and 9.1 of the 2016 and 2019 Codes and Clauses 5.1 and 25.4 of the 2021 Code.

LUNDBECK'S RESPONSE

Lundbeck noted that the PMCPA had received a complaint from an anonymous contactable complainant who had made allegations about market research activities contracted by Otsuka and Lundbeck between 2017/2018 and 2022.

Lundbeck stated that the complaint related specifically to activities in relation to the medicine Abilify Maintena (aripiprazole) that Lundbeck co-promoted with Otsuka, who was the marketing authorisation holder for the medicine.

Lundbeck stated that it took this complaint very seriously and had carried out as thorough an investigation as possible, based on the information the complainant had provided in their communications to the PMCPA.

Lundbeck's response is set out below, following the company's investigations.

Complaint and alleged breaches

Lundbeck provided a summary of the complainant's allegations in relation to the market research activities referred to in the period of 2018–2022, as they applied to Lundbeck, outlined below:

- That Lundbeck and Otsuka undertook repetitive and similar market research during this period, which involved a questionnaire that repeatedly named the company's product brand name (Abilify Maintena). Therefore, the activity was an activity with a promotional purpose, thus the inferred allegation was that of a breach of Clause 25.4 (2021 Code) (Clause 12.2, 2016 & 2019 Code) and subsequently a breach of Clause 5.1 (2021 Code) (Clause 9.1 2016 & 2019 Code).

- That the market research requested the health professional to transcribe data from patients' clinical records and that these questions were more akin to clinical study questions instead of market research questions. Therefore, the complainant alleged that the real purpose of the market research was to investigate patient clinical records; subsequently the inferred allegation was that of a breach of Clause 5.1 (2021 Code) (Clause 9.1 2016 & 2019 Code).

Response

In order to address the allegations made by this anonymous complainant in a clear and concise manner, Lundbeck had broken down its response into five different sections:

A. Background to the market research
B. Background to the market research in the UK
C. Participant selection for market research in the UK
D. Allegation around the market research having a promotional purpose
E. Allegation around the market research as a means of investigating patient clinical records

A. Background to the market research

Lundbeck noted that the complainant did not attach the market research their complaint was in relation to; however, based on the information they had shared, Lundbeck were confident it related to an Abilify Maintena Awareness, Trial, and Usage (ATU) tracking market research project contracted and funded jointly by H. Lundbeck A/S (Global) and Otsuka OPEL (Europe) in a selection of countries across the globe, including the UK, between 2018 and 2022. Lundbeck stated this market research was conducted by expert global market research companies, on behalf of both companies, with psychiatrists from these selected countries.

Lundbeck submitted that the global objective of this market research was to gauge the awareness of the usage of the different medicines within the schizophrenia therapy area and to better understand the drivers for relevant clinicians in this area for prescribing the different medicines available. Additionally, the market research sought to gain a better understanding from across the clinicians of the patient profile(s) that Abilify Maintena (aripiprazole), in a long-acting injection formulation (LAI), was most suitable for. Lundbeck submitted this would allow the companies to gain a general view on how their medicine was perceived by relevant clinicians across a selection of countries, compared to other relevant medicines, and the types of patients that health professionals deemed suitable to prescribe the medicine for, which would subsequently help shape future company global commercial strategy for the brand.

Lundbeck submitted that this extremely valuable activity, which was adopted by most pharmaceutical companies in the industry, was then typically repeated at significant time periods (approximately 12–18-month intervals, if deemed appropriate) to allow the companies to understand how both environmental and strategy changes had impacted on the awareness, perception, and usage of their medicine, as well as the other medicines in the therapy area. Lundbeck stated it was extremely effective at enabling the companies to gauge how changes to their brand campaigns and messaging was resonating and being received by clinicians, or not, as might also be the case. Lundbeck submitted that this was educational for the companies and ensured that they were able to secure important feedback from a small sample of relevant clinicians in the field following often very expensive investments in the brand, from updates to campaign materials to recruitment of representatives. Additionally, it allowed companies to understand and appreciate the impact of significant changes to global and local healthcare

environments which could often result in substantial changes to the access and usage of their medicine, and all relevant medicines, in the therapy area. A prominent recent example of this could be seen with the difficulties created by the global COVID-19 pandemic which had posed sustained challenges to patients' access and adherence to certain medication, and subsequently changes to clinicians' prescribing habits in order to provide solutions to the rolling challenges they had been experiencing.

B. Background to the Market Research in the UK

Lundbeck stated that the UK was selected as one of the countries to take part in the aforementioned Global Market Research Project.

Lundbeck submitted that, similarly, to its Global colleagues, Lundbeck UK saw the value in the objective of this market research project, especially as the UK affiliate were making a number of significant strategic brand changes during this time. Notably, the UK affiliate planned to make significant changes to the Abilify Maintena Brand Campaign in late 2018, which followed the planned read out of Wave 1 of the market research in question in June 2018. There was then also a further campaign evolution globally in late 2020, which was adopted in the UK in 2021 as changes to the product's campaign materials were implemented following significant healthcare environmental changes (i.e. the COVID-19 pandemic).

Lundbeck UK stated that it was very aware of the impact that the COVID-19 pandemic was having on the NHS from early 2020 all the way through to 2022, particularly in terms of patient access to care and treatments for conditions such as schizophrenia, and the impact that this was having on medication adherence, among other things. Therefore, it wanted to gauge the impact of this pandemic on medicine usage in the area, which was particularly relevant for Abilify Maintena as it was a long-acting injection (LAI) which could therefore potentially provide a solution for patients in areas where regular healthcare access and utilisation was a challenge due to the rolling COVID restrictions in place.

Lundbeck submitted that the UK team therefore needed to make sure that they were aware of the impact that these various factors were having on clinicians' perception of the different medicines, and whether it was resulting in a change to the patient profile(s) that would be most appropriate to be prescribed its product. As a result, the quality of the outputs and feedback provided by the market research project in question were invaluable as Lundbeck sought to make strategic changes, for these various reasons, throughout the time period in question.

Lundbeck noted that the Panel should be aware, however, that Lundbeck did appreciate that market research in the UK must follow the guidance outlined in the Code and the British Healthcare Business Intelligence Association (BHBIA) guidelines.

Lundbeck submitted that the format of this market research was an online questionnaire (approved copies of the screener and questionnaire for each wave were provided). Lundbeck requested that the Panel note that there were several different versions of the screener and questionnaire used during the course of the fieldwork for each wave. This was primarily due to the nature of the activity spanning numerous countries and the need over time to adapt the screener to achieve a sufficient sample size (copies of the different fielded versions used for each wave across the different countries which included the UK were provided). Lundbeck stated that only materials approved in the UK were used in the UK (with UK health professionals) and any changes to materials that impacted the UK were agreed and approved by the companies.

C. Participant selection for market research in the UK

Lundbeck submitted that, in the UK, the third-party expert market research agency, [NAMED] was responsible for securing the relevant participants for this piece of research. Across the four waves of market research conducted between 2018 and 2021, three methods of recruitment were utilised to secure participants. The three methods of recruitment are listed below:

- Panel-matched recruitment from the market research agency (fieldwork partner) panel
- Recruitment directly from a target list of psychiatrists
- Randomised recruitment from the market research agency panel.

The target list comprised psychiatrists visited by the respective companies in relation to Abilify Maintena within a specified time period, e.g. within the last 12 months. For the panel-matched recruitment, the market research agency's fieldwork partner matched psychiatrists on the target list against their panel of health professionals. The individuals taking part in the market research remained anonymous to Otsuka and Lundbeck regardless of the recruitment methodology. The objective of using the target list or panel matching was to assess whether the aforementioned, and described, marketing activities and investments by the company showed an effect in the results of the ATU tracking and outputs.

Lundbeck stated that, in terms of participant numbers, the projects sought to secure enough participants to allow for a subgroup analysis as highlighted in the market research output documents and therefore only sufficient numbers to achieve the pre-agreed objectives of the market research. This sample size was assessed and considered satisfactory to the UK affiliate when the size of the therapy area was evaluated, as highlighted below.

Lundbeck submitted that the sample size of participants included in this market research could in no way be alleged to be widespread or disproportionate to the number of clinicians working in this therapy area in the UK. Lundbeck submitted that the sample size was sufficient to achieve the objectives of the research whilst being small relative to the number of psychiatrists in the UK, as confirmed by the Royal College of Psychiatrists Census of 20211, which showed that there had been an increase in the total number of Consultant Psychiatrist posts (headcount) from 5932 in 2017 to 7782 in 2021. This number did not take into consideration other working Psychiatrists who were not fulfilling consultant posts, who would also be included in the random pool held by the market research agency. Lundbeck submitted that these statistics supported its stance that the sample size was proportionate and appropriate for the objectives of the market research and the number of (relevant) clinicians in the UK.

D. Allegation around the market research having a promotional purpose

Lundbeck stated that the response as outlined thus far had sought to establish to the Case Preparation Manager and, potentially, the Panel that the market research activity in question had a clearly defined and valid objective. It had highlighted that the participants that were selected to take part in the research were the correct relevant, anonymised, participants (psychiatrists) and that the number of participants did not in any way exceed that which was required to achieve the objective, nor was it disproportionate to the size of the therapy area.

From this point, Lundbeck focused its response on the market research material itself and specifically the allegations from the complainant that it repeatedly named the company's product

brand name and was repetitive in nature and therefore was an activity with a promotional purpose.

Lundbeck submitted that the market research approved and used in the UK only made mention of the company's product brand name when it was imperative to the question being asked and ultimately the objective of the research activity, and in all instances, it was mentioned alongside the brand names of other companies' products. In addition to this, when the medicine or brand names were required to be mentioned in the market research, the order in which they appeared was randomised for each participant. This could be seen in the 'programming notes' throughout the market research in question.

Lundbeck submitted that the use of a product/brand name was allowed under the Code, provided it was required to achieve the objective of the market research, and was in accordance with section 5.2 of the BHBIA guidelines which stated:

> 'You must avoid brand names as much as possible. Using them unnecessarily or repeatedly could make your MR [market research] look like promotion. Use 'Product X' unless:
>
> − reaction to the name or its visual representation is an objective
>
> − using a name is essential to the interpretation of the stimulus, and this is in turn essential to the study objectives
>
> − you need to refer to a specific product e.g. in brand tracking. If possible, compare with other brands to reduce the product's standout and so reduce the risk of the MR being considered promotion.'

Lundbeck submitted that, considering the objective of this market research, it was essential for clinician recall to include the product brand names to ensure that the market research achieved its primary research purpose, as previously outlined.

Lundbeck stated that the complainant also alleged that the market research was repetitive and similar. Lundbeck submitted that, as previously described, to meet its objective it was necessary to repeat the market research to monitor the uptake within the LAI antipsychotic class and track the relative importance of treatment characteristics for LAI prescribing across this class over time. Lundbeck submitted that the period between waves of the market research was approximately 12 months, during which time there were significant changes in market dynamics and the companies needed to be aware of this in order to inform their activities.

Therefore, considering everything outlined above, Lundbeck refuted the allegations by the complainant that there was repeated use of the company's product brand name across the market research materials, which thus gave it a 'promotional purpose' or that the Market Research activity was in any way repetitive in order to disguise a promotional intent. Lundbeck submitted that the market research in question, as carried out in the UK on behalf of Lundbeck, followed the BHBIA guidelines and the Code, and had a clear legitimate business purpose and, as such, Lundbeck refuted the alleged breaches of Clause 25.4 (2021 Code) (Clause 12.2, 2016 and 2019 Code) and subsequently a breach of Clause 5.1 (2021 Code) (Clause 9.1 2016 and 2019 Code).

E. Allegation around the market research as a means of investigating patient clinical records

Lundbeck stated that, in addition to the allegation around the market research having a promotional purpose, the complainant had also alleged that it requested the health professional to transcribe data from patients' clinical records and that these questions were more akin to clinical study questions, therefore the real purpose of the market research was to investigate patient clinical records.

Lundbeck stated that it adamantly refuted this allegation. This section of the market research asked the participating psychiatrists to recall the last three patients that they had seen and to whom they had prescribed an LAI treatment. Lundbeck submitted that there was no request for the clinician to transcribe confidential patient information as implied, and the purpose of the questions in this section was to get an anonymous understanding of the profile of the patient(s) who clinicians would prescribe an LAI for. The project would then allow the companies to see if there was a consistent profile that emerged and then gauge whether this changed as the healthcare environment changed and/or as the companies refined and invested in the brand strategy. Lundbeck submitted that this important feedback would enable the outputs of the market research to be used in evolving the brand campaign materials of the product as previously highlighted earlier in the response.

Lundbeck submitted that the European Pharmaceutical Market Research Association (EPHMRA) Code of Conduct 2022 provided differentiation between market research and non-market research and non-interventional studies:

> 'Market Research is carried out for a commercial purpose i.e. to investigate market behaviour and opportunities to inform business decision making, clinical endpoints are not needed for Market Research.'

Whereas:

> 'Non-interventional research is carried out for a clinical purpose i.e. to assess safety, efficacy or tolerability, its ultimate purposes are to advance science, the treatment of disease, and improve patient outcomes.'

The EPHMRA Code of Conduct 2022 further stated:

> 'Even Market Research that involves the collection of anonymised patient data detailing conditions, symptoms and treatments this does not mean it is non-interventional research. Market Research using anonymised patient record data is analysed in aggregated form to generate information upon market patterns.'

This patient data presented in the subsequent market research output reports was anonymised and aggregated and allowed the companies to track treatment dynamics as well as anonymously understand, among other things, the typical gender, age, symptoms, referral pathway and disease severity of the patients that would be prescribed an LAI antipsychotic treatment. This would be very typical of market research of this nature, and it was made clear to the clinician at the outset of the activity that these questions would be asked. Lundbeck did not see it as a breach of any guideline or Code requirement to seek to ascertain this information in this anonymous aggregated manner in an activity like this and therefore refuted a breach of Clause 5.1 (2021 Code) (Clause 9.1 2016 & 2019 Code) on this point as well.

Summary

In summary, Lundbeck hoped the Case Preparation Manager and the Panel were reassured by the comprehensive nature of this response, that it reflected the thoroughness of Lundbeck's investigation and that the company took all complaints extremely seriously.

Lundbeck submitted that the response outlined above demonstrated this market research project was conducted with a clear and legitimate educational purpose to understand changes in the awareness and usage of different medicines within the schizophrenia therapy area. Specifically, to understand how awareness and usage had changed following the evolution of brand campaigns and the impact of the COVID-19 pandemic. Lundbeck submitted that the response also highlighted that the market research was in no way developed with a promotional purpose or to in some way disguise promotion to participating UK health professionals. Lundbeck stated that the questions posed were legitimate and justified, and contrary to the complainant's allegation were not in any way an attempt to disguise promotion or investigate patients' clinical records. Participant's identities were anonymous to Lundbeck, furthermore, the total number of participants represented a small percentage of the total profession. Subsequently, Lundbeck maintained that there had been no breach of the Code in relation to disguised promotion and at all times the high standards expected by the industry were met and maintained.

Lundbeck appealed to the Case Preparation Manager, on receipt of this response, to avail of the powers granted to them (by Section 5.5 of the PMCPA Constitution and Procedure) and make the determination that based on what had been submitted by the complainant, and subsequently Lundbeck in response, that there had been no *prima facie* case established.

Lundbeck asked that the complaint, as it related to Lundbeck, be dismissed.

FURTHER RESPONSE FROM LUNDBECK

After giving preliminary consideration to the case, the Panel asked Lundbeck to confirm whether the final form of the screener/questionnaire for each wave of the market research was examined in accordance with the requirements of the Code, having noted Lundbeck's statement that '… any changes to materials that impacted the UK were agreed and approved by the companies'.

Lundbeck requested clarification as to why the Panel had requested confirmation that the final form of the market research materials was examined. Lundbeck submitted that there was no requirement for examined materials to be in the final form.

Lundbeck submitted that the specific allegation from the complainant was in regard to market research material having a promotional purpose and concerns that market research participants had been asked to transcribe patient data. There was no allegation related to how Lundbeck had reviewed or approved the market research materials and, specifically, that the final form of the market research had not been examined. Lundbeck noted that it was an established principle under the Code that the Panel can only consider the matters alleged by the complainant. This was demonstrated in Case AUTH/2473/1/12 which stated 'The Constitution and Procedure did not permit the Panel to consider matters which were not the subject of a complaint or voluntary admission and thus it could not rule on this matter.'

PANEL RULING

The Panel noted that Otsuka Europe was the marketing authorisation holder for Abilify Maintena (aripiprazole), an atypical long acting injectable (aLAI) antipsychotic, which was supplied in the UK by Otsuka UK and Lundbeck under a co-promotion agreement. There were several formulations of aripiprazole available in the UK, most of which were in tablet form and were available from several companies; Abilify Maintena was the only injectable form of aripiprazole available in the UK.

The Panel noted that the complainant alleged that market research by Otsuka Europe Ltd and Lundbeck was repetitive and promotional in nature. The complainant alleged that the market research questionnaire repeatedly mentioned the product brand name (Abilify Maintena) and that the questions seemed more like clinical study questions than market research questions.

The Panel noted that the market research, which was an online questionnaire, had been undertaken in a number of countries, including the UK. The Panel noted that the use of the market research in the UK was not unacceptable, providing it complied with the requirements of the Code. Clause 25.4 of the 2021 Code (Clause 12.2 of the 2016 and 2019 Codes) stated that market research activities, clinical assessments, post-marketing surveillance and experience programmes, post-authorisation studies (including those that were retrospective in nature) and the like must not be disguised promotion. They must be conducted with a primarily scientific or educational purpose. The supplementary information referred to the Legal and Ethical Guidelines for Healthcare Market Research produced by the British Healthcare Business Intelligence Association (BHBIA). It also stated that market research must be unbiased and non-promotional and that market research material should be examined to ensure that it does not contravene the Code.

The Panel noted Lundbeck's submission that this complaint related to an Abilify Maintena Awareness, Trial, and Usage (ATU) tracking marketing research project contracted and funded jointly by H. Lundbeck A/S (Global) and Otsuka OPEL (Europe). The Panel noted Lundbeck's submission that the objectives of this market research were to gauge awareness of the usage of the different medicines within the schizophrenia therapy area, to better understand the drivers for prescribing the different medicines available, and to better understand the patient profile(s) that Abilify Maintena was most suitable for. This would subsequently help shape future company global commercial strategy for the brand.

The Panel noted that the market research was conducted once each year between 2018 and 2021 (referred to as waves 1 to 4); copies of the screener and questionnaire were provided by Lundbeck for each wave.

In relation to the complainant's allegation that the series of questionnaires was repetitive, the Panel noted Lundbeck's submission that this type of activity was adopted by most pharmaceutical companies and that it was typically repeated at appropriate intervals to allow the companies to understand how both environmental and strategy changes had impacted on the awareness, perception and usage of their medicine and other medicines in the therapy area.

In relation to the complainant's allegation that the market research was promotional and repeatedly mentioned the product brand name, the Panel noted Lundbeck's submission that the questionnaire only made mention of the company's product brand name when it was imperative to the question being asked and ultimately the objective of the research activity, and in all instances, it was mentioned alongside the brand names of other companies' products, with an

instruction to randomise the order in which the products appeared. The Panel examined the template market research questionnaire for each wave and noted that where Abilify Maintena was mentioned by name, this was followed by a list of other products and it appeared that on each occasion the scripter was directed to randomise the list order for each participant. The Panel also noted that where Abilify Maintena was one of the products mentioned by name identification of the products by brand appeared to be necessary to the question.

In relation to the complainant's allegation that the questions seemed more like clinical study questions than market research, the Panel noted that Lundbeck adamantly refuted this allegation. Lundbeck submitted that there was no request for the clinician to transcribe confidential patient information as implied, and the purpose of the questions in this section was to get an anonymous understanding of the profile of the patient(s) who clinicians would prescribe an LAI for.

In this regard, the Panel noted that the questionnaire asked the participant to provide information about the last three adult patients diagnosed with schizophrenia the participant had seen who had received an aLAI antipsychotic as the primary treatment for schizophrenia (not the last three hypothetical patients, as alleged by the complainant). The questionnaire also stated that the patient must not be participating in any clinical trials and should currently be personally treated by the responding psychiatrist; and that participants should have the actual patient records at hand when completing this section of the market research. Instructions to the participant made it clear that patient identifiable information should not be given.

The Panel noted the distinction between market research and non-interventional study research made by the European Pharmaceutical Market Research Association (EPHMRA), as cited by Lundbeck in its response. The Panel noted Lundbeck's submission that the objective of the market research was 'to gauge awareness of the usage of the different medicines within the schizophrenia therapy area' and that the patient data was 'anonymised and aggregated'. The Panel considered that neither the questionnaires nor the outcome reports went beyond the stated business objectives of the market research.

The Panel considered that the overall objective of the market research, as stated by Lundbeck and evidenced in the questionnaires and outcome reports provided, appeared to address a legitimate business matter. The Panel considered that it was not unreasonable for a pharmaceutical company to conduct market research to monitor and track the position of a particular medicine within a class and to gain an understanding of the factors affecting prescribing, provided it met the requirements of the Code.

The Panel, noting all of its comments above, did not consider that either the content of the market research questionnaires or the way in which the market research was conducted was promotional for the reasons alleged by the complainant. The Panel accordingly ruled **no breaches of Clause 12.2 of the 2016 Code (Wave 1), Clause 12.2 of the 2019 Code (Waves 2 and 3) and Clause 25.4 of the 2021 Code (Wave 4)**.

The Panel noted the complainant's allegation that 'the internal procedure of Otsuka Europe Ltd does not provide for any filter by European compliance, on the European minimum requirements for market research materials and questionnaire, EU Compliance review the purpose or the design of the market research, but they do not review the questionnaire'. The Panel noted the broad nature of the allegation which appeared to refer to the review and approval process. The Panel also noted that the allegation appeared to be directed at the approval process within Otsuka (considered under Case AUTH/3722/1/23) and that Lundbeck

had offered no substantive comments in this regard, although it did provide certificates for the screeners/questionnaires as part of its submission and did state that 'only materials approved in the UK were used in the UK (with UK [health professionals]) and any changes to materials, that impacted the UK, were agreed and approved by the companies.'

The Panel noted that Clause 8.3 of the 2021 Code (Clause 14.3 of the 2016 and 2019 Codes) did not require that market research materials were certified. The relevant Supplementary Information (Examination of Other Material), and the Supplementary Information to Clause 25.4 of the 2021 Code (Clause 12.2 of the 2016 and 2019 Codes) (Market Research), provided that they should be examined to ensure they did not contravene the Code or the relevant statutory requirements. The Panel noted that these clauses had not been cited by the Case Preparation Manager and therefore considered the broad allegation relating to review and approval under Clause 5.1 of the 2021 Code (Clause 9.1 of the 2016 and 2019 Codes).

The Panel noted that Lundbeck and Otsuka had submitted separate and distinct responses to the complaint and the Panel had to consider the evidence in relation to each case separately. The two responses were not entirely consistent. The Panel noted this was a co-promotion arrangement whereby the companies would be jointly responsible for the activity and materials, the questionnaire etc. The companies had not made any detailed submissions about the examination arrangements, whether each company examined market research material separately or whether there were joint arrangements with one signatory. However, the Panel noted that it had to consider the matter in relation to the allegations raised and the evidence before it in each separate case.

In relation to the examination and approval, whilst the Panel was concerned about Lundbeck's submission about examination of the final form, in the Panel's view the allegation of a failure to maintain high standards was very clearly limited to the complainant's concerns about certain matters within Otsuka. There was no allegation about this matter in relation to Lundbeck. In this regard, the Panel ruled **no breaches of Clause 9.1 of the 2016 (wave 1) and 2019 (waves 2 and 3) Codes** and **no breaches of Clause 5.1 of the 2021 Code (wave 4)** in relation to Lundbeck. The Panel nonetheless noted with concern the differences between the companies' responses on this point.

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During its consideration of this case the Panel noted Lundbeck's submission that 'there is no requirement for examined materials to be in the final form'. The Panel considered that, while the examination of material to ensure that it did not contravene the Code or the relevant statutory requirements did not require a certificate, it was clear that a signatory or an appropriately qualified person (AQP) was required to examine the version of the material that was ultimately used.

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Post-hoc note: After the completion of this case, an appeal was heard by the Code of Practice Appeal Board for the associated case in relation to Otsuka Europe (Case AUTH/3722/1/23). Readers are advised to refer to the Appeal Board's determination in relation to examination of materials in that case.

Complaint received **9 December 2022**

Case completed **4 April 2024**