CASE AUTH/3174/3/19

ANONYMOUS EMPLOYEES v OTSUKA EUROPE

Conduct of Otsuka Europe

A 'group of concerned employees' complained about the arrangements for international meetings and comments made by a senior Otsuka Europe employee at an internal meeting.

The detailed response from Otsuka Europe is given below.

The complainants alleged that previous international meetings had been misclassified and certified as non-promotional events when it was clear that such activities were promotional. The complainants alleged that these had been classified incorrectly due to commercial pressure to get more attendees for non-promotional meetings. Such activities were disguised promotion as health professionals thought they were attending a non-promotional meeting as part of an exchange of scientific material. One example was a symposium at the 2018 European Renal Association – European Dialysis and Transplant Association (ERA-EDTA) Congress. The symposium had been certified as non-promotional when in fact it was promotional.

These concerns had been highlighted to the compliance department, but no action had been taken, probably because no-one was well versed with the ABPI Code, and Otsuka Europe had to rely on a third party for most of its compliance activities.

The Panel noted Otsuka Europe's submission that the symposium was led by the medical department and was classified as non-promotional in the approval system. Otsuka Europe stated that its investigation identified that the symposium slides were approved by the country of the congress affiliate (Denmark) as promotional.

The Panel noted Otsuka Europe's submission that on review of the symposium slides it was clear to the company that it was promotional and disguised in that regard; it discussed treatment with tolvaptan (Jinarc marketed by Otsuka) which according to Otsuka Europe was the only medicine licensed for the indication. The Panel noted Otsuka Europe's submission that the materials used to advertise the symposium all referred to a discussion of the ERA-EDTA guidelines on Autosomal Dominant Polycystic Kidney Disease (ADPKD), which were in fact guidelines on the use of tolvaptan in ADPKD.

The Panel noted that the symposium slides included multiple references to tolvaptan. It was difficult for the Panel to understand how Otsuka could have classified and treated this meeting as anything but promotional. It had been classified as promotional by the Danish affiliate. In this regard, the Panel ruled a breach of the Code as Otsuka Europe had failed to maintain high standards.

In the Panel's view, it was clear that the symposium was an Otsuka Europe promotional symposium. However, the Panel considered that, on the balance of probabilities, not all health professionals, based on the materials used to advertise the symposium at the scientific congress, would have expected the symposium to be a promotional meeting. In that regard it was disguised promotion and a breach was ruled as acknowledged by Otsuka Europe.

The Panel noted that Otsuka Europe had identified a number of other issues during its investigation into this matter including, *inter alia*, the symposium slides not being consistent with the tolvaptan SPC and lack of prescribing information. Whilst the Panel was extremely concerned with regard to the issues identified, there had been no allegation on these points and therefore the Panel could make no rulings.

Whilst the Panel was concerned that Otsuka Europe classified a clearly promotional symposium as non-promotional, it did not consider that, on balance, the particular circumstances of this case warranted a ruling of a breach of Clause 2 and ruled accordingly. The complainants appealed this ruling.

The Appeal Board noted that the symposium at issue was led by Otsuka Europe's medical department and was classified as non-promotional in the approval system. The Appeal Board noted that the symposium slides included multiple references to tolvaptan. The symposium slides were approved as promotional by the Danish affiliate. In addition, Otsuka Europe had a promotional booth for Jinarc (tolvaptan). The Appeal Board agreed with the Panel in that it was difficult to understand how the symposium in question could have been anything other than promotional.

The Appeal Board noted Otsuka Europe's submission that its investigation indicated that the company did not properly understand the distinction between promotional and non-promotional activities as defined by the Code and this failure was at an organisational level. Otsuka Europe submitted that it was not conscious misclassification of non-promotional meetings, but gross incompetence caused by a lack of training, management and support. Otsuka Europe submitted that these failings had reduced confidence in the pharmaceutical industry.

The Appeal Board considered that such failings reduced confidence in the pharmaceutical industry and ruled a breach of Clause 2 as acknowledge by the company. The appeal on this point was successful.

The Appeal Board noted the issues found during Otsuka Europe's investigation and the actions taken. It noted that some of these were identified

in the recent audits of Otsuka Europe and Otsuka UK required in Cases AUTH/3041/6/18 and AUTH/3123/11/18.

The complainants provided information about an internal company meeting held in March. It was a weekly management update meeting that focused on the Appeal Board meeting on 13 March. There was a debrief on the presentation and the types of questions asked by the Appeal Board.

The complainants stated that attendees were informed that culture was of particular interest, especially around whistleblowing. A senior employee at Otsuka Europe (named) went on to add that during this 'period' it was very easy to finger point individuals and departments. This person then stated that there might be some individuals in the audience that wondered what he/she was still doing in the organisation.

The complainants alleged that the senior employee then asked all present to raise their right hand and swear that they would not complain about individuals or departments to anyone for the next 6 months. He/she added that when staff were questioned during the PMCPA audit, they had to be careful with their answers. The PMCPA would open up with easy questions, and then tackle more difficult areas, eg were we happy with the processes and the organisation? He/she hinted that staff would receive training to indicate their appropriate answers.

The complainants alleged that, in summary, they should not be holding each other to account (by swearing not to complain) and would receive training to provide the answers the PMCPA want to hear during the audit (lack of transparency).

The complainants alleged that it was clear that the culture in Otsuka Europe was going from bad to worse and they did not see it improving imminently.

The complainants provided a copy of an email (22 March) to staff following the meeting on 18 March which suggested that even the leadership team felt that the pledging episode was not appropriate. The complainants wanted to find out what specific feedback had been received from the leadership team, and if a formal investigation had begun (especially as this had been brought to the attention of the PMCPA).

The complainants believed that the email was not entirely accurate (the complainants stated that they did not know what would be communicated to the PMCPA). Before making all of the employees pledge that they would not complain, he/she shared a restaurant motto – 'If you are happy tell everyone, if you are not tell us'. This action was to stop disgruntled employees from going outside the company to complain about certain issues. The complainants believed with the restaurant story in mind and the forced pledging, the direct message was not to further whistle blow.

The complainants stated that, given this evidence, the senior employee conceded that he/she was not clear with his/her messaging and that his/her actions caused certain employees to feel deeply uncomfortable.

It was not entirely clear to the Panel what exactly was said at the meeting in question. The Panel noted the interview notes with some of the meeting attendees who were also on the leadership team.

The Panel noted that the comments were made at a meeting which was to inform staff that Otsuka UK and Otsuka Europe would be audited by the Authority later that year. The audit was in relation to three cases and in each case it appeared that the complainant was an Otsuka employee. The Panel further noted that at the time of the meeting in question there were ongoing Otsuka cases at the Authority where the complainant appeared to be an anonymous employee or employees. The Panel considered that it was a critical time for the company with regard to compliance and comments made by senior members of staff at this time would be fundamental in driving the company's compliance culture.

The Panel considered, based on the evidence before it, that the comments made at the meeting in question would, on the balance of probabilities, have been interpreted by some as saying do not complain outside the company. In the Panel's view, such comments from a senior employee would have a huge impact on the culture within the company at a critical time when the company ought to be actively encouraging open dialogue about compliance matters. The Panel considered that Otsuka Europe had therefore failed to maintain high standards and a breach was ruled as acknowledged by the company.

In the Panel's view, the implied message 'do not complain outside the company' was a serious matter that undermined the Code and self-regulation. Regardless of whether or not such a message was intended or misinterpreted, the Panel considered that the comments at the meeting in question meant Otsuka Europe had brought discredit upon and reduced confidence in the pharmaceutical industry. The Panel therefore ruled a breach of Clause 2.

With regard to the allegation in relation to training staff to ensure that appropriate answers are given during the upcoming audit, the Panel noted Otsuka Europe's submission that audit readiness training for employees would focus on what to expect and would convey the importance of answering questions completely and honestly. Otsuka Europe made no submission about whether such matters were within the scope of the Code. The Panel noted that it was not inappropriate to provide training in preparation for an audit. The training had not taken place at the time of the complaint. The complainants had not shown that their concerns gave rise to a Code matter. No detail was provided. The Panel ruled no breach of the Code as the subject matter of complaint was outside the scope of the Code.

A 'group of concerned employees' complained about the arrangements for international meetings and comments made by a senior Otsuka Europe employee at an internal meeting.

1 International meetings

COMPLAINT

The complainants alleged that it had come to their attention that previous international meetings had been misclassified and certified as non-promotional events when it was clear that such activities were promotional. The complainants alleged that these had been classified incorrectly due to commercial pressure to get more attendees for non-promotional meetings.

The complainants alleged that such activities were disguised promotion as health professionals thought they were attending a non-promotional meeting as part of an exchange of scientific material. One such example was the 2018 European Renal Association – European Dialysis and Transplant Association (ERA-EDTA) Congress symposium, which had been certified as non-promotional when in fact it was promotional.

The complainants stated that these concerns had been highlighted to the compliance department, but no action had been taken, probably because none of the compliance personnel in Otsuka Europe was well versed with the Code, and Otsuka Europe had to rely on a named third party for most of its compliance activities.

When writing to Otsuka Europe, the Authority asked it to bear in mind the requirements of Clauses 2, 9.1 and 12.1.

RESPONSE

Otsuka Europe submitted that the meeting that the complainant referred to was the European Renal Association – European Dialysis and Transplant Association congress which took place in Copenhagen, 24-27 May 2018. A concern about the 2018 ERA-EDTA congress was identified to European Compliance on 7 March 2019, and an internal incident stating that the 2018 ERA-EDTA Otsuka-sponsored symposium discussed the use of Jinarc (tolvaptan) in Autosomal Dominant Polycystic Kidney Disease (ADPKD) which was 'coded' as non-promotional was raised. An investigation commenced on 8 March and would be completed no later than 19 April 2019. The investigation identified that the slides used at the symposium were approved by the local affiliate for Denmark as promotional; the investigation did not review the Denmark job bags but a quick search confirmed that the local affiliate consistently treated the symposium and its materials as promotional.

Otsuka Europe submitted that its presence at this congress was a promotional booth for Jinarc and a symposium. Neither Otsuka Europe nor Otsuka UK took UK health professionals to the congress but a presentation sourced from the ERA-EDTA website indicated 279 of the registered attendees at the congress were from the UK (there were 9,598 participants in total).

The Otsuka Europe symposium was led by the medical function and was classified as non-promotional in the Otsuka Europe approval system. The certified programme for the symposium submitted to the meeting organisers noted that the objectives of the symposium were:

- Present the latest scientific data, and ensure health professionals understand the diagnosis and treatment/management of rapid progression in patients with ADPKD
- Raise awareness of the need for regular follow up, investigations and early treatment
- Discuss the ERA-EDTA guidelines and their practical application
- Present case studies – challenging cases that could require early intervention.

Otsuka Europe submitted that on review of the slides presented at the symposium it was clear that the entire symposium was in fact promotional and disguised in that regard, as it discussed treatment with tolvaptan (which was the only medicine licensed for this indication), in breach of Clause 12.1. In addition, various material used to advertise the symposium all referred to a discussion of the ERA-EDTA guidelines on ADPKD, which were in fact guidelines on the use of tolvaptan in ADPKD.

Otsuka Europe submitted that during the investigation in to this complaint, other issues were identified. These included:

- Misclassification of other materials as non-promotional that were, in fact, promotional (for example the various materials used to advertise the symposium as noted above, the videos of the presentations which were intended to be placed on the ERA-EDTA website after the congress). Otsuka Europe considered that these materials were also in breach of Clause 12.1, and that this amounted to a failure to maintain high standards, in breach of Clause 9.1.

- Content in the presentations which, when viewed correctly as promotional activity, was not consistent with the particulars of the SPC, specifically:

    - 'How to start tolvaptan – patient toolkit' where the speaker stated 'Take the first pill at ~6am in the morning …' where Section 4.2 of the SPC stated 'The morning dose is to be taken at least 30 minutes before the morning meal' and later '… (45 mg taken upon waking and prior the morning meal …'.
    - 'How to start tolvaptan – patient toolkit' where the speaker stated 'Stop 4 weeks before trying to get pregnant' where the SPC listed pregnancy as a contraindication and Section 4.6 stated 'Women of childbearing potential must use adequate contraceptive measures during Jinarc use. Jinarc must not be used during pregnancy'.
    - Two slides indicate dosing which did not match Section 4.2 of the SPC. The SPC stated

'The initial dose is 60mg tolvaptan per day as a split-dose regimen of 45mg +15 mg …. The initial dose is to be titrated upward to a split-dose regimen of 90mg tolvaptan (60mg + 30mg) per day and then to a target split-dose regimen of 120mg tolvaptan (90mg + 30mg) per day, if tolerated, with at least weekly intervals between titrations'. It went on to state 'Patients may down-titrate to lower doses based on tolerability. Patients have to be maintained on the highest tolerable tolvaptan dose'. The presenter provided a bar graph indicating a dosage of 30 mg tolvaptan (15mg +15 mg) per day under the heading 'Target dose?' A possible polling slide included below a heading 'How should uptitration be done? Which answer do you consider most appropriate?' three options – 'All patients have to be uptitrated to 90/30 mg', which was inconsistent with 'Patients may down-titrate to lower doses based on tolerability' from the SPC; 'Seeing the data [sic] 45/15 mg is sufficient', which was inconsistent with this same statement from the SPC as well as its accompanying statement that 'Patients have to be maintained on the highest tolerable tolvaptan dose' and 'Uptitration should be the target, however, lower doses may be sufficient in case of problems' which was difficult to assess based on the lack of specificity in the latter part of the sentence.

Otsuka Europe submitted that it had not been asked to respond to the requirements of Clause 3.2 in relation to this case but considered that this amounted to a failure to maintain high standards, in breach of Clause 9.1.

Otsuka Europe submitted that:

- The presentations did not contain prescribing information and there was no indication that it was present at the symposium. Otsuka Europe had not been asked to respond to the requirements of Clause 4.1 in relation to this case, but the company considered that this amounted to a failure to maintain high standards, in breach of Clause 9.1.
- No formal certified speaker briefing for symposium speakers was developed although it appeared that there may have been an informal brief. Otsuka Europe considered that failing to formally brief speakers, in combination with the numerous other errors in relation to its congress participation amounted to a failure to maintain high standards, in breach of Clause 9.1.
- Certain promotional materials were not certified:
    - The signatory signed the incorrect part of the certificate for the item.
    - Further, one job bag (OPEL/0518/JIN/1282) was a medical information request form and therefore did not require certification; however, it was raised for certification and was not certified before use; additionally, the hard copy approval (which was also after first use) occurred before the certification.

Otsuka Europe stated that it had no explanation as to why many of the job bags were not certified correctly. It had not been asked to respond to the requirements of Clause 14.1 in relation to this case but considered that this amounted to a failure to maintain high standards, in breach of Clause 9.1.

The additional material used at the congress, including the promotional booth for Jinarc was provided.

Otsuka Europe stated that it recognized the seriousness of the issues identified and considered that it's approach to the symposium amounted to a failure to maintain high standards, in breach of Clause 9.1. Additionally, given the severity of the failings in relation to participation in this congress, it acknowledged a breach of Clause 2.

There were indications that as an organisation Otsuka Europe did not properly understand the distinction between promotional and non-promotional activities as defined by the ABPI Code. Reference was made to an extract from the 2018 brand plan for Jinarc; this categorisation was used for at least one other brand (Samsca). Otsuka Europe reviewed the presentation for both brand plans with a view to identifying the source of the mischaracterisation. Given that this failure appeared to be at an organisational level, this amounted to a failure to maintain high standards, in breach of Clause 9.1 and brought the industry in to disrepute, in breach of Clause 2.

With regards to the complainants' reference to 'commercial pressure to get more attendees for non-promotional meetings', it had no evidence as to whether this was the case for ERA-EDTA in 2018. However, as part of the investigation in to this complaint Otsuka Europe uncovered an email in relation to ERA-EDTA 2019 which indicated that there might have been such pressure (a comment in particular from a commercial employee which notes 'Clinicians are nowadays not interested in promotional Sympo, but want to talk about disease management, patient outcome and guidelines'). Otsuka Europe's participation in the congress in 2019 was cancelled.

As a result of these above issues as well an on-going case currently with the Panel (Case AUTH/3153/1/19), Otsuka Europe reviewed planned activities at congresses. Plans for Otsuka Europe presence at congresses in 2019 were requested from the brand teams and reviewed by Compliance using the following criteria:

- Has the process been correctly followed and sufficient time given for preparing the project?
- For projects initiated after 31 January 2019 (when the Concept Form was introduced), has a Concept Form been completed?
- Based on the documentation provided, did the meeting meet the expectations of the ABPI Code and/or local codes?

Otsuka Europe submitted that where there were identified issues with the preparation for a meeting and insufficient time to correct these, the company's presence at the congress had been cancelled. As part of this review, further misclassification of meetings as non-promotional had been identified and addressed.

Otsuka Europe submitted that based on this further misclassification, which was subsequent to the ABPI Code baseline training and European Regional SOP training provided in 2018 and 2019, the company had determined that compliance issues had not been remediated, and additional effort was necessary. Therefore, all Otsuka Europe initiated promotional and non-promotional activities, including the below (unless such activities were required for legal, regulatory (eg, prescribing information and risk minimisation materials) or contractual reasons were stopped. Work done jointly with Lundbeck would be subject to additional scrutiny and external signatory support might be used):

- Congresses
- Advisory boards
- Promotional material
- PR and advertising
- Interactions with patient advocacy groups
- Market research.

Otsuka Europe stated that it would only resume these activities once it was confident that they could be executed in compliance with the Code. In addition, it would review current brand plans as a matter of urgency to identify any similar issues and take appropriate action, as necessary.

Otsuka Europe stated that it was obvious it needed to retrain employees (including signatories) on the Code (including the distinction between promotional and non-promotional activities). Additionally, as employees had begun to work with the company's revised European Regional SOPs, their feedback indicated that they needed more specific detail in the documents. Therefore, it was conducting a comprehensive review of certain SOPs to obtain all feedback and would implement more specific SOPs to ensure employees had a level of direction that made them confident in their daily activities. Finally, a retrospective review of all external meetings from 2016 to current day was also planned to ensure that any additional issues could be identified and addressed.

In April, an employee raised a concern to compliance with regards to the ERA-EDTA guidelines on ADPKD that required an investigation. Otsuka Europe raised an incident and cross-linked it to an earlier, related complaint that was raised in March. Otsuka Europe would conduct the investigation and provide the PMCPA with the conclusion as it might have direct bearing on this case.

PANEL RULING

The Panel noted Otsuka Europe's submission that a concern regarding the Otsuka sponsored symposium at the 2018 ERA-EDTA congress in Copenhagen was raised internally prior to the Authority's receipt of the complaint.

The Panel noted Otsuka Europe's submission that the symposium was led by the medical department and was classified as non-promotional in the electronic approval system. Otsuka Europe stated that its investigation identified that the symposium slides were approved by the country of the congress affiliate (Denmark) as promotional.

The Panel noted the objectives of the symposium and that they referred to, *inter alia*, treatment/ management of Autosomal Dominant Polycystic Kidney Disease (ADPKD), the ERA-EDTA guidelines and case studies.

The Panel noted Otsuka Europe's submission that on review of the symposium slides it was clear to the company that it was promotional and disguised in that regard; it discussed treatment with tolvaptan (Jinarc marketed by Otsuka) which according to Otsuka Europe was the only medicine licensed for the indication. The Panel noted Otsuka Europe's submission that the materials used to advertise the symposium all referred to a discussion of the ERA-EDTA guidelines on ADPKD, which were in fact guidelines on the use of tolvaptan in ADPKD.

The Panel noted that the symposium slides included multiple references to tolvaptan. It was difficult for the Panel to understand how Otsuka could have classified and treated this meeting as anything but promotional. It had been classified as promotional by the Danish affiliate. In this regard, the Panel considered that Otsuka Europe had failed to maintain high standards and a breach of Clause 9.1 was ruled.

The Panel noted that the symposium slides stated, on the welcome and introduction slide, in small font, 'This meeting is organised and funded by Otsuka Pharmaceutical Europe Ltd'. The Panel further noted that this statement was on various materials used to advertise the symposium including the advertisement in the industry symposium booklet, the symposium invitation for electronic distribution, the flyer for distribution at the congress, room signage, poster board, banner stands and symposium booklet. These materials used to advertise the symposium made no mention of tolvaptan but referred to ADPKD and the ERA-EDTA guidelines which, according to Otsuka Europe, were guidelines on the UK of tolvaptan in ADPKD.

The Panel noted that promotional material did not have to be labelled as such but must not mislead in that regard. The Panel noted that at international congresses, it was not uncommon for companies to conduct both promotional and non-promotional activities and therefore health professionals must not be misled as to which activities were promotional and which were either non-promotional and/or the legitimate exchange of medical and scientific information during the development of a medicine.

In the Panel's view, it was clear that the symposium in question was an Otsuka Europe promotional symposium. However, the Panel considered, noting its

comments above, that, on the balance of probabilities, not all health professionals, based on the materials used to advertise the symposium at the scientific congress, would have expected the symposium to be a promotional meeting. In that regard it was disguised promotion and a breach of Clause 12.1 was ruled as acknowledged by Otsuka Europe.

The Panel noted that Otsuka Europe had identified a number of other issues during its investigation into this matter including, *inter alia*, the symposium slides not being consistent with the tolvaptan SPC and lack of prescribing information. Whilst the Panel was extremely concerned with regards to the issued identified, there had been no allegation on these points and therefore the Panel could make no rulings.

The Panel noted that Clause 2 was a sign of particular censure and reserved for such use. Whilst the Panel was concerned that Otsuka Europe classified a clearly promotional symposium as non-promotional, it did not consider that, on balance, the particular circumstances of this case warranted a ruling of a breach of Clause 2 and ruled accordingly.

APPEAL BY THE COMPLAINANT

The complainants alleged that it was clear that Otsuka Europe was unable distinguish between promotional and non-promotional activities. However, this was in part due to commercial pressure to certify such activities as non-promotional (as identified by Otsuka Europe). The internal investigation by Otsuka Europe did not complete by 19 April 2019 (no feedback was provided) – this was not an accurate representation by Otsuka Europe.

The complainants appealed the Panel's ruling of no breach of Clause 2.

The complainants alleged that this was a systemic problem within Otsuka for the following reasons:

- Conscious misclassification of non-promotional meetings.
- Failure to maintain high standards.

RESPONSE FROM OTSUKA

Otsuka Europe submitted that as acknowledged in its initial response to this case, it considered that this matter amounted to a breach of Clause 2. During the investigation conducted there was an indication that Otsuka Europe did not properly understand the distinction between promotional and non-promotional activities as defined by the Code and this failure was at an organisational level. This issue had recently been reinforced by a third party consultancy review of all Otsuka Europe meetings from 1 January 2016 which noted:

> 'We are concerned that the expectations of delegates accepting an invitation might be misguided as many of the events focus far more on Otsuka products than might be expected from the meeting titles and descriptions. This is particularly true for ADPKD meetings. Where the content is within label, these events should be regarded as promotional events.'

Otsuka Europe submitted that it was currently reviewing the information from the third party and would ensure that remediation activities were put in place to provide the necessary education and support in areas where concerns had been identified.

As noted by the Panel, it was difficult to understand how the symposium in question could have been anything other than promotional. Otsuka Europe considered this a systemic issue. This, combined with historical indications that there might have been commercial pressure to miscategorise such symposia as non-promotional, amounted to an activity that reduced confidence in the industry, and brought it into disrepute.

Otsuka Europe noted that the complainants stated that the investigation into the congress at issue in this case was not completed by the date proposed in the Otsuka Europe response (19 April 2019). This was correct. The investigation report was approved internally in June 2019. This delay was unacceptable and was attributable to a lack of capacity and a lack of leadership in certain areas. Information on action taken to address this appeared below.

Otsuka Europe submitted that whilst it acknowledged that the above amounted to a breach of Clause 2, it considered it vital that the Appeal Board understood the significant actions that had been taken in order to address these and the other issues faced by Otsuka Europe:

- Details of various staff changes and appointments were provided.
- As communicated to the PMCPA on 6 April 2019, Otsuka Europe had ceased initiating promotional and non-promotional activities unless such activities were required for legal, regulatory (eg, prescribing information and risk minimisation materials) or contractual reasons. The latter included work done jointly with Alliance partners. From June 2019, any Otsuka Europe signatories had to have completed comprehensive third party validation.
- A cross-functional project team had developed Otsuka Europe specific procedures for all Code-related activities conducted by Otsuka Europe, in order to provide the depth of detail required by the organisation. These had been extensively reviewed and were currently being cross-checked to ensure that they were robust. These would then be rolled out with comprehensive face-to-face training and knowledge and would then be validated via Otsuka's learning management system.
- The July meeting of the newly formed European Pharmaceutical Leadership Team (EPLT) included an assessment of the current challenges faced by Otsuka Europe, what the future held for the organisation and what the leadership team wanted, and how the leadership team intended to achieve their goals. Details were provided. These included:

  - Creation of a Vision and Roadmap to 2024.
  - Strategy to achieve Roadmap to 2024.

    - Continue to strengthen Culture & Engagement.
    - Continue CORE activities.
- Get the 'Basics' right on business processes.

The above goals were presented at a town hall meeting in July 2019.

- A European Code of Conduct for all employees that would set out the ethical standards for employees to adhere to was being developed.
- Otsuka Europe was committed to transparent communication within the organisation and expected the same from its leadership team. In addition to the weekly town hall meetings, Otsuka Europe had instituted weekly 'Ask EPLT' sessions where any staff member might ask questions as part of a small group in a more informal setting.

Otsuka Europe hoped that the above demonstrated the approach that Otsuka Europe was taking to address the significant issues that it faced.

FINAL COMMENTS FROM THE COMPLAINANT

The complainants acknowledged that Otsuka Europe accepted a breach of Clause 2. The complainants were surprised by the statement from the third party that had conducted a review of all Otsuka Europe meetings from 1 January 2016. If this had revealed that the issues in Otsuka Europe were widespread, surely all activities should have been stopped (material and activities were still carrying on), and all employees should undergo retraining immediately? The findings had not been shared. The complainants presumed that the reason for confidentiality was that Otsuka was still in the process of reviewing the report. The complainants advised Otsuka to share the learnings so that previous mistakes were not repeated.

The complainants urged Otsuka's current leadership to have more tangible outputs for those on the ground. The complainants stated that they did not see a significant difference between the past and present leadership.

APPEAL BOARD RULING

The Appeal Board noted that the symposium at issue was led by Otsuka Europe's medical department and was classified as non-promotional in the electronic approval system. The Appeal Board noted that the symposium slides included multiple references to tolvaptan. The symposium slides were approved as promotional by the Danish affiliate. In addition, Otsuka Europe had a promotional booth for Jinarc (tolvaptan). The Appeal Board agreed with the Panel in that it was difficult to understand how the symposium in question could have been anything other than promotional.

The Appeal Board noted Otsuka Europe's submission that its investigation indicated that the company did not properly understand the distinction between promotional and non-promotional activities as defined by the Code and this failure was at an organisational level. The representatives from Otsuka Europe submitted that it was not conscious misclassification of non-promotional meetings, but gross incompetence caused by a lack of training, management and support. Otsuka Europe submitted that these failings had reduced confidence in the pharmaceutical industry.

The Appeal Board considered that such failings reduced confidence in the pharmaceutical industry and ruled a breach of Clause 2 as acknowledge by the company. The appeal on this point was successful.

The Appeal Board noted the issues found during Otsuka Europe's investigation and the actions taken. It noted that some of these were identified in the recent audits of Otsuka Europe and Otsuka UK required in Cases AUTH/3041/6/18 and AUTH/3123/11/18.

2 Internal meeting 18 March

COMPLAINT

The complainants provided additional information about an internal company meeting held that day (18 March). It was a weekly management update meeting that focused on the Appeal Board meeting on 13 March. There was a debrief on the presentation and the types of questions asked by the Appeal Board.

The complainants stated that attendees were informed that culture was of particular interest, especially around whistleblowing. A senior employee at Otsuka Europe (named) went on to add that during this 'period' it was very easy to finger point individuals and departments. This person stated that there might be some individuals in the audience that wondered what he/she was still doing in the organisation, especially as the impression might be that he/she 'is no good/ an idiot' [sic] … given the numerous failings. This person announced that he/she was not 'going anywhere'.

The complainants alleged that the senior employee then asked all present to raise their right hand and swear that they would not complain about individuals or departments to anyone for the next 6 months. He/she added that when staff were questioned during the PMCPA audit, they had to be careful with their answers. He/she declared that the PMCPA would open up with easy questions, and then tackle more difficult areas, eg were we happy with the processes and the organisation? He/she hinted that staff would receive training to indicate their appropriate answers.

The complainants alleged that, in summary, they should not be holding each other to account (by swearing not to complain) and would receive training to provide the answers the PMCPA want to hear during the audit (lack of transparency).

The complainants alleged that it was clear that the culture in Otsuka Europe was going from bad to worse and they did not see it improving imminently.

The complainants provided a copy of an email (22 March) to staff following the meeting on 18 March which suggested that the leadership team felt that the pledging episode was not appropriate. The

complainants wanted to find out what specific feedback he/she received from the leadership team, and if a formal investigation had begun (especially as this had been brought to the attention of the PMCPA). The complainants believed that the email was not entirely accurate (the complainants stated that they did not know what would be communicated to the PMCPA). Before making all of the employees pledge that they would not complain, he/she shared a restaurant motto – 'If you are happy tell everyone, if you are not tell us'. This action was to stop disgruntled employees from going outside the company to complain about certain issues. The complainants believed with the restaurant story in mind and the forced pledging, the direct message was not to further whistle blow.

The complainants stated that, given this evidence, the senior employee conceded that he/she was not clear with his/her messaging and that his/her actions caused certain employees to feel deeply uncomfortable.

When writing to Otsuka Europe, the Authority asked it to bear in mind the requirements of Clauses 9.1 and 2 of the Code

RESPONSE

Otsuka Europe stated that the complainant was referring to the weekly management update meeting that took place on 18 March 2019. These meetings occurred every Monday as part of the commitment to employees to provide open, transparent communication and to update on progress on the CORE programme as well as other business updates. All Otsuka Europe employees and office based Otsuka UK and OEDC employees were invited to attend and the slides were made available on the intranet site for those who were unable to attend in person.

The CORE programme was a key initiative in Otsuka Europe aiming to improve processes, culture and how the different entities in Otsuka work together more effectively. The complainant referenced CORE as being a 'positive initiative' with 'more transparent communication'.

At the meeting on 18 March, the main agenda item was to update the organisation on the outcome of the Appeal Board that took place on 13 March. The employees were taken through the same slides that were used in the Appeal Board presentation on 13 March and were informed of the outcome that Otsuka Europe and Otsuka UK would be audited by the PMCPA in late June/early July and that both companies would receive a public reprimand.

Otsuka Europe submitted that the comments that the complainants referred to were taken out of context. Some of the comments quoted by the complainants were made but with a very different intention. As part of the CORE programme, there was as real focus on improving the culture in Otsuka Europe. The comments made around asking the audience to raise their right hands and pledge not to complain around others were simply made to try to promote an open culture of giving and receiving feedback to individuals and teams. An email was sent to all employees following the meeting (22 March) to clarify this. As part of the CORE programme, there was a work-stream focusing on Audit Readiness. The aim of this initiative was to ensure that Otsuka was audit ready at all times both for internal and external audits. It had been communicated to employees that they would be supported both before any such audits, during the audits and in the remediation post-audit. Employees were not told that they would 'receive training to indicate our appropriate answers'.

Otsuka Europe submitted that the communication at these meetings had been transparent at all times. It continued to execute its culture strategy and would provide audit readiness training for employees; this training would focus on what to expect from an audit (including that the interviews would be entirely confidential) and would convey the importance of answering questions completely and honestly.

In relation to the comments made by the senior employee at the meeting on 18 March, Otsuka Europe submitted that there had been no breach of Clauses 9.1 or 2.

In a further response following notification of the additional information from the complainants, some members of the leadership team fed back that the comments could have been misinterpreted by staff to mean do not complain outside of the company, or potentially do not complain. It was acknowledged that high standards had not been maintained, in breach of Clause 9.1 but there was not a breach of Clause 2.

PANEL RULING

The Panel noted the complainants' allegation that employees were asked to raise their right hand and swear that they would not complain about individuals or departments to anyone for the next 6 months. The Panel noted Otsuka Europe's submission that all Otsuka Europe employees, office-based Otsuka UK and OEDC employees were invited to attend the weekly management update meeting in question which was also placed on the intranet.

The Panel noted Otsuka Europe's submission that the comments referred to by the complainants were taken out of context and the company was trying to promote an open culture of giving and receiving feedback to individuals and teams.

It was not entirely clear to the Panel what exactly was said at the meeting in question. The Panel noted the interview notes with some of the meeting attendees who were also on the leadership team; these referred to the comments in question potentially being misinterpreted as saying to staff do not complain outside of the company and staff should not have been asked to do the pledge; and that the intention was not to say 'don't complain' but to say 'also discuss this with the person you have a concern with so that they have a chance to change their behaviours/actions', but this could have been misinterpreted.

The Panel noted that the comments were made at a meeting which was to inform staff that Otsuka UK and Otsuka Europe would be audited by the Authority later that year. The audit was in relation to three cases and in each case it appeared that the complainant was an Otsuka employee. The Panel further noted that at the time of the meeting in question there were ongoing Otsuka cases at the Authority where the complainant appeared to be an anonymous employee or employees. The Panel considered that it was a critical time for the company with regard to compliance and comments made by senior members of staff at this time would be fundamental in driving the company's compliance culture.

The Panel considered, based on the evidence before it, that the comments made by a senior employee at the meeting in question would, on the balance of probabilities, have been interpreted by some as saying do not complain outside the company. In the Panel's view, such comments from a senior employee would have a huge impact on the culture within the company at a critical time when the company ought to be actively encouraging open dialogue about compliance matters. The Panel considered that Otsuka Europe had therefore failed to maintain high standards and a breach of Clause 9.1 was ruled as acknowledged by the company.

The Panel noted that the email sent on 22 March, following the company's notification of the complaint, to the attendees to apologise that his/her pledge request and the intended message might not have been clear to all. The email further stated that there were complaint mechanisms such as the Speak Up line run by a third party which protected anonymity.

In the Panel's view, the implied message 'do not complain outside the company' was a serious matter that undermined the Code and self-regulation. Regardless of whether or not such a message was intended or misinterpreted, the Panel considered that the comments at the meeting in question meant Otsuka Europe had brought discredit upon and reduced confidence in the pharmaceutical industry. The Panel therefore ruled a breach of Clause 2.

With regard to the allegation in relation to training staff to ensure that appropriate answers are given during the upcoming audit, the Panel noted Otsuka Europe's submission that audit readiness training for employees would focus on what to expect and would convey the importance of answering questions completely and honestly. Otsuka Europe made no submission about whether such matters were within the scope of the Code. The Panel noted that it was not inappropriate to provide training in preparation for an audit. The training had not taken place at the time of the complaint. The complainants had not shown that their concerns gave rise to a Code matter. No detail was provided. The Panel ruled no breach of the Code as the subject matter of complaint was outside the scope of the Code.

Complaint received	**20 March 2019**
Case completed	**16 October 2019**