CASE AUTH/3059/8/18

ANONYMOUS, NON-CONTACTABLE v LUNDBECK

Company webpage and certification of promotional material

An anonymous, non-contactable complainant, who appeared to be a Lundbeck employee, complained about the product section of the Lundbeck website and the certification of promotional materials under a co-promotion agreement with Otsuka. Lundbeck and Otsuka co-promoted Abilify Maintena (aripiprazole prolonged-release suspension for injection) which was indicated for maintenance treatment of schizophrenia in adult patients stabilised with oral aripiprazole.

The complainant alleged that the product section of the company webpage was available to all and constituted promotion to the public. Both the brand and generic names were stated and the complainant queried whether the prescribing information should have been provided. The complainant further queried what additional information had been provided to consumers to 'encourage correct usage'.

The complainant further alleged that a member of the Lundbeck medical department was responsible for Lundbeck not certifying materials correctly for the product it co-promoted with Otsuka; he/she had not realised that two signatories were required to certify items under co-promotion agreements and most of Lundbeck's promotional material since this individual was appointed had not been certified correctly and was in breach of the Code.

The detailed response from Lundbeck is given below.

The Panel noted Lundbeck's submission that the aim of the webpage in question was to provide the public with correct information about its products, including the doses where relevant, and their licensed indication. The Panel noted that the webpage in question included the medicines' brand names, non-proprietary names, dosages, formulations and indications in a tabular format. Beneath the table was a link to the electronic medicines compendium (eMC) website homepage.

The Panel considered that given the combination of the medicine's name and indication and the fact that members of the public looking for information on a particular product would see such information for all Lundbeck's products meant that the webpage advertised prescription only medicines to the public and on the balance of probabilities might encourage members of the public to ask their health professional to prescribe a specific prescription only medicine and breaches of the Code were ruled.

The Panel noted that the supplementary information to the Code stated, *inter alia*, that under co-promotion arrangements the companies concerned could agree to have only one final signatory to certify on behalf of all the companies, however, this must be agreed beforehand and the MHRA and PMCPA must be informed in advance who the signatory would be.

The Panel considered that the time period within the scope of the complaint was from February 2017 onwards and noted that during this time a number of promotional items were certified by only one company without prior notification to the MHRA and PMCPA as required by the Code. Other promotional material, which was signed by a registered medical practitioner or a pharmacist registered in the UK from one company and a commercial person from the other, was also ruled in breach of the Code. The commercial person was no longer recognised as a final signatory under the Code and the relevant material had therefore only been certified by one company without prior notification to the MHRA and PMCPA. Consequently, the materials had not been certified in accordance with the Code and breaches were ruled.

An anonymous, non-contactable complainant, who appeared to be a Lundbeck employee, complained about the product section of the Lundbeck website and the certification of promotional materials under a co-promotion agreement with Otsuka. Lundbeck and Otsuka co-promoted Abilify Maintena (aripiprazole prolonged-release suspension for injection) which was indicated for maintenance treatment of schizophrenia in adult patients stabilised with oral aripiprazole.

1 Company webpage

COMPLAINT

The complainant alleged that the company webpage http://www.lundbeck.com/uk/our-products/our-products which stated 'Here you will find information that is provided to consumers on each of our Lundbeck distributed products to encourage correct usage' was available to all and constituted promotion to the general public. Both the brand and generic names were stated and the complainant queried whether the prescribing information should have been provided. The complainant further queried what additional information had been provided to consumers to 'encourage correct usage'.

When writing to Lundbeck, the Authority asked it to consider the requirements of Clauses 26.1, 26.2 and 28.3 of the Code.

RESPONSE

Lundbeck submitted that the webpage in question was compliant with Clauses 26.1 and 26.2. The

intended audience was members of the public and Lundbeck refuted the allegation that the webpage promoted to the public. Lundbeck submitted that the website provided factual and balanced information about its products. The only information provided was the brand names, any associated black triangles, the generic names, the doses and formulations, and the licensed indications. Under the product list was information about reporting of adverse events and where readers could find the summary of product characteristics (SPC) and patient information leaflets (PIL) through the electronic medicines compendium (eMC) website. Lundbeck submitted that prescribing information was not required as the purpose of the webpage was to simply inform the public and not to promote to them; as such prescribing information was neither indicated nor appropriate for the webpage in question.

Lundbeck re-iterated that its intention was to simply inform the public of correct information about its products including the doses (where relevant) and their licensed indication. Lundbeck submitted that by complying with Clause 26.2 it was also in compliance with Clause 28.3 and, furthermore, its intention was also to comply with Clause 28.5 and its supplementary information on MHRA guidance.

In response to a request for further information, Lundbeck was not able to provide the certificate and job bag summary for the webpage in question as it did not go through certification when it was last updated in 2015. Furthermore, Lundbeck submitted that a discrepancy between the company webpage and the SPCs on the eMC website for Cipramil (citalopram) and Ebixa (memantine) was due to the fact that the webpage was last updated prior to the SPC updates in 2016. Lundbeck stated that this was an unintentional error. Unfortunately, due to unexpectedly high workload and recent internal resource limitations, it was regrettable that errors had been made. Lundbeck stated that it took this very seriously and was instituting a corrective and preventative action plan and had immediately suspended its Lundbeck UK website. In the meantime, there was a holding page containing obligatory medical information and pharmacovigilance contacts and reporting details. The website would undergo review, update, amendment and certification (where appropriate eg where products were mentioned) urgently.

Lundbeck had taken steps to address its resource limitations within its medical department.

PANEL RULING

The Panel noted that Clause 26.1 prohibited the promotion of prescription only medicines to the public. Clause 26.2 permitted information about prescription only medicines to be supplied directly or indirectly to the public but such information must be factual, presented in a balanced way, must not raise unfounded hopes of successful treatment and must not encourage members of the public to ask their health professional to prescribe a specific prescription only medicine. The Panel noted that the supplementary information to Clause 26.2 required reference information, if provided, to be, *inter alia*, up-to-date and Clause 28.3 required information on the internet covered by Clauses 28.1 and 28.2 which was intended for members of the public, to comply with Clause 26.2.

The Panel noted Lundbeck's submission that the aim of the webpage in question was to provide the public with correct information about its products, including the doses where relevant, and their licensed indication. The Panel noted that the webpage in question included the medicines' brand names, non-proprietary names, dosages, formulations and indications in a tabular format. Above the table were the statements: 'Here you will find information that is provided to consumers on each of our Lundbeck distributed products to encourage correct usage' and 'N.B The following products are licensed for the indicated treatments in the UK only'. The Panel noted that beneath the table listing Lundbeck's products was the statement 'For summary of product characteristics and patient information leaflets click here for the eMC (electronic Medicines Compendium) website'. The link took readers to the eMC homepage. In the Panel's view a patient was unlikely to be familiar with navigating the eMC website.

The Panel noted that the webpage in question listed the product names and indications for Lundbeck's prescription only medicines in one table. The Panel considered that given the combination of the medicine's name and indication and the fact that members of the public looking for information on a particular product would see such information for all Lundbeck's products meant that the webpage advertised prescription only medicines to the public and a breach of Clause 26.1 was ruled. The Panel considered that on the balance of probabilities the information might encourage members of the public to ask their health professional to prescribe a specific prescription only medicine and ruled a breach of Clause 26.2.

The Panel noted that Clause 28.3 required that information about medicines on the internet which was intended for members of the public must comply with Clause 26.2. The Panel noted its comments and rulings above and consequently ruled a breach of Clause 28.3.

2 Certification of promotional material

COMPLAINT

The complainant alleged that a member of the Lundbeck medical department applied the Code as it suited him/her and at times was 'incredibly strict' and at other times not. The complainant stated that the individual in question was responsible for Lundbeck not certifying materials correctly for the product it co-promoted with Otsuka and this information was well known throughout the organisation. The individual had not realised that two signatories were required to certify items under co-promotion agreements. The complainant alleged that most of Lundbeck's promotional material since

this individual was appointed was in breach of the Code (not certified correctly). The complainant stated that senior executives at Lundbeck were aware of the situation but did not voluntarily admit a breach to the PMCPA.

When writing to Lundbeck, the Authority asked it to consider the requirements of Clauses 14.1, 14.3 and 14.4 of the Code.

RESPONSE

Lundbeck stated that the names of its UK medical signatories who were registered with the General Medical Council (GMC) with licence to practice were provided to the PMCPA and MHRA before signatory duties were undertaken. Lundbeck submitted that the position for current material that required certification as per Clause 14.3 for the product co-promoted with Otsuka Pharmaceuticals UK was that one medical signatory from each company reviewed and certified the material in its final form prior to issue, ie two medical signatories' signatures on the certificate. Lundbeck hoped that it was evident from the information above that it was compliant with Clauses 14.1, 14.3 and 14.4. Lundbeck attached an example of a piece of current material (UK/AM/0817/0050c(2)) which had been certified by one medical signatory from Otsuka and one medical signatory from Lundbeck, which it submitted was evidence of its compliance.

In response to a request for further information from the Panel, Lundbeck submitted that the certification process for Abilify Maintena materials had undergone several changes since February 2017 due to changes in personnel within both Lundbeck and Otsuka. In April 2017, Otsuka and Lundbeck met and agreed to change the approval process to comply with the 2016 Code. The change in approval process agreed was that central and joint materials required certification from both companies' medical signatories. Internal training/briefing materials and local meeting materials (small representative meetings) organised and executed by one company required certification from one medical signatory from that respective company. In December 2017, the companies agreed to seek clarification from the PMCPA regarding whether local meetings' materials by a single company required dual company sign-off. In January 2018, a member of the Otsuka medical department confirmed verbally to Lundbeck, after consulting with the PMCPA, that all materials to be certified required certification by medical signatories from both companies. In June 2018, a memorandum of understanding for working practices between Otsuka and Lundbeck was finalised, which outlined the approval process above. Lundbeck provided a list of Abilify Maintena materials that were certified between 1 February 2017 and 17 August 2018.

Lundbeck submitted that Otsuka and Lundbeck UK operated jointly as an Alliance. Work on the memorandum of understanding on the working practices between the two companies in the UK started in January 2018 and was finalised in June 2018 and signed by a senior executive from each company. The previous Alliance joint approvals SOP was dated 2014. Both Lundbeck and Otsuka had agreed that the 2014 SOP was not in compliance with the 2016 Code and a new approval process was agreed via email between senior executives of both companies and was implemented and operational whilst a formal SOP was drafted. The SOP was delayed due to a change of personnel in Otsuka. An amended approval process was implemented and operational from mid-December 2017. The current approvals process and procedures were covered in the memorandum of understanding, June 2018.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure for the PMCPA stated that anonymous complaints would be accepted but like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities.

The Panel noted that the case preparation manager raised Clause 14.3. In the Panel's view, the complaint only referred to promotional material and therefore it made no ruling with regard to Clause 14.3.

The Panel noted Lundbeck's submission that the current position with regard to certification of Abilify Maintena materials was that one medical signatory from each company in the Alliance must certify all materials that required certification under the Code.

The Panel noted the complainant's allegation that a member of the Lundbeck medical department had not realised that two signatories were required to certify items under co-promotion agreements and that most of Lundbeck's promotional material since this person was appointed was not certified correctly and was therefore in breach of the Code. The Panel noted Lundbeck's submission that the individual in question was notified to the PMCPA and MHRA as a signatory at the end of January 2017. The Panel therefore considered that the time-period within the scope of the complaint was from February 2017 onwards.

The Panel noted Lundbeck's review of its copy approval systems from February 2017 to August 2018, excluding jobs that were either: cancelled, waiting for upload, currently undergoing review or which were never used, which gave a final list of 790 Abilify Maintena materials/activities.

The Panel noted that Lundbeck provided four separate spreadsheets; 2018 Alliance job bags; 2017 Alliance job bags which included joint/central activities that Lundbeck and Otsuka had agreed required medical signatory certification by both companies; 2017 Lundbeck only job bags which included materials for local meetings or single company training sessions/briefings initiated for use by a single company and certified by one company as agreed between Lundbeck and Otsuka; and the 2017 and 2018 Lundbeck only Veeva MLR job bags.

The Panel noted that the list of Alliance 2017 job bags included 60 promotional job bags that had

been certified by only one company (only one final signatory or was certified by a commercial and medical signatory from the same company) and 18 promotional job bags that had been certified by a medical signatory from one company and a commercial signatory from the other. The Panel noted that 78 job bags were listed on the 2017 Lundbeck only Zinc job bag list and 93 job bags on the 2017 and 2018 Lundbeck only Veeva MLR job bag list. The Panel noted that the job bags in the two latter lists had only been certified by Lundbeck.

The Panel noted that in February 2017 the SOP in place with regard to Abilify materials and copy approval procedure (ref OPUK-LUN-JWP-003 V 1.0, effective from 11 February 2014) required that under co-promotion agreements, each company should certify the promotional material involved as they would be held jointly responsible for it under the Code. The SOP further stated, in a section headed final certification, that promotional materials must be certified by one Otsuka signatory and one Lundbeck signatory. In general, if the material owner was from Lundbeck then the commercial signatory should be Lundbeck and the medical Otsuka. The reverse was true if the material owner was from Otsuka.

The Panel noted that under the 2016 Code, which came into operation on 1 January 2016, Clause 14.1 stated that the person certifying material on behalf of a company must be a registered medical practitioner or a pharmacist registered in the UK. In the Panel's view, regardless of the fact that Abilify Maintena materials were being certified by a medical signatory from one company and a commercial signatory from the other, commercial signatories were no longer recognised as final signatories in Clause 14.1 of the 2016 Code and in effect materials signed off in this manner had effectively only been certified by one medical signatory and therefore one company.

The Panel noted that the supplementary information to Clause 14.1 stated, *inter alia*, that under co-promotion arrangements the companies concerned could agree to have only one final signatory to certify on behalf of all the companies, however, this must be agreed beforehand and the MHRA and PMCPA must be informed in advance who the signatory would be.

The Panel noted that Clause 14.4 required that, *inter alia*, the names of those nominated as final signatories, together with their qualifications, be notified in advance to the Advertising Standards Unit, Vigilance and Risk Management of Medicines of the MHRA and to the PMCPA. The names and qualifications of designated alternative signatories must also be given. Changes in the names of nominees must be promptly notified.

The Panel noted that a number of promotional items were certified between February 2017 and April 2017 by a final signatory from only one company without prior notification to the MHRA and PMCPA as required by the Code. The Panel thus ruled a breach of Clause 14.4. Consequently, the materials that had been certified by only one company, whose signatory had not been notified in advance to the MHRA and PMCPA as certifying on behalf of both Lundbeck and Otsuka, had not been certified in accordance with Clause 14.1 and its supplementary information. The Panel thus ruled a breach of Clause 14.1 in relation to those materials.

The Panel noted Lundbeck's submission that in April 2017 Lundbeck and Otsuka personnel met and agreed to change the approval process to comply with the 2016 Code. The change in approval process, agreed via email by senior executives of both companies, was that central and joint materials required certification from both companies' medical signatories and internal training/briefing materials and local meeting materials (small representative meetings) organised and executed by one company only required certification from one medical signatory from that respective company. The Panel noted it was clear from the email that both companies understood that both would still be accountable for the materials certified by only one company. The Panel noted that this arrangement was not reflected in any SOP.

The Panel considered its comments and rulings above which were relevant. The Panel noted that between April 2017 and mid-December 2017, numerous Abilify Maintena promotional materials/activities were certified by only one medical signatory from either Otsuka or Lundbeck without prior notification to the MHRA and PMCPA as required by the Code. The Panel noted that its ruling of a breach of Clause 14.4 above applied here and it made no additional ruling in this regard. The Panel noted that the materials that had been certified between April 2017 and mid-December 2017 by only one company, whose signatory had not been notified in advance to the MHRA and PMCPA as certifying on behalf of both Lundbeck and Otsuka, had not been certified in accordance with Clause 14.1 and its supplementary information. The Panel thus ruled a breach of Clause 14.1 in relation to these materials.

The Panel noted Lundbeck's submission that it was brought to its attention in December 2017 that the PMCPA required all promotional materials including materials for local representative meetings to be certified by medical signatories from both companies. The Panel noted Lundbeck's submission about advice given by the PMCPA on this matter in January 2018. The Panel noted that the PMCPA could not approve any activities or materials, it could only give informal guidance based on its interpretation of the Code. In the event of a complaint being received about a matter upon which advice had been given, it would be considered in the usual way. The Panel had no details with regard to the advice which Lundbeck stated had been given but in the Panel's view it was clear in the supplementary information to Clause 14.1 that under co-promotion arrangements the companies concerned could agree to have only one final signatory to certify on behalf of all the companies, however, this must be agreed beforehand and the MHRA and PMCPA must be informed in advance who the signatory would be.

The Panel noted that a member of the Lundbeck medical department confirmed in emails sent to

Lundbeck employees in mid-December 2017 and again in January 2018 that all Abilify Maintena materials for use from 14 December that required certification under the Code, required certification by medical signatories from both companies. The Panel noted that this was documented in a memorandum of understanding which started in January 2018 but was not finalised until June 2018.

The Panel noted that from January 2018 to August 2018, four Abilify Maintena materials were not certified by a medical signatory from both companies. The Panel noted Lundbeck's submission that one of these materials (UK/AM/0518/0225) was only certified by an Otsuka medical signatory due to a technical error in the Zinc approval system which resulted in the Lundbeck medical signature not being captured on the certificate. The second (UK/AM/0618/0261) was only certified by a Lundbeck medical signatory and the company gave no reason for this. The third (UK/AM/0118/0005) was only certified by a Lundbeck medical signatory and the company stated that this was due to the Otsuka medical signatory leaving the company prior to certification. The fourth (UK-ABIM-0104) was only certified by a Lundbeck medical signatory and the company stated that this was an error. The Panel noted that its ruling of a breach of Clause 14.4 above applied here and it made no additional ruling in this regard. The Panel noted its comments above about the relevant supplementary information to Clause 14.1. The above four promotional materials that had been certified by only one company, whose signatory had not been notified in advance to the MHRA and PMCPA as certifying on behalf of both Lundbeck and Otsuka, had not been certified in accordance with Clause 14.1 and its supplementary information. The Panel thus ruled a breach of Clause 14.1 in relation to those materials.

Complaint received **20 August 2018**

Case completed **19 December 2018**