INTERIM CASE REPORT

An interim case report has been published in this case as the final report was delayed because the Code of Practice Appeal Board required a specific scope audit of Moderna's procedures in relation to the ABPI Code, in accordance with Paragraph 13.4 of the Constitution and Procedure. The audit will specifically focus on Moderna's culture, governance and compliance framework.

CASE/0316/10/24

COMPLAINANT v MODERNA

Allegations about Moderna's response to a previous complaint

CASE SUMMARY

This case was in relation to allegations about the completeness of Moderna's response to Case AUTH/3886/3/24 and, specifically, a discrepancy in timelines regarding when Moderna became aware of an unauthorised offer of £1,500 to participants in a COVID-19 vaccine trial.

The outcome under the 2021 Code was:

Breach of Clause 2	**Bringing discredit upon, and reducing confidence in, the pharmaceutical industry**
Breach of Clause 5.1	**Failing to maintain high standards**

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 on behalf of UsForThem, a parent-led campaign group calling for children's needs to be prioritised during the COVID-19 pandemic response, was received about Moderna Biotech UK Ltd.

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected:

> "We write in relation to PMCPA case [Case AUTH/3886/3/24], which concerns a complaint brought against Moderna, the findings of which were recently published by the PMCPA in a full case report on its website.

We have read the PMCPA's findings with interest. In particular we note that Moderna was found to have breached Clause 2 (Upholding Confidence in the Industry), the most serious breach under the ABPI Code and, in the words of the PMCPA Panel in their decision, "*Clause 2 [is] a sign of particular censure and reserved for such use*".

We understand from the case report that the complaint related to the unapproved use of social media to solicit the recruitment of children into a clinical trial using inappropriate and unethical financial incentives. The core concern was the communication via a group WhatsApp message sent by a paediatrician at a major [named region] NHS Trust which had been recruited on behalf of Moderna, of the offer of an incentive of £1,500 for the purposes of recruiting 12–18-year-old children into Moderna's Phase 3 clinical trial of a version of its COVID-19 vaccine [Ref: NextCOVE Study (CTA Ref 51307/0015/001-0001)].

As a group concerned with the interests and welfare of children, UsForThem raised serious concerns about the ethical basis of this trial with Moderna in a letter sent to [two named senior employees] of Moderna on 4 August 2023. For ease of reference a copy of that letter is attached, as are Moderna's reply and subsequent correspondence between UsForThem and Moderna.

We believe there to be a significant discrepancy between what appears to have been the PMCPA's understanding of Moderna's conduct, informed by evidence provided to it by Moderna, and comments made by Moderna as documented in this correspondence.

Discrepancy

The key issue in the complaint at issue was the inappropriate use of WhatsApp by a paediatrician acting, via a chain of delegates, on behalf of Moderna to offer £1,500 for children to take part in Moderna's Covid booster vaccine trials. Moderna's response to the complaint has been reproduced – we believe in full – in the PMCPA's case report. In that response, Moderna is recorded as having told the PMCPA that:

"The existence of the WhatsApp message was brought to Moderna's attention on January 19th, 2024, following a meeting with the HRA. A URL was provided to Moderna and the article at the location mentioned the WhatsApp message. The article was published on August 6th, 2023, we assume that the messages must has been [sic] sent out prior to this date, however the specific time is not known."

It appears from the case report that this timeline was relied upon by the PMCPA Panel which, in reaching its conclusions, recorded that:

"The Panel noted Moderna's submission that the message was not part of the approved recruitment materials provided by Moderna for use during the NextCOVE trial and that Moderna had been unaware of the message until several months after it had been sent."

This timeline is, however, contradicted by the content of the correspondence between UsForThem and Moderna, as follows:

1. Letter from UsForThem, to [named senior employee 1], Moderna Biotech UK Ltd, copying [named senior employee 2] and others, dated **4 August 2023**.

   This letter set out a number of serious concerns held by UsForThem relating to the NextCOVE trial, one of which was the offer of the £1,500 payment, a matter which had been independently brought to UsForThem's attention by a concerned Parliamentarian. UsForThem's letter included the following sentence:

   "Finally, the brochure notes that "Compensation may be provided for your time". We have been led to understand that at least one of the UK medical centres involved in Moderna's trial has offered to pay a lump sum of £1,500 to each child at the completion of the trial."

2. Moderna UK response to UsForThem dated **18 August 2023** and signed and sent by [named senior employee 1], copying [named senior employee 2] and others.

   In its reply to UsForThem's letter, Moderna stated:

   "Finally, we would like to clarify that the statement in your letter: "We have been led to understand that at least one of the UK medical centres involved in Moderna's trial has offered to pay a lump sum of £1,500 to each child at the completion of the trial" is incorrect. We have followed the legislative and ethical framework for reimbursement in the UK, which is limited to travel and reasonable out-of-pocket expenses, and is in line with expectations from the National Institute for Health and Care Research."

3. Email from UsForThem to [named senior employee 1], copying [named senior employee 2] and others, dated **1 September 2023**.

   This subsequent reply by email recorded the following on behalf of UsForThem that:

   "We note your assertion that our understanding that lump sum payments have been offered for participation in your trial is incorrect. We shall take this up separately, but in the meantime we appreciate your implicit acceptance that any such payments would not be lawful or ethical."

No further response was received from Moderna to this email.

As evidenced by this chain of correspondence, the fact that an offer of payment of £1,500 had been made was unequivocally flagged to Moderna on 4 August 2023. Two weeks later, Moderna definitively denied this to have been the case. [Named senior employee 1] presumably did so after having made enquiries as to whether it could have been the case and having received confirmation that it had not (incorrectly, it seems); or else [named senior employee 1] made that assertion without having made any further enquiry.

Either way, any suggestion that Moderna UK was not made aware of the existence of a potential serious breach of ethical and legal rules until January 2024 is plainly false. At least two of the most senior officers of Moderna UK were made aware in August 2023.

Explanation required

[The two named senior employees] might wish to characterise Moderna's submission to the PMCPA as having been accurate on the basis that UsForThem's letter did not provide a URL link or specifically identify the source of the financial offer that we understood had been made. We suggest that to do so would be disingenuous at best, not least because [named senior employee 1] could have sought that information from us at the time, and certainly having been put on notice could and should have taken steps properly to investigate the issue before definitively dismissing it on 18 August 2023. Had the issue been investigated in August 2023 but had failed to identify the source of that unethical and unlawful financial incentive, Moderna's submission plainly could and should have explained this fact to the PMCPA.

Moderna UK might also wish to suggest that its personnel involved in responding to the PMCPA may not have been aware of [named senior employee 1]'s earlier correspondence with UsForThem. It would be surprising if this were the case because it would imply that the [named role of senior employee 1] of Moderna had not at any point been consulted prior to Moderna UK attesting a formal submission to the PMCPA on a matter concerning allegations of serious regulatory misconduct.

We assume that in any dealings with the PMCPA, pharmaceutical companies are expected to be not only truthful and accurate, but transparent and candid. The public has a right to expect no less, otherwise the PMCPA, and the Code of Practice, are rendered impotent. Under similar regulatory regimes in the UK, such as the regime for controlling the promotion of financial services products, a firm that knowingly or recklessly provided inaccurate information to its regulator could be guilty of a criminal offence.

Incidentally, this was one of two PMCPA decisions published in the space of a single week in which the PMCPA found Moderna guilty of a breach of Clause 2 (*Upholding Confidence in the Industry*) of the Code of Practice, the most serious breach of the Code (the other case being case AUTH/3746/2/23: Complainant v. Moderna, Allegations regarding promotion of Spikevax, decision dated 9 August 2024).

Given that Moderna has been found guilty twice in a single week of the most serious breach possible under the Code of Practice – presumably some kind of record even in an industry which seems now routinely to breach its regulatory commitments – any suggestion that Moderna may have dealt with the PMCPA other than transparently, candidly and accurately must be a matter of serious concern.

With this in mind we therefore wish to ask the following:

[Named PMCPA senior employee]: please could the **PMCPA** confirm what further action it proposes to take in respect of the matters we have brought to your attention above?

> [Named Moderna senior employee 1]: please could **Moderna UK** confirm whether it wishes to amend any part of its earlier statements to the PMCPA, or otherwise whether it wishes to comment on the discrepancy identified above?
>
> Trust in the pharmaceutical industry and its self-regulatory regime is at an all time low, and Parliamentary interest in the sector is rising rapidly. We intend to put this correspondence into the public domain and will pass it also to interested Parliamentarians; accordingly we shall also publish any comments provided."

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

MODERNA'S RESPONSE

The response from Moderna is reproduced below:

> "Thank you for your letter dated 14 October 2024, regarding the submission from UsForThem, specifically concerning allegations related to the NextCOVE trial and Case AUTH/3886/3/24.
>
> We wish to address the core issue raised in the complaint: an alleged discrepancy in the timelines we provided in our initial response to you under Case AUTH/3886/3/24. We respectfully dispute the allegations made by UsForThem for the following reasons.
>
> In their letter to Moderna, on 4 August 2023, UsForThem stated:
>
> *"Finally, the brochure notes that "Compensation may be provided for your time". We have been led to understand that at least one of the UK medical centres involved in Moderna's trial has offered to pay a lump sum of £1,500 to each child at the completion of the trial."*
>
> In our response dated 18 August 2023, we clarified:
>
> *"Finally, we would like to clarify that the statement in your letter: 'We have been led to understand that at least one of the UK medical centres involved in Moderna's trial has offered to pay a lump sum of £1,500 to each child at the completion of the trial' is incorrect. We have followed the legislative and ethical framework for reimbursement in the UK, which is limited to travel and reasonable out-of-pocket expenses, and is in line with expectations from the National Institute for Health and Care Research."*
>
> At the time of our response to UsForThem, our initial proposal of a £1,505 reimbursement had already been revised in accordance with the Research Ethics Committee's (REC) recommendations. To Moderna's knowledge the updated, approved materials were distributed to all sites by August 2023, and contractual obligations requiring exclusive use of only approved materials. UsForThem's comments that Moderna could have sought additional information from UsForThem contravenes the burden of proof a complainant bears under the Code and the expectations of accuracy and transparency in the allegations made, where at a minimum all relevant details should be provided so that a respondent can fully respond to all allegations.

In our initial response to the PMCPA concerning Case AUTH/3886/3/24, we stated:

"The existence of the WhatsApp message was brought to Moderna's attention on January 19, 2024, following a meeting with the HRA. A URL was provided to Moderna at that time, which mentioned the WhatsApp message. We assume the messages were sent prior to the publication date of August 6, 2023, though the specific time the messages were disseminated remains unknown."

Our position remains that it was not until our meeting with the Health Research Authority (HRA) on January 19, 2024, that the specific WhatsApp message offering payment of £1,500, contrary to the approved recruitment materials, was brought to our attention.

In UsForThem's 4 August 2023 letter, no details were provided regarding the alleged offer, beyond the £1,500 reference, nor that it had been communicated via WhatsApp. In responding to this complaint, we became aware that a separate online article referencing the trial by the HRA was picked up by routine monitoring on 3 August 2023 and circulated within Moderna separately to the UsForThem correspondence. Reference within the body of that article to the existence of a WhatsApp message was not noted at that point. Our response to UsForThem reflected Moderna's genuine understanding at the time, that this was an erroneous reference to the outdated, unapproved version of the trial recruitment materials.

Irrespective of the timelines, the fact remains that the WhatsApp message offering £1500 was sent by the physician in question without Moderna's prior knowledge or agreement, in contravention of site contractual obligations requiring the site, including its employees, to only use approved recruitment materials provided.

Conclusion

In summary, Moderna was, of course, aware of the initial £1,500 proposed reimbursement in the draft clinical trial materials and took action to revise this amount by April 2023. Before the HRA disclosed the WhatsApp message details, we believed that no recruitment activities used materials not approved by us. We strongly disagree with the allegations made by UsForThem and believe we have complied with Clauses 5.1 or 2 of the Code in the context of this case.

Should you require further documentation or have any additional questions, we are available to provide further information. We remain committed to full cooperation with the PMPCA and upholding the highest standards in our responses."

PANEL RULING

The complainant described themselves as a representative of UsForThem, a parent-led campaign group calling for children's needs to be prioritised during the COVID-19 pandemic response. They raised concerns regarding the completeness of Moderna's response to Case AUTH/3886/3/24 and, specifically, a discrepancy in timelines regarding when Moderna became aware of an unauthorised offer of £1,500 to participants in a COVID-19 vaccine trial.

In its response to the current case, Moderna confirmed its position that it was unaware of the specific WhatsApp message offering payment of £1,500 until 19 January 2024. Moderna submitted that, before that date, it "believed that no recruitment activities used materials not approved by [Moderna]". Moderna submitted that at the time of its response to UsForThem (August 2023), the £1,505 reimbursement initially proposed in draft clinical trial materials had already been revised in accordance with the Research Ethics Committee's recommendations.

The Panel noted that the case preparation manager had asked Moderna to provide "a clear chronology of events in relation to the allegations in UsforThem's complaint" and "details of steps taken to investigate the issue raised to Moderna by UsForThem in August 2023". The Panel was concerned that Moderna's response to this case did not include this information, as requested. The Panel considered that a clear chronology of events was needed to consider the case and took account of the following timeline of events, constructed from the evidence provided by the parties including that available in the published report for Case AUTH/3886/3/24:

- **3 August 2023** – An online article (different to that published on 6 August 2023 and referred to below) referencing the trial by the Health Research Authority (HRA) was picked up by Moderna's routine monitoring and circulated within Moderna. "Reference within the body of that article to the existence of a WhatsApp message was not noted at that point."

- **4 August 2023** – UsForThem wrote to Moderna raising concerns about the clinical trial. The letter included the statement: "We have been led to understand that at least one of the UK medical centres involved in Moderna's trial has offered to pay a lump sum of £1,500 to each child at the completion of the trial."

- **6 August 2023** – An article mentioning the WhatsApp message was published. This article was brought to Moderna's attention in January 2024 by the HRA.

- **18 August 2023** – Moderna responded to UsForThem, including the statement: "Finally, we would like to clarify that the statement in your letter: *'We have been led to understand that at least one of the UK medical centres involved in Moderna's trial has offered to pay a lump sum of £1,500 to each child at the completion of the trial'* is incorrect. We have followed the legislative and ethical framework for reimbursement in the UK, which is limited to travel and reasonable out-of-pocket expenses, and is in line with expectations from the National Institute for Health and Care Research."

- **1 September 2023** – UsForThem replied to Moderna, including the statement: "We note your assertion that our understanding that lump sum payments have been offered for participation in your trial is incorrect. We shall take this up separately, but in the meantime we appreciate your implicit acceptance that any such payments would not be lawful or ethical."

- **19 January 2024** – Moderna became aware of the article dated 6 August 2023 which referred to the specific WhatsApp message offering £1,500, contrary to the approved recruitment materials, following a meeting with the HRA.

- **3 April 2024** – The PMCPA wrote to Moderna, advising it of Case AUTH/3886/3/24

- **25 April 2024** – Moderna submitted its response to Case AUTH/3886/3/24, including the statement: "The existence of the WhatsApp message was brought to Moderna's attention on January 19th, 2024, following a meeting with the HRA. A URL was provided to Moderna and the article at the location mentioned the WhatsApp message. The article was published on August 6th, 2023, we assume that the messages must have been sent out prior to this date, however the specific time is not known."

From the evidence before it, the Panel considered that, in August 2023, Moderna was aware of an allegation that there was an offer of £1,500 reimbursement figure for participation in the trial. The Panel noted that the letter from UsForThem did not provide details of which medical centre had made the offer or that the offer was made in a WhatsApp message.

The Panel disagreed with Moderna's comments in relation to the complainant bearing the burden of proof under the Code – the UsForThem letter was not a complaint made to the PMCPA under the PMCPA Constitution and Procedure, it was a complaint sent directly to Moderna.

The Panel noted that UsForThem's letter mentioned the specific value of £1,500, which was closely similar to the initial reimbursement value of £1,505 in the draft clinical trial materials which had been sent to clinical trial sites on 5 April 2023. In the Panel's view it was therefore not unreasonable to expect that, on receipt of the letter, Moderna should have investigated this allegation and in addition sought additional information from UsForThem, with whom it was in direct correspondence, if needed.

The Panel also noted that the online article that the HRA brought to Moderna's attention in January 2024 and which mentioned the WhatsApp message was dated 6 August 2023, two days after receipt of UsForThem's letter and before Moderna's response to it.

The Panel considered that the fact that Moderna had received and taken no apparent action to investigate an allegation that a centre involved with the clinical trial had offered £1,500 reimbursement to participants prior to the receipt of the complaint from the PMCPA was important information that should have been included in its response to Case AUTH/3886/3/24. The Panel considered that high standards had not been maintained in this regard and ruled a **breach of Clause 5.1** of the 2021 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 all relevant information in its submission for Case AUTH/3886/3/24, Moderna had brought discredit upon and reduced confidence in the pharmaceutical industry. The Panel ruled a **breach of Clause 2** of the 2021 Code.

The Panel noted its comments in Case AUTH/3886/3/24 that the unique circumstances of the COVID-19 pandemic, and the particular circumstances of the clinical trial, which involved the recruitment of children, meant that Moderna should have been especially cautious. The Panel considered that if all the relevant information had been before it in that case, it may have decided to report the company to the Code of Practice Appeal Board for the consideration of additional sanctions. 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 Moderna'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. The Panel decided to **report the company to the Code of Practice Appeal Board**, in accordance with Paragraph 10.2 of the Constitution and Procedure for the Appeal Board to consider in relation to Paragraph 13.4.

COMMENTS FROM MODERNA ON THE REPORT

Moderna's written response is reproduced below.

> "We acknowledge receipt of your letter dated 19 February 2025 regarding *Case 0316/10/24*, specifically in relation to allegations concerning Moderna's response to *Case AUTH/3886/3/24* and the upcoming Appeal Board hearing on 13 March 2025. Our decision not to appeal the Panel's ruling reflects our commitment to addressing the issues identified and using this as an opportunity to further strengthen our compliance framework.
>
> Moderna takes these matters very seriously and welcomes the opportunity to set out our position in response. We acknowledge the Panel's ruling regarding breaches of Clauses 2 and 5.1, and we respectfully submit the following summary of our position and outline the corrective measures we have taken to mitigate the need for any further sanctions in relation to this matter.
>
> **Summary of Our Position**
>
> The core issue pertains to discrepancies in our response to a previous complaint regarding the NextCOVE trial. As outlined in our previous communication, Moderna believed it was acting in good faith when responding to *Case AUTH/3886/3/24*. Despite this, we acknowledge and have rectified the inconsistencies in our response.
>
> The omission in our original response to *Case AUTH/3886/3/24* was a genuine oversight resulting from the fact that Moderna believed UsForThem's complaint reference to £1,500 was an erroneous reference to a draft of the clinical trial materials. In responding to UsForThem, Moderna did take action to confirm that the sum approved in the clinical materials provided to sites was not £1,500 as alleged. We recognize that these facts do not justify that we did not uncover the WhatsApp message and have taken steps to enhance our internal review and response activities and fully accept the PMCPA's ruling.
>
> In responding to this Case *AUTH/0316/10/24* Moderna proactively disclosed that internal monitoring activities had identified a website, in August 2023, containing reference to a WhatsApp message offering the sum of £1500. Although this was not referenced in the materials giving rise to the specific complaint in *Case 0316/10/24*, we recognised its relevance to *Case AUTH/3886/3/24* and proactively and transparently disclosed this further finding [in] our response to Case *AUTH/0316/10/24*. We hope this demonstrates that Moderna is committed to full and frank disclosure and transparency.
>
> **Corrective Actions Implemented**
>
> In response to the Panel's concerns, Moderna has undertaken several proactive measures to reinforce our compliance framework and help ensure that such a situation does not reoccur:

1. Governance and Oversight Enhancements:
    - We are reviewing and strengthening our compliance and governance protocols.
    - Our internal compliance working group monitors compliance activities, reviews PMCPA communications, and implements targeted training to address identified risks.

2. Revised Internal Escalation Procedures:
    - We are reinforcing our internal escalation processes to ensure concerns raised by external stakeholders are thoroughly investigated, documented, and recorded.
    - These records are to be structured to ensure accessibility across relevant teams to support any future retrospective investigations.

Appeal Board Hearing and Next Steps

We believe the actions outlined above reflect Moderna's commitment to upholding the highest standards of compliance and governance while addressing the concerns raised in this case. We remain available to provide any additional clarification the PMCPA may require."

At the consideration of the report, Moderna presented slides detailing the context of this case and key points for improving its compliance.

CONSIDERATION OF THE REPORT FROM THE PANEL

At the consideration of the report, Moderna's representatives accepted its failings in this case. Moderna submitted that it had taken active steps to strengthen its compliance framework and that the failings were due to human error in a rapidly expanding company.

The Appeal Board took account of the Panel's rulings of breaches of the Code, including Clause 2, as Moderna had received, and taken no apparent action to investigate, an allegation that a clinical trial centre had offered £1,500 reimbursement to participants prior to the receipt of the complaint from the PMCPA. This was important information that should have been included in its response to Case AUTH/3886/3/24.

The Appeal Board observed the Panel's comments that the unique circumstances of the COVID-19 pandemic, and the particular circumstances of the clinical trial, which involved the recruitment of children, meant that Moderna should have been especially cautious.

The Appeal Board agreed with the Panel that the lack of transparency was completely unacceptable.

The Appeal Board considered that self-regulation relied upon the provision of full and frank disclosure of information by pharmaceutical companies when responding to complaints. The Appeal Board was extremely concerned about Moderna's failings in this regard and, having considered all the sanctions available under Paragraph 13.4 of the Constitution and Procedure, it decided that the company should be publicly reprimanded for providing incomplete information to the PMCPA.

The Appeal Board considered that Moderna's response to the Appeal Board lacked appropriate granular detail regarding what changes it would make to address the issues highlighted in this case and in Case AUTH/3835/10/23, which was considered at the same Appeal Board hearing. Given all of its concerns, the Appeal Board decided to require a specific scope audit of Moderna's procedures in relation to the ABPI Code, in accordance with Paragraph 13.4 of the Constitution and Procedure. The audit will specifically focus on Moderna's culture, governance and compliance framework. On receipt of the audit report, the Appeal Board would consider whether further sanctions were necessary.

The audit was required in relation to both this case and Case AUTH/3835/10/23. It was agreed that details of any further actions would be recorded in the case report for this case (Case/0316/11/24) only.

The published public reprimand would state:

> "Moderna has been publicly reprimanded by the Code of Practice Appeal Board for failure to provide a full and frank disclosure of all the facts in its response to a previous case (Case AUTH/3886/3/24).
>
> In Case/0316/11/24, the Panel concluded that in failing to include all relevant information in its response to the previous complaint, Moderna had brought discredit upon, and reduced confidence in the pharmaceutical industry. The Panel reported the company to the Appeal Board, in accordance with Paragraph 10.2 of the Constitution and Procedure.
>
> Self-regulation relies on full and frank disclosure of all the facts; the Appeal Board considered that a lack of transparency in this regard was completely unacceptable.
>
> In addition to the public reprimand, the Appeal Board also decided to require a specific scope audit of Moderna's procedures in relation to the ABPI Code. The audit will specifically focus on Moderna's culture, governance and compliance framework."

Complaint received	**14 October 2024**
Undertaking received	**12 February 2025**
Appeal Board consideration	**13 March 2025**
Interim case report first published	**01 May 2025**