

**CASE AUTH/3757/3/23**

**COMPLAINANT v OTSUKA**

**Allegations about Otsuka’s submission in relation to a previous case**

**CASE SUMMARY**

A complaint was received in 2023 in relation to Otsuka’s submission to the PMCPA in a previous case which was completed in 2015. The complainant was an ex-employee of Otsuka who had given a statement during an internal investigation. The complainant alleged that Otsuka had failed to disclose all relevant information to the PMCPA, that Otsuka had not allowed witnesses to see or sign the statements submitted to the PMCPA and had removed information from them, and that three employees were forced out of the business because they were whistleblowers.

The outcome under the 2015 Code was:

<b>Breach of Clause 2</b>	<b>Bringing discredit upon, and reducing confidence in, the pharmaceutical industry</b>
<b>Breach of Clause 9.1 (x2)</b>	<b>Failing to maintain high standards</b>
<b>No Breach of Clause 2 (x2)</b>	<b>Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry</b>
<b>No Breach of Clause 9.1</b>	<b>Requirement to maintain high standards</b>

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

**FULL CASE REPORT**

A complaint was received from a named ex-employee of Otsuka relating to Otsuka’s submission in response to Case AUTH/2752/3/15.

Note: In this case, the term ‘the complainant’ refers to the complainant in Case AUTH/3757/3/23. There are no references to the complainant for Case AUTH/2752/3/15.

**COMPLAINT**

The complainant stated that they were involved in giving a statement in relation to Case AUTH/2752/3/15. In that case, the company (Otsuka) was found to have breached Clauses 2, 9.1 and 12.1 of the 2015 Code. It was noted in the PMCPA case report that three statements were unsigned. The complainant stated that they were one of the individuals that did not sign their statement, along with the two other individuals (colleagues). The complainant alleged that it was not that they (and the other two individuals) did not sign them, they were not allowed to

see the final statement sent on their behalf and not allowed to sign them. The complainant believed the reason for this was the company altered their statement to remove vital information. The complainant alleged the reason they knew this was because, prior to any investigation by the PMCPA, the individual that witnessed the events described in Case AUTH/2752/3/15 submitted a statement to the company outlining their concerns and a potential breach of the Code. The complainant alleged that this complaint was never investigated and was 'brushed under the carpet' and this was never mentioned in any of the documents submitted to the PMCPA. The complainant believed that the company tried to cover this up. The complainant alleged that, subsequent to the investigation, they and colleagues involved were perceived as whistleblowers and pushed out of the company, which 'had a significant impact on the lives of a certain individuals' [sic]. The complainant stated they had made contact with Otsuka to raise their concerns but Otsuka could not find any evidence relating to the case to validate or otherwise their complaint.

The complainant included a copy of an email with 'the original statement given to the company that all three witnesses submitted prior to any investigation' as part of this new complaint.

The complainant summarised their allegations as follows:

1. Otsuka failed to reveal all the information to the PMCPA that was highly relevant and did not give full disclosure of the fact, by admitting they were aware of the complaint and took no action.
2. Otsuka failed to allow the witnesses to sign their statements and removed crucial information from their statement, informing the PMCPA that the employees that witnessed the incident had reported the event to senior management in Otsuka prior to any PMCPA investigation.
3. Otsuka forced three employees out of the company as they were seen to be whistleblowers.

When writing to Otsuka, the PMCPA asked it to consider the requirements of Clauses 9.1 and 2 of the 2015 Code.

## **RESPONSE**

Otsuka stated that the complainant wrote to Otsuka on 28 February 2023 outlining their concerns, which Otsuka began to investigate. Otsuka carried out a physical search of the hard copy folders and an electronic search of the Otsuka UK shared drive including any relevant HR folders.

As noted in the response letter from Otsuka to the complainant, Otsuka was unable to locate the response letter and enclosures for Case AUTH/2752/3/15. Otsuka stated that, unfortunately, due to the passage of time and the significant personnel changes within Otsuka Pharmaceuticals UK Ltd in the past eight years, (there were no currently serving Otsuka UK head office staff who were employed by Otsuka UK in 2015), this case had been extremely difficult to investigate.

Otsuka stated that Case AUTH/2752/3/15, which was the case the complainant referred to, was ruled upon in 2015 and Otsuka was found in breach of Clauses 2, 9,1 and 22.1 of the 2015 Code. Otsuka submitted that, since that time, it had been through a number of PMCPA audits and there had been substantial changes to its compliance programme, governance, operations and whistleblowing procedures.

On receipt of this complaint (Case AUTH/3757/3/23) on 4 April 2023 and after reviewing the allegation, Otsuka's understanding was that the complainant was concerned that Otsuka had altered their statement and that vital information had been withheld when the response to Case AUTH/2752/3/15 was submitted to the PMCPA in 2015. Otsuka submitted that it carried out a further proportionate IT search to try and locate the complaint response for Case AUTH/2752/3/15 and details around the email that was submitted by the complainant as part of this new complaint, which had not previously been provided to Otsuka by the complainant. Unfortunately, Otsuka was still unable to locate the response letter and enclosures which were previously submitted as a response to Case AUTH/2752/3/15 or the email provided by the complainant.

Otsuka stated that it had reviewed the PMCPA case report, and the attached witness statement provided by the complainant and there did not appear to be any vital information missing from the case report that appeared in the witness statement.

Having reviewed what was sent to Otsuka and reviewed the case report, Otsuka saw no evidence before it of any wrongdoing in response to Case AUTH/2752/3/15. Otsuka therefore denied any alleged breach of the Code.

## **FURTHER RESPONSE**

Following receipt of Otsuka's response, above, the case preparation manager provided Otsuka with a scanned copy of Otsuka's response letter and enclosures to Case AUTH/2752/3/15 to enable Otsuka to further investigate and provide a full response to this complaint.

Otsuka stated that, due to the passage of time and the significant personnel changes within Otsuka Pharmaceuticals UK Ltd in the past eight years, this case had been extremely difficult to investigate. However, the provision of the response letter, enclosures, and additional requests by the case preparation manager had been particularly useful and allowed the company to locate additional information related to the investigation of this complaint at the time.

Considering this new information, Otsuka re-addressed each of the complainants' allegations and provided the requested documents/responded to the questions raised by the PMCPA case preparation manager.

## **Background**

Otsuka stated that the complainant wrote to Otsuka on 28 February 2023 outlining their concerns, which Otsuka began to investigate. Otsuka carried out a search of the hard copy folders and an electronic search of the Otsuka UK shared drive including any relevant HR folders.

As noted in the response letter from Otsuka to the complainant, Otsuka was unable, at that point in time, to locate the response letter and enclosures for Case AUTH/2752/3/15.

On receipt of this complaint (Case AUTH/3757/3/23) on 4 April 2023, Otsuka carried out a review of its HR files and a proportionate IT search to try and locate the complaint response for Case AUTH/2752/3/15 and details around the email that was submitted by the complainant as part of this new complaint. Otsuka carried out a further search on receipt of the letter from the PMCPA case preparation manager that included a copy of Otsuka's response letter and

enclosures for Case AUTH/2752/3/15. During this second search, Otsuka was able to identify that the investigation for Case AUTH/2752/3/15 was carried out by the Otsuka European Human Resource (HR) team and the relevant information pertinent to this case was saved in the Otsuka Pharmaceuticals Europe Ltd HR files.

With reference to the email provided by the complainant, Otsuka stated that its IT email archive search could only go back to June 2015. This was because the application that did the archiving was not installed until this time; before this, Otsuka did not have a solution for archiving the emails. The email appeared to be from March 2015 and therefore Otsuka was unable to find it.

It was Otsuka's understanding that the complainant raised three main concerns, as noted below:

1. Otsuka failed to reveal all the relevant information to the PMCPA in response to Case AUTH/2752/3/15. Otsuka were aware of this case and did not take any action.
2. Otsuka did not allow witnesses to sign their statements and had removed crucial information from the statement.
3. Three employees were forced out of the business as they were whistleblowers.

Otsuka addressed each of these allegations separately below.

- 1. Otsuka failed to reveal all the relevant information to the PMCPA in response to Case AUTH/2752/3/15. Otsuka were aware of this case and did not take any action.**

***Process for the creation of the statements provided as enclosures in Case AUTH/2752/3/15***

From a review of the Otsuka Europe HR complaint folder for Case AUTH/2752/3/15, Otsuka understood that invitations to attend investigation meetings relating to the complaint in Case AUTH/2752/3/15 were sent out to the four Otsuka UK employees who were described in Case AUTH/2752/3/15 as having met in the public bar following the gala dinner at a British clinical group meeting which took place in Ireland in January 2015. It appeared that each of these meetings took place individually on 25 or 26 March 2015.

Otsuka stated that it appeared that the interviews were recorded, and transcripts produced. However, Otsuka had only been able to locate three of the four recordings but all four transcripts. Otsuka submitted that, following the meetings, a brief statement was then created (for each person interviewed) by those carrying out the interview, which described the details of the events of the night of the gala dinner specifically.

Otsuka noted that from the email correspondence with some of the individuals interviewed, it was highlighted that factual details were provided in these statements and personal opinions which were expressed during the interviews were not included. Otsuka had evidence that the complainant and one of the other employees interviewed were shown a version of their statement and were allowed to provide comments. However, Otsuka submitted that there appeared to be some changes from the versions that these individuals reviewed compared to the final versions submitted. Otsuka did not have this same email correspondence relating to the other two employees interviewed and therefore Otsuka was unsure what statements were shared with them. Otsuka did, however, have the transcripts from the investigation meetings and the final statements submitted to the PMCPA in 2015.

***Evidence this issue had been raised to Otsuka before the PMCPA complaint was received.***

Otsuka submitted that during one of the interviews, the interviewee stated that a report had been provided to [a named employee from the Otsuka UK HR team]. The interviewee further stated that following the report to HR, they had been informed that there had been some discussions with Medical relating to one of the issues raised around it being a Code breach. However, following the discussion with Medical it appeared it was agreed that this was not a breach. Otsuka submitted that it had been unable to find any documentation stating specific details of what actions were taken and there was no evidence that an investigation was carried out prior to the investigation relating to the PMCPA complaint.

Otsuka stated that it could therefore confirm that Otsuka were aware of this issue before the PMCPA complaint had been received.

Otsuka submitted that it did not have specific evidence of the date the report was sent to HR. However, the date reflected on the report letter provided by the complainant was 2 March 2015. Otsuka had not been able to locate this report during its investigation. Assuming that it was sent on the same date, there were 12 working days between the date on the report and the date that the PMCPA complaint was received. As those involved in the investigation were no longer employed by Otsuka, the company was not able to ascertain why this information was not highlighted in the response provided by Otsuka to Case AUTH/2752/3/15 in 2015.

**2. Otsuka did not allow witnesses to sign their statements and had removed crucial information from the statement.**

Otsuka referred to the details above for the process which it understood was followed at the time to create the statements.

As the individuals involved in investigating this complaint and those involved in providing witness statements were no longer with the organisation, Otsuka was not able to confirm this point. However, these final statements were not signed, and Otsuka stated that it had no evidence to confirm or refute that these were provided/shown to those interviewed before the response was submitted.

Otsuka stated that it now had a robust incident response process in place and, as part of this process, there was a requirement that all interview notes were documented and that final notes were agreed by the interviewee. Otsuka submitted that these requirements would avoid such failures in future.

**3. Three employees were forced out of the business as they were whistleblowers.**

Otsuka stated that it was aware that there were a number of changes to the Otsuka UK organisation implemented in 2015. Otsuka provided copies of the organograms from March 2015 and April 2016.

Otsuka submitted that, in 2015, within Otsuka UK there was a restructuring called 'Project Spring'. This restructuring focused on capabilities and putting resources in the right place and affected multiple departments. This was announced in June 2015 and those affected left the organisation from October 2015 onwards. Otsuka stated that two of the employees mentioned

above left at this time. Another of these employees had left the organisation earlier in the year. Otsuka submitted that there were a number of people who left as part of the restructure.

From a review of the documentation regarding this point, Otsuka saw no evidence that the three employees were forced out of the business due to whistleblowing and therefore refuted this allegation.

There was a whistleblowing process in place in 2015. Otsuka submitted that in 2015 there did not appear to have been a tracker or system in place which documented incidents raised, this process of recordkeeping was introduced in 2017.

Having now reviewed all the documentation and the complaint investigation folder, Otsuka acknowledged that relevant information discussed in the interviews (e.g. awareness of the incident before the PMCPA complaint) was not included in the witness statements submitted to the PMCPA for Case AUTH/2752/3/15. Otsuka therefore accepted that high standards had not been maintained in this regard and accepted a breach of Clause 9.1 and Clause 2 of the 2015 Code.

Otsuka stated that these matters related to a historical case and since this time Otsuka had been through a number of PMCPA audits and there had been substantial changes to its leadership, employees, compliance programme, governance oversight, operations, and whistleblowing procedures. Therefore, Otsuka submitted, these matters did not reflect Otsuka's organisation today.

## **PANEL RULING**

The Panel noted the complainant described themselves as an ex-employee of Otsuka who had given a statement during an internal investigation to enable the company to respond to a complaint to the PMCPA in relation to a case from 2015 (Case AUTH/2752/3/15).

Case AUTH/2752/3/15 was regarding the conduct of a senior Otsuka employee following the dinner at a British clinical group meeting that took place in Ireland in January 2015. In that case, the Panel ruled breaches of Clause 22.1 (relating to provision of hospitality), Clause 9.1 (failure to maintain high standards at all times) and Clause 2 (bringing discredit upon or reducing confidence in the pharmaceutical industry) of the 2015 Code.

The Panel noted that the complainant had contacted Otsuka with their concerns in February 2023, before making this complaint to the PMCPA, but that Otsuka was unable to perform an investigation into the complaint because of the time that had elapsed between the original incident and this complaint (eight years). The complainant then submitted their complaint to the PMCPA.

### **Allegation 1: Failing to disclose all relevant information to the PMCPA**

The complainant alleged that Otsuka had failed to disclose all relevant information to the PMCPA as part of its response to Case AUTH/2752/3/15. They further alleged that Otsuka was aware of the incident referred to in Case AUTH/2752/3/15 before the PMCPA notified Otsuka of the complaint: an employee had already submitted a report to Otsuka's HR team about the incident; however, the complainant alleged, this had been 'brushed under the carpet'. The

complainant stated that as part of its submission for Case AUTH/2752/3/15, Otsuka should have acknowledged that it was already aware of the incident but had taken no action.

Otsuka submitted that a report about the issue that was later the subject of Case AUTH/2752/3/15 had been provided to a member of the Otsuka UK HR team and that Otsuka had, therefore, been aware of the issue before the PMCPA complaint was received. Otsuka was not able to ascertain why this information was not included in Otsuka's response to Case AUTH/2752/3/15. Otsuka acknowledged that relevant information was not included in the witness statements submitted to the PMCPA; Otsuka accepted that high standards had not been maintained in this regard and accepted a breach of Clause 9.1 and Clause 2 of the 2015 Code.

The Panel noted that the incident referred to in Case AUTH/2752/3/15 took place at the end of January 2015. The PMCPA notified Otsuka of the complaint in mid-March 2015. As part of its investigation into the complaint, employees from Otsuka Europe conducted interviews with four Otsuka UK employees on 25 and 26 March 2015. Otsuka's submission included, among other things, unsigned witness statements from the four employees. Otsuka had, at that time, not submitted any information that indicated that Otsuka had been aware of the incident prior to the receipt of the complaint.

The Panel noted that Otsuka's submission in response to the current case included transcripts and audio recordings of interviews with the four witnesses, from which the witness statements were produced. The Panel noted that in one of the interviews, the witness mentioned that they had raised their concerns with their line manager 'a couple of weeks' after the incident. In another of the interviews, the witness talked about having submitted a report about the incident to the Otsuka UK HR team around four or five weeks after the incident. They said that they 'wanted to make it clear that [they were] making the company aware that there was a possible breach of the Code and therefore it was [their] duty to report it.' They encouraged the interviewers to look at the report for more information when compiling the witness statement because it was written nearer to the time of the incident.

Comparing the content of the witness statements submitted for Case AUTH/2752/3/15 with the transcripts and audio recordings of the interviews, the Panel determined that the witness statements did not reflect the full content of the interviews. The Panel considered that the fact that both Otsuka UK and Otsuka Europe had been aware of the incident prior to the receipt of the complaint from the PMCPA was important information that should have been included in its response to Case AUTH/2752/3/15. The Panel considered that high standards had not been maintained in this regard, as acknowledged by Otsuka, and ruled **a breach of Clause 9.1** of the 2015 Code.

The Panel noted that self-regulation relied on full and frank disclosure of all the facts; a lack of transparency in this regard was of considerable concern. The Panel considered that in failing to include relevant information in its submission for Case AUTH/2752/3/15, Otsuka had brought discredit upon and reduced confidence in the pharmaceutical industry. The Panel ruled **a breach of Clause 2** of the 2015 Code, as acknowledged by Otsuka.

## **Allegation 2: Removing crucial information from witness statements**

The complainant's second allegation was that Otsuka had not allowed the witnesses to see or to sign the final statements submitted for Case AUTH/2752/3/15 and that 'crucial information' was

removed from their statements – specifically, that one of the witnesses had submitted a report (about the incident in Case AUTH/2752/3/15) to Otsuka UK's HR team prior to the notification of the complaint from the PMCPA.

Otsuka submitted that it had no evidence to confirm or refute the allegation that the witnesses were not shown the final wording of the statements before they were submitted to the PMCPA, but acknowledged that the statements were not signed. The Panel noted Otsuka's comment that it now had a process in place that required that all final interview notes were agreed by the interviewee.

The Panel noted from the evidence before it (provided by Otsuka) that the complainant and at least one of the other witnesses were offered the opportunity to comment on at least one version of their statement. By comparing against the final versions of the witness statements submitted for Case AUTH/2752/3/15, the Panel noted that not all of the comments and proposed amendments made by these two witnesses appeared to have been actioned. The complainant, in particular, had provided Otsuka with a revised version of the statement where they included mention of having raised their concerns on the evening of the incident with colleagues present, including their line manager, and also after the event, during a field visit with their line manager. The Panel noted these points were not included in the final version of the complainant's statement submitted to the PMCPA.

As the Panel noted above from the interview transcripts and audio recordings, there were points raised by the witnesses that were not included in the final witness statements, such as the report of the incident that had been made to the Otsuka UK HR team. The Panel had no way, however, of determining whether this information had been removed from any final draft statement that the witnesses had seen, or whether it was never included. The Panel noted that Otsuka had not provided evidence that the witnesses were shown the final statements and that the final statements were not signed.

The Panel noted Otsuka's submission that it **now** [emphasis added] had 'a robust incident response process' in place and, as part of this process, there was a requirement that all interview notes were documented and that final notes were agreed by the interviewee. Otsuka submitted that these requirements would avoid such failures in future. With the evidence before it, the Panel considered that Otsuka's processes had not been robust; the interviewees had not been given the opportunity to agree and sign the witness statements produced as a record of their interviews. The Panel considered that high standards had not been maintained and ruled a **breach of Clause 9.1** of the 2015 Code.

Clause 2 was a sign of particular censure and reserved for such use. The Panel considered its comments above – in particular, that the final witness statements submitted in Case AUTH/2752/3/15 had not included points raised in the interview transcripts and audio recordings. This was a concern, however the Panel noted there was no definitive evidence, before them that Otsuka had 'removed' information from the statements. On this narrow ground the Panel ruled **no breach of Clause 2** of the 2015 Code.



### **Allegation 3: Forcing three employees out of the business because they were whistleblowers**

The complainant's third allegation was that, subsequent to Otsuka's investigation of the complaint in Case AUTH/2752/3/15, the complainant and other colleagues involved were 'perceived as whistleblowers and pushed out the company'.

The Panel noted that whistleblowers are protected by law, under the Employment Rights Act 1996. If a whistleblower believes that they have been unfairly treated because they have blown the whistle, they may decide to take their case to an employment tribunal. The Panel noted that its sole role was to rule in relation to the Code.

The Panel considered Otsuka's submission that two of the employees referred to by the complainant left the company in 2015 following an organisational restructure and one had left earlier in 2015 before the restructuring. The Panel considered the two organograms provided by Otsuka that showed the structure before and after the reorganisation and noted that a number of employees had left as part of the restructure.

The Panel noted that there did not appear to have been any formal finding of unfair dismissal in relation to this complaint. The Panel considered that in the absence of such a formal finding, the complainant, who bore the burden of proof, had not established that the whistleblowers had been treated unfairly by Otsuka or 'pushed out' of the company. The Panel ruled **no breach of Clauses 9.1 and 2** of the 2015 Code in this regard.

### **Concluding remarks**

The Panel was disappointed that Otsuka was initially unable to respond in full to this complaint and that its response had been reliant on the PMCPA case preparation manager providing Otsuka with its original submission for Case AUTH/2752/3/15. Having initially refuted any breaches of the Code, in its revised submission, Otsuka acknowledged potential breaches of the Code including Clause 2. While the Panel acknowledged that there had been significant changes in personnel since 2015, the Panel considered that Otsuka should have been able to locate the relevant information regarding Case AUTH/2752/3/15 in which it had been found to have breached the Code, including Clause 2.

The Panel noted that the complaint was a historic one and that eight years had passed since the events that were the subject of the complaint had occurred. The Panel noted that this complaint concerned both Otsuka UK (in receiving the initial HR report) and Otsuka Europe (in conducting the witness interviews) and that the PMCPA had conducted four audits of Otsuka UK and Otsuka Europe in this time (between July 2019 and January 2022).

The Panel noted that one of the cases that led to the audits, Case AUTH/3123/11/18, was regarding Otsuka Europe not being transparent in its response to the PMCPA regarding Case AUTH/3041/6/17. The Panel was concerned and disappointed that this was another example of Otsuka not being transparent in its response to the PMCPA. The integrity of self-regulation, and the reputation of the industry relied upon the provision of complete and accurate information by pharmaceutical companies; a lack of transparency in this regard was of considerable concern. The Panel was concerned with Otsuka's conduct; the failure to provide a full and frank disclosure and the lack of transparency which had come to light in this case was unacceptable. Such circumstances would ordinarily result in the Panel reporting a company to the Code of

Practice Appeal Board, in accordance with Paragraph 8.2 of the Constitution and Procedure for the Appeal Board to consider in relation to Paragraph 11.3. The Panel noted the PMCPA audits that the company had undergone between 2019 to 2022 and Otsuka's submission that there had been substantial changes since 2015 to its leadership, employees, compliance programme, governance oversight, operations, and whistleblowing procedures. The Panel considered that, on balance, and bearing in mind the need for proportionate regulation, it would not report Otsuka to the Appeal Board.

The Panel bore in mind that the Appeal Board received all cases completed at the Panel level and, under Paragraph 11.1 of the Constitution and Procedure, could, at that point, consider whether additional sanctions might be appropriate.

**Complaint received**      **31 March 2023**

**Case completed**        **15 April 2024**