CASE AUTH/3153/1/19

ANONYMOUS v OTSUKA EUROPE

Out-of-date promotional materials

An anonymous, non-contactable individual who described themselves as a recent employee at Otsuka complained about material used at two overseas meetings. The complainant submitted that he/she had reported the matters at issue but as nothing had happened, decided to complain to the Authority.

The first matter concerned an alleged out-of-date advertisement that was used in association with a congress in France held in March 2018 (European Psychiatric Association (EPA)) which the complainant alleged was non-compliant.

Secondly, the complainant alleged that materials used at the European College of Neuropsychopharmacology (ECNP) Congress held in Spain in October 2018 were unapproved.

The detailed response from Otsuka Europe is given below.

The Panel noted Otsuka Europe's submission that it had made funding available for Otsuka France to support the EPA Congress and as part of its sponsorship agreement it could place an advertisement in the final congress programme. The advertisement used was retrieved from the CNS Resource Centre, for which it appeared Otsuka Europe was responsible.

The Panel ruled a breach, as acknowledged by Otsuka Europe, as the withdrawn advertisement placed in the EPA Congress programme had not been certified for such use.

The Panel considered that Otsuka Europe had failed to maintain high standards in relation to governance of withdrawn materials and a breach was ruled as acknowledged by Otsuka Europe.

Whilst the Panel was very concerned that withdrawn material was available in the CNS Resource Centre and that it appeared, from Otsuka Europe's submission, that there was only an informal agreement with the affiliates that if they used any material from the resource centre they must first obtain local approval for the item, it did not consider that the circumstances were such as to warrant a breach of Clause 2 which was a sign of particular censure. On balance, no breach of Clause 2 was ruled.

The Panel noted Otsuka Europe's submission that it had both promotional and non-promotional materials and activities at the ECNP Congress.

The Panel noted Otsuka Europe's submission that of the 64 job bags relating to pieces of material used at or in relation to the congress, 62 had one or more errors including not being certified, being certified incorrectly, being certified after first use and being used before the final hard copy was certified. According to interview notes materials included slides, invitations, agenda, abstract book and banner stand. The Panel therefore ruled a breach of the Code as acknowledged by Otsuka Europe.

The Panel noted Otsuka Europe's submission that its formal approval process in place at the time was not followed in relation to the certification and/or checking of material used at the congress. The Panel considered that Otsuka Europe had failed to maintain high standards and a breach was ruled.

The Panel noted the importance of certification and its role in underpinning the self-regulatory compliance system. The Panel noted the scale of errors. In addition, the Panel noted that these included a number of materials that had been used prior to final certification. In the Panel's view, the cumulative effect of the errors was that Otsuka Europe had reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel did not consider that the complainant had provided evidence that compliance had attempted to cover up the issues or were not doing anything about them as alleged and therefore ruled no breach of the Code in this regard.

An anonymous, non-contactable individual who described themselves as a recent employee at Otsuka complained about the promotional practices of Otsuka UK. The complaint was about material used at two overseas meetings. The complainant submitted that he/she had reported the matters at issue but as nothing had happened, decided to complain to the Authority.

COMPLAINT

The first matter concerned an alleged out-of-date advertisement that was used in association with a congress in the South of France held in March 2018 which the complainant alleged was non-compliant.

Secondly, the complainant alleged that materials used at the European College of Neuropsychopharmacology held in October 2018 were unapproved. The complainant stated that he/she had tried to chase an individual in medical but that he/she had refused to sign-off the materials. The complainant alleged that the compliance people were covering up the matter because the individual from medical was senior but that this was wrong.

When writing to Otsuka, the Authority asked it to bear in mind the requirements of Clauses 2, 7.2, 9.1, 14.1 and 14.2 of the 2016 Code.

RESPONSE

In a preliminary response Otsuka UK and Otsuka Europe noted that the two events referred to by the complainant were the European Psychiatric Association (EPA) Congress in Nice, France, 3-6 March 2018; and the European College of Neuropsychopharmacology (ECNP) Congress in Barcelona, Spain, 6-9 October 2018. Otsuka Pharmaceuticals Europe, not Otsuka UK had a presence at these meetings. No one from Otsuka UK attended the EPA and only one member of the Otsuka UK medical department attended the ECNP as a delegate; he/she was not involved in any Otsuka Europe activities at the conference (eg he/she did not staff the Otsuka Europe stand). Otsuka UK was not involved in any of the planning for these meetings or the production/sign off of any of the associated materials including the material provided by the complainant.

Both Otsuka Europe and Otsuka UK were one company (Otsuka) and were committed to self-regulation and high ethical standards. However, given Otsuka UK had no role in either congress at issue or in the approval of any material used at those meetings, Otsuka Europe asked if only it could respond to the case.

In its subsequent response, Otsuka Europe reiterated that the two events cited by the complainant, the EPA Congress and the ECNP Congress, were its responsibility.

The EPA congress took place in Nice from 2-6 March 2018. Otsuka Europe stated that it did not provide any support directly for the meeting, however, it made available funding to the affiliates should any wish to support the congress. Otsuka France decided to sponsor the congress, but Otsuka Europe submitted that it was responsible for the sponsorship as it had provided the funding for the congress. Otsuka UK had no role in the congress.

Otsuka France put in place a sponsorship agreement with the EPA which stated that, in return for funds, Otsuka France would be a Gold Sponsor of the event and Otsuka France cross-charged Otsuka Europe for the cost of sponsoring the congress. Part of this package was that Otsuka France could place an advertisement in the final programme (a copy of the sponsorship contract was provided).

Otsuka Europe did not have any presence at the meeting other than three employees who attended as delegates. After returning from the congress, one of the Otsuka Europe attendees realised that there was an Abilify Maintena advertisement on what was described as the conference abstract book (the final programme) that contained several mistakes; this was raised internally at Otsuka Europe as an incident on 7 March 2018.

Otsuka Europe explained that at the end of January 2018, an employee who had recently joined Otsuka France emailed an employee at Otsuka Europe to ask for an advertisement in English for Abilify Maintena and the contact details for a particular employee from the UK. The Otsuka Europe employee directed his/her Otsuka France colleague to the 'CNS Resource Centre'; this was a resource for the affiliates that provided access to marketing materials for Otsuka CNS products; it was also an archive of previously used material. As part of this email conversation, the European employee also, by way of introduction, copied in a UK employee.

The Otsuka France employee retrieved the advertisement in question from the CNS Resource Centre and suggested in the email conversation that this was used. The UK employee stated that the advertisement had already been withdrawn and the European employee directed his/her French colleague to other materials in the CNS Resource Centre and attached a current example.

The French employee initially sent the out-of-date advertisement on to the agency in charge of the congress, but then sent the replacement advertisement stating 'Can you please use this Ad instead of the first one I sent you?'. An email from the agency received by the employee when he/she submitted the final advertisement indicated that it had been accepted. However, the advertisement which was placed in the final programme was not the replacement version sent by the Otsuka France employee. Only after the event when questions were asked of the agency was Otsuka France told that it had missed the deadline for submission for changes to the printed material.

The advertisement placed in the final programme had in fact been withdrawn from the approval system in March 2017 but remained as a resource for the affiliates as the resource centre was also an archive. The informal agreement with the affiliates was that if they used any material from the resource centre, they must first obtain local approval for the item. Unfortunately, Otsuka France sent the advertisement at issue to EPA without local approval. This was the advertisement that was used on the EPA booklet, a partial copy of which was provided to the PMCPA by the complainant. A copy of the full advertisement certified by Otsuka Europe in 2014 was provided.

As a result of the above, the CNS Resource Centre was closed in March 2018 and relaunched in June 2018 with current material only. In addition, every item had a watermark which stated that local approval was required before the affiliates could use it.

As well as lacking prescribing information, the advertisement had not been certified since the initial certification on 9 January 2014 and referred to Abilify Maintena as 'new'. Otsuka Europe acknowledged that as the material was used in 2018 there had been a failure to recertify material that was still in use beyond the two years post-certification; the relevant clause was Clause 14.5 however, the company noted that it had not been asked to consider the requirements of that clause. Nevertheless, it considered that continued use without recertification amounted to a breach of Clause 14.1.

In relation to the use of 'new' in the advertisement beyond the permitted 12 months after the

medicine was generally available, Otsuka Europe acknowledged a breach of Clause 7.11. Again, the company had not been asked to respond in relation to the requirements of that clause, but rather Clause 7.2; Otsuka Europe considered that the use of 'new' in relation to the medicine was misleading, in breach of Clause 7.2.

The advertisement printed in the congress booklet did not contain prescribing information, contrary to the requirements as it was certified by a UK company (Otsuka Europe) and therefore prescribing information was required to be provided and so Otsuka Europe acknowledged a breach of Clause 4.1, although it noted that it had not been asked to consider the requirements of that clause.

Otsuka Europe acknowledged that maintaining material that had been withdrawn in a central repository, without making it abundantly clear that the item required additional approval before use, amounted to a failure to maintain high standards and had the potential to bring the industry into disrepute, in breach of Clauses 9.1 and 2.

Otsuka Europe did not consider that Clause 14.2 was relevant in relation to the EPA, given that the company did not take any health professionals to the congress or support their attendance in any way.

The European College of Neuropsychopharmacology (ECNP) Congress took place in Barcelona, from 6-9 October 2018. This was a major conference for Otsuka in 2018 and Otsuka Europe had both promotional and non-promotional materials and activities at the congress, for example, symposia and meetings led by medical, a promotional booth, a medical information booth and other material.

There was an internal incident raised on 12 December 2018 that there were a number of items used at the congress without being formally approved in the electronic approval system. This was logged in the incident registry and an investigation launched. There were two other similar incidents raised and logged in January 2019. Otsuka Europe stated that it did not have an explanation for the delay in the incident being reported; however, face-to-face training on its revised standard operating procedure (SOP) for promotional and non-promotional material approval had been conducted on 23 and 30 November, and on 3 December 2019.

Otsuka Europe explained that more than 60 pieces of material were used at or in relation to the congress. The internal incidents raised were in relation to medical-led materials and activities that were not certified and/or checked (in relation to printed items) before they were used at the congress. A relevant employee in medical left Otsuka shortly after the congress in October 2018; however, the company had spoken to members of staff who were involved in the preparation for the ECNP congress and/or who attended and certain relevant emails had been reviewed. Relevant staff in medical had been trained on the process.

There was extensive activity on email in relation to the approval of material for the congress. This was not surprising given that both Otsuka medicines in this therapy area were jointly promoted with a partner company that did not share the same electronic approval system as Otsuka Europe. During this time, there was a lengthy discussion as to whether the material should be classified as promotional or non-promotional.

Some months before the congress, most of the job bags relating to the planned material were created on the electronic approval system, but in some cases material was not progressed through the formal approval process until the first day of the congress, during the congress or after the congress had finished. Some staff were aware during the congress that material had not been approved or checked and attempted to address this, for example by asking signatories to certify material in Zinc whilst on site at the congress, or by taking photographs of hard copy material in order for a signatory to conduct a check of hard copy material. The review of material identified numerous procedural errors and issues.

Of the 64 job bags, 62 had one or more errors. Otsuka Europe acknowledged that the formal approval process in place at the time was not followed in relation to the certification and/or checking of material used at the congress. Additionally, materials were not certified in time for use at the congress, the gallery notes did not always support the certification being an attestation that the material would have been approvable and was not always clear it was not a retrospective approval. Additionally, a large number of the certification errors appeared after the employees who made them attended a series of face-to-face baseline trainings on the Code, including approval standards.

Given that certain material was not certified, or checked where required, before use, Otsuka Europe accepted a breach of Clause 14.1. It appeared that internal process was not followed for a large number of items that were used at the congress, and the company acknowledged that this amounted to a failure to maintain high standards, in breach of Clause 9.1. The company also considered that such poor planning in approach for a congress where Otsuka had a major presence brought the industry into disrepute, in breach of Clause 2.

Otsuka Europe noted the complainant's comment that 'I don't think that the compliance people are doing anything except covering this up'. As noted above, Otsuka Europe had a process for handling internal incident reports. The issues raised by the complainant had both been raised internally with the European compliance department and were logged on the incident register when they were reported and the individual raising the concern was so informed. In the case of the EPA congress, the incident was investigated and closed out in October 2018. In the case of the ECNP, the investigation was ongoing when this complaint was received.

Given the concern raised by the complainant in this case that compliance was 'covering up' these

incidents, European compliance requested an internal investigation in to how these incidents were processed. A copy of the report from this investigation was provided. The report concluded that the concerns raised were handled appropriately. Given this, Otsuka Europe did not consider that there has been any breach of the Code in this regard.

Otsuka Europe stated that on the evening of 13 February 2019, a senior employee received a self-identified report that five items used at a third congress, the European Haematology Association, held from 14-17 June 2018 in Stockholm, Sweden, were approved but not certified before use. The five items included ones that both would and would not be required to be certified under the Code. An incident was raised and an investigation was pending; there was not enough time to conduct a thorough review before submitting this response. Therefore, given the information it currently had on hand, Otsuka Europe considered this was a breach of Clause 14.1. Additionally, given the fact that the pattern repeated across two Otsuka Europe-led events, the company considered this a failure to maintain high standards and therefore a breach of Clause 9.1. If the investigation provided any different conclusions on root causes than those identified as part of the investigation into ECNP, Otsuka Europe would provide a summary to the PMCPA including an evaluation of the applicability of Clause 2, as well as an amended remediation plan.

In response to these serious and repeated failures to ensure material was properly reviewed and certified before use, and that certified material complied with the Code, Otsuka Europe would complete a review of all current materials which it still used in 2018, starting with all currently effective materials. This would be completed by May 2019. Additionally, it had already started a review of the currently planned congresses for 2019, which would complete by 31 March 2019. Finally, all employees with a role in the planning, execution, or approval of congresses would be retrained by May 2019 and the company planned comprehensive retraining and validation of all signatories.

PANEL RULING

The Panel noted Otsuka's submission that Otsuka Pharmaceuticals Europe, not Otsuka UK had a presence at the two meetings referred to by the complainant. The Panel noted that Otsuka Europe was based in the UK and was a member of the ABPI and, as such, it was obliged to comply with the Code. Otsuka Europe had responded to the complaint.

In the Panel's view, Otsuka Europe would not necessarily be held responsible for the activities of its affiliates if its only role was to be cross-charged by the affiliate for the activity in question. Whether Otsuka Europe was responsible, and whether the Code applied, would be determined on a case-by-case basis taking into account all the circumstances including: Otsuka Europe's role in relation to the activity and whether such activity was directed or encouraged by Otsuka Europe.

European Psychiatric Association (EPA) Congress

The Panel noted Otsuka Europe's submission that it had made funding available for Otsuka France to support the EPA Congress. In the Panel's view, the proactive offering of funding to its affiliate for a specific meeting meant that Otsuka Europe had some responsibility with regard to the sponsorship. The Panel noted Otsuka Europe's submission that it was responsible for the sponsorship of the EPA Congress.

The Panel noted that Otsuka France as part of its sponsorship agreement with the EPA could place an advertisement in the final congress programme. The Panel noted that the advertisement placed in the final congress programme was retrieved by a recently appointed Otsuka France employee from the CNS Resource Centre, for which it appeared Otsuka Europe was responsible, after being directed to it by a European employee. The Panel noted Otsuka Europe's submission above about how the advertisement in question, which was withdrawn in March 2017, came to be published.

The Panel noted its comments above with regard to Otsuka Europe and its responsibility for the sponsorship of the EPA Congress. The Panel further noted Otsuka Europe's responsibility with regard to the 'CNS resource centre' to which the Otsuka France employee was directed by an Otsuka Europe employee. In the Panel's view, the advertisement in the Congress programme fell within the scope of the UK Code; Codes, laws and regulations in other countries might also be applicable. The Panel noted that it could only make rulings with regard to the UK Code.

The Panel noted the narrow allegation; that the advertisement in question was out of date which the complainant considered to be non-compliant. The complainant made no allegation about the content of the advertisement. The Panel considered that there was no allegation in relation to Clause 7.2 and 14.2 as cited by the case preparation manager and thus the Panel made no ruling in relation to these clauses. In addition, the Panel noted that Otsuka Europe had unilaterally raised and responded to Clauses 4.1 and 7.11 which were not the subject of complaint and thus the Panel made no ruling on these clauses.

The Panel noted that the withdrawn advertisement had been placed in the EPA Congress programme and had not been certified for such use. The Panel therefore ruled a breach of Clause 14.1 as acknowledged by Otsuka Europe.

The Panel noted Otsuka Europe's submission that maintaining material that had been withdrawn in a central repository, without making it abundantly clear that the item required review and approval before use, amounted to a failure to maintain high standards. The Panel further noted that an Otsuka Europe employee had directed an Otsuka France employee to the resource centre.

The Panel considered that Otsuka Europe had failed to maintain high standards in relation to governance

of withdrawn materials and a breach of Clause 9.1 was ruled as acknowledged by Otsuka Europe. The Panel noted its rulings and comments above. Whilst the Panel was very concerned that withdrawn material was available in the CNS resource centre and that it appeared, from Otsuka Europe's submission, that there was only an informal agreement with the affiliates that if they used any material from the resource centre they must first obtain local approval for the item, it did not consider that the circumstances were such as to warrant a breach of Clause 2 which was a sign of particular censure. On balance, no breach of Clause 2 was ruled.

European College of Neuropsychopharmacology (ECNP) Congress

The Panel noted Otsuka Europe's submission that it had both promotional and non-promotional materials and activities at the ECNP Congress which took place in Barcelona, from 6-9 October 2018, for example, symposia and meetings led by medical, a promotional booth, a medical information booth and other materials. The Panel noted that Otsuka Europe had responsibility under the UK Code as the organiser of these materials and activities. Codes, laws and regulations in other countries might also be applicable. The Panel noted that it could only make rulings with regards to the UK Code.

The Panel noted Otsuka Europe's submission that of the 64 job bags relating to pieces of material used at or in relation to the congress, 62 had one or more errors including not being certified, being certified incorrectly, being certified after first use and being used before the final hard copy was certified. According to interview notes materials included slides, invitations, agenda, abstract book and banner stand. The Panel therefore ruled a breach of Clause 14.1 as acknowledged by Otsuka Europe.

The Panel noted that Clause 14.2 of the 2016 Code required all meetings involving travel outside the UK where a UK company funded delegates to be certified in advance. In addition, all meetings involving travel outside the UK that were wholly or mainly for UK delegates must also be certified in advance. The Panel noted that neither of these appeared to be the case with regards to the ECNP Congress and therefore, in the Panel's view, Clause 14.2 was not relevant and it made no ruling in that regard.

The Panel noted Otsuka Europe's submission that its formal approval process in place at the time was not followed in relation to the certification and/or checking of material used at the congress. The Panel considered that Otsuka Europe had failed to maintain high standards and a breach of Clause 9.1 was ruled. The Panel noted the importance of certification and its role in underpinning the self-regulatory compliance system. The Panel noted the scale of errors; of 64 job bags 62 had one or more errors. In addition, the Panel noted that these included a number of materials that had been used prior to final certification. In the Panel's view, the cumulative effect of the errors was that Otsuka Europe had reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

Compliance

The Panel noted Otsuka Europe's submission that it had a process for handling internal incident reports. The issues raised by the complainant had both been raised internally with the European compliance department and were logged on the incident register when they were reported and the individual raising the concern was so informed. In the case of the EPA congress, the incident was investigated and closed out in October 2018. In the case of the ECNP, the investigation was ongoing when this complaint was received.

The Panel noted Otsuka Europe's submission that given the complainant stated that compliance was 'covering up' these incidents, European compliance requested an internal investigation in to how these incidents were processed. The Panel noted that the report provided suggested that the concerns raised had been or were being handled appropriately.

The Panel did not consider that the complainant had provided evidence that compliance had attempted to cover up the issues or were not doing anything about them as alleged. The Panel therefore ruled no breach of Clause 9.1.

The Panel noted Otsuka Europe's submission that on 13 February 2019, a senior employee received a self-identified report that five items used at a third congress, the European Haematology Association, held from 14-17 June 2018 in Stockholm, Sweden, were approved but not certified before use and it considered this was a breach of Clause 14.1. The Panel noted Otsuka Europe's submission that the five materials included both those that would and would not require certification under the Code. The Panel noted that this matter had not been raised by the complainant and therefore it could make no ruling.

Complaint received **30 January 2019**

Case completed **5 July 2019**