CASE AUTH/3791/7/23 ***NO BREACH OF THE CODE***

COMPLAINANT v MODERNA

Allegations about whistleblowing processes and off-label promotion

CASE SUMMARY

This case was in relation to Moderna's internal whistleblower systems/processes and a webcast by Moderna US.

The outcome under the 2021 Code was:

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 3.1	**Requirement that a medicine must not be promoted prior to the grant of its marketing authorisation**
No Breach of Clause 5.1	**Requirement to maintain high standards at all times**

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

FULL CASE REPORT

A complaint was received from an anonymous, non-contactable complainant, who described themselves as a health professional, about Moderna.

COMPLAINT

The complaint wording is reproduced below:

> "Lack of internal systems and processes to deal with Whistleblower complaints and also the potential off-label promotion by [medical affairs individual] in the US [united states] on a webcast (? HCPs geographies for attendants)."

When writing to Moderna, the PMCPA asked it to consider the requirements of Clauses 2, 3.1 and 5.1 of the 2021 Code.

MODERNA'S RESPONSE

> "We believe the complainant is a former contractor [details provided] and is the same complainant as in Case AUTH/3789/7/23 and AUTH/3790/7/23 in which the complainant describes him/herself as an ex-employee.

The screen shots provided by the complainant show a third-party platform [named] which Moderna phased out in January 2022 and the US webinar referenced took place on 9 September 2021. The complaint's allegations are alleged to have occurred before Moderna Biotech Limited ('Moderna UK') voluntarily became a member of the ABPI and accepted the jurisdiction of the PMCPA in January 2023, and agreed to abide by the ABPI Code.

Moderna UK accepted the jurisdiction of the PMCPA from the date of joining the ABPI, however, Moderna UK was not and cannot reasonably be expected to have been subject to the ABPI Code requirements prior to becoming an ABPI member.

If the PMCPA's position is that the ABPI Code applies retrospectively to all members upon joining the ABPI, this should have been made clear to companies prior to joining. In Moderna's case this expectation was not communicated. In the absence of any indication of a retroactive application of the ABPI Code, Moderna UK had a reasonable and legitimate expectation that activities conducted prior to joining the ABPI would not be assessed under the requirements of the ABPI Code.

Although Moderna UK does not believe that the ABPI Code applies here, we have provided responses to the complaint allegations below with reference to the specific clauses of the Code referenced in your letter.

Whistleblowing systems and processes

The complainant alleges that Moderna UK has a '*lack of internal systems and processes to deal with Whistleblower complaints'* and as supporting evidence has provided the PMCPA with two screen shots of Moderna's internal system and process for dealing with whistleblower complaints.

Although the complainant has not provided any evidence that proves such a lack on the balance of probabilities as is required under the ABPI Code, as requested, we have provided information on our current internal system and process to deal with whistleblower complaints below.

The PMCPA's 'Guidelines on Company Procedures Relating to the ABPI Code of Practice for the Pharmaceutical Industry' include that 'access to confidential resources should be available and regularly communicated to staff including details of the company whistleblowing policy'.

The extracts provided by the complainant show that Moderna did as of the date of the screen shots have a whistleblower system and process in place, including a secure web form for submitting concerns.

In 2021, Moderna utilized a third-party system [named] to handle the Speak Up process, with the available reporting channels outlined in the applicable Code of Conduct at that time. The [named] platform was first introduced in 2018 when Moderna implemented a compliance hotline as part of its Initial Public Offering. This solution, designed for investor management, facilitated anonymous reporting through a website and Interactive Voice Response (IVR) system. As Moderna transitioned into a commercial and international

entity in 2021, it became evident that [named platform]'s functionality was no longer sufficient to meet Moderna's evolving needs.

In 2022, Moderna revamped its Global Ethics & Compliance Framework, starting with a new Speak Up line. In January 2022, we introduced a new multi-lingual whistleblower system [named]. This system was chosen for its ability to facilitate confidential conversations with reporters while asking questions or reporting concerns, ensuring reporters can remain anonymous (where local law and regulations permit). Moderna's current Speak Up line offers additional avenues for reporting, such as email, telephone (including a dedicated line for Europe), and access to Legal and Compliance.

In September 2022, our CEO introduced the new Code of Conduct, which took effect in January 2023. The Code of Conduct was revised to serve as a principles-based guide, rooted in Moderna's Mindsets and Values, to assist every employee, regardless of location, in making ethical decisions and acting in the right way. Our Code of Conduct also set the expectations on speaking up to address questions and concerns and includes all the reporting channels available on page 23.

We inform all employees about the process during onboarding and Code of Conduct training sessions. Moreover, the Speak Up process can be accessed on our 'My Moderna' intranet, specifically on the main page under 'How to Report a Concern'. In addition, in August 2022, we launched a campaign to promote our culture of speaking up, which included a video, that remains available on our Intranet today.

Both the Code of Conduct and the Speak Up line are also accessible to the public on our external website.

Moderna takes all reports seriously. Each matter is addressed on a case-by-case basis and investigations are handled according to 'Instructions for Intake & Routing' in [named platform] and our 'Speak Up Case Manager Guide'. Where necessary, Moderna develops and implements corrective actions in line with the documents attached and with the PMCPA's Guidance referred to above.

Whistleblowing complaints

The two whistleblowing reports linked to the reference numbers in the extracts provided by the complainant relate to the following:

<u>Report 1</u>

- An anonymous whistleblowing report was received on 10 September 2021 with an allegation of disguised promotion and off label promotion at a Moderna US Medical Affairs led webinar held on 9 September 2021. This webinar was prior to Moderna UK joining the ABPI Code. This appears to correspond with the complainant's allegation of potential off-label promotion by [a member of the medical affairs department] in the US on a webcast with the comment '*? HCPs geographies for attendants'.*
- The details of the complaint in the whistleblowing report are set out in the documents provided by the complainant to the PMCPA.

- The webinar was an activity organized by Moderna US with no involvement from Moderna UK. The target audience for the webinar was US participants - of the 221 attendees, nearly all were from the US with only one individual registered as located in the UK.
- The slides used were approved in line with US legal requirements as the target audience was US HCPs and customers. The content was not reviewed for compliance with UK legal requirements as the UK was considered out of scope. This approach was consistent with the position on international materials and events in the MHRA Blue Guide.
- Moderna US investigated the complaint thoroughly and concluded that it was not substantiated. This conclusion was based on the slides having been reviewed and approved according to Moderna's policy, the speaker's adherence to approved material instructions, the absence of product disparagement, evidence that the TeenCOVE study data discussed was in response to specific questions and the audience attendance. The invites, EUA statements, and slide content, which largely presented data without drawing conclusions, made it clear that the intent was to share information on mRNA-1273. We no longer have access to the recording of the webinar.

Report 2 and 3

- Two anonymous whistleblowing reports relating to a Moderna employee sharing/presenting confidential data at a meeting with [external overseas organisation] and discussion of the same at an [internal medical] training meeting were received by Moderna on 14 September 2021, which was prior to Moderna UK joining the ABPI Code.
- The details of the complaints in the whistleblowing reports are set out in the documents provided by the complainant to the PMCPA.
- We enclose a copy of the slide containing the data in question.
- Moderna investigated the complaint thoroughly and concluded that Moderna did have permission to share this data, although there was a typo relating to the reference to 100mcg/50mcg which was then corrected, and the remainder of the complaint was not substantiated. We also referred to the investigation and correction of this typo in our response to Case AUTH/3790/7/23.

As requested, we also enclose the SPC [Summary of Product Characteristics] for Spikevax.

In relation to the Clauses of the Code listed in your letter:

Clause 3.1: As set out in detail above, the complaint of off-label promotion relates to a US webinar that took place before Moderna UK became an ABPI member, was intended for US attendees and not targeted at UK HCPs. Moderna US investigated the complaint and concluded that it was not substantiated.

Moderna UK has therefore not promoted a medicine prior to the grant of the marketing authorization which permits its sale or supply in breach of Clause 3.1 of the ABPI Code. The complainant has not provided evidence that Moderna UK has breached Clause 3.1 of the ABPI Code on the balance of probabilities.

Clause 5.1: Moderna UK has not breached the ABPI Code or failed to maintain high standards. The complainant has not provided evidence that Moderna UK has breached Clause 5.1 of the ABPI Code on the balance of probabilities.

Clause 2: Moderna UK has not breached the ABPI Code or brought discredit upon or reduced confidence in the pharmaceutical industry. The complainant has not provided evidence that Moderna UK has breached Clause 2 of the ABPI Code on the balance of probabilities."

PANEL RULING

The complaint related to Moderna's internal systems and processes which dealt with whistleblower complaints and the alleged off-label promotion by a member of the medical affairs department in the United States (US) on a webcast. The complainant provided documents detailing three whistleblower complaints made to Moderna in September 2021, one of which was in relation to the US webcast.

Moderna explained that at the time of the US webcast on 9 September 2021, Moderna UK was not a member of the ABPI and became a member of the ABPI and accepted the jurisdiction of the PMCPA in January 2023. Moderna submitted that as Moderna UK was not an ABPI member, at the time of the webcast or the whistleblower complaint in September 2021, it had not voluntarily committed to comply with the ABPI Code.

In such circumstances, the Panel noted that it was not unusual for the activity in question to have occurred before the company joined the ABPI and as such was required to comply with the Code. Whether such cases fell within the jurisdiction of the PMCPA was decided on a case-by-case basis. The Panel also bore in mind the long-established principle that if the subject matter of the complaint could very broadly be described as potentially a matter covered by legal requirements, such as off-label promotion of a medicine, then the complaint would be considered in the usual way. The Panel further noted that it was established that a UK company was responsible for the acts or omissions of its overseas affiliates that came within the scope of the ABPI Code.

The Panel noted that the complainant was anonymous and non-contactable and had described themselves as a health professional. As with any complaint, the complainant had the burden of proving their complaint on the balance of probabilities; the matter would be judged on the evidence provided by the parties.

1. **Alleged lack of internal systems and processes to deal with whistleblower complaints**

The complaint was made to the PMCPA in July 2023, however, the complainant provided extracts of whistleblower reports from three complaints made to Moderna in September 2021.

The Panel noted Moderna's submission that the extracts provided by the complainant showed that Moderna did, in September 2021, have a whistleblower system and process in place, including a secure webform for submitting concerns. At the time these whistleblower complaints were submitted, Moderna utilised a third-party system to handle the 'Speak Up' process, with the available reporting channels outlined in the applicable Moderna Code of Conduct at that time, which was dated January 2021. The Panel noted that the January 2021 Code of Conduct

referred to four ways compliance concerns could be raised, three of which allowed for anonymity, and included a 'no retaliation' statement. Moderna submitted that a new multilingual whistleblower system had been introduced in 2022, which was operational at the time of the complaint to the PMCPA in July 2023. This new system also allowed for anonymity and included a dedicated telephone line for Europe.

Moderna provided a copy of the investigation report and outcomes in relation to the US webcast complaint, carried out by Corporate Compliance, which concluded that the reporter's concerns were unsubstantiated. The report was dated 23 September 2021, thirteen days after the complainant submitted their concerns.

The Panel noted that the complainant bore the burden of proof. While the complainant may have been unsatisfied with the outcome of their whistleblower complaint, on the evidence before it, and based on the narrow allegation, the Panel considered that the complainant had not established that Moderna lacked internal systems and processes to deal with whistleblower complaints as alleged, either in September 2021 or at the time of the complaint to the PMCPA in July 2023. The Panel considered that the complainant had not established that Moderna had failed to maintain high standards in this regard and the Panel ruled **no breach of Clause 5.1** of the 2021 Code.

2. Alleged off-label promotion by a member of the medical affairs department in the US on a webcast

Moderna submitted that the webinar was organised by Moderna US with no involvement from Moderna UK and that the target audience was the US. There was some discrepancy between the numbers submitted by Moderna in its response letter and those in the investigation report, however, both confirmed that over 200 individuals attended the webcast and only one was registered as located in the UK.

The investigation report stated that the vast majority of attendees were from the US with only four from outside the US (including the one UK attendee).

The first matter the Panel had to consider was whether the webcast was within the scope of the ABPI Code. Whether the ABPI Code applied to materials and activities organised by a non-UK company, which took place outside the UK, would be decided on a case-by-case basis.

The Panel had no information before it regarding how the UK attendee became aware of this US webcast. The Panel did not know whether the UK individual had found details of the webcast while searching for related information online or whether they received details from Moderna. The Panel had little information before it regarding how the webcast was advertised other than brief reference in the investigator report to dissemination of invites by US field-based representatives. The Panel noted that more than 200 attendees were from the US with only four being from outside the US (including one individual located in the UK). The Panel considered, on the balance of probabilities, that UK individuals were not invited or directed to the webcast. The webcast was organised by a US company, with a US speaker and intended for a US audience. The webcast slides referred to the emergency use authorisation by the FDA and there was no specific reference to the availability or use of the medicine in the UK. While the Panel considered that the US company could have done more to prevent non-US individuals registering, without any information before it in relation to how the one UK individual came across the details for this webcast, the Panel considered that the complainant had not

established that the webcast was within the scope of the ABPI Code. The Panel therefore ruled **no breach of Clause 3.1** of the 2021 Code as the webcast was not within the scope of the ABPI Code.

Overall

Taking account of the above no breach rulings, and with the aforementioned reasons, the Panel considered the complainant had not established that Moderna had brought discredit upon, or reduced confidence in, the pharmaceutical industry, therefore the Panel ruled **no breach of Clause 2** of the 2021 Code.

Complaint received **3 July 2023**

Case completed **11 December 2024**