CASE AUTH/3790/7/23 ***NO BREACH OF THE CODE***

EX-EMPLOYEE v MODERNA

Allegations about misleading use of scientific data from preprint publication

CASE SUMMARY

This case concerned the use of data from a preprint publication in presentations made by Moderna. The complainant made allegations around the misleading presentation of data, that was not peer-reviewed, and the presentation of this data to gain more contract sales in the UK. The complainant also alleged that data presented to a group of Spanish organisations was cherry picked.

The outcome under the 2021 Code was:

No Breach of Clause 5.1	**Requirement to maintain high standards at all times**
No Breach of Clause 6.1 (x3)	**Requirement that information must be accurate, up-to-date and not misleading**
No Breach of Clause 6.2	**Requirement that information must be capable of substantiation**
No Breach of Clause 6.3	**Requirement that all artwork must conform to the letter and spirt of the Code**

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

COMPLAINT

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

> "Misleading use of scientific data from preprint publications to infer benefits versus a competitor and manipulation of images as they were originally presented to augment this inference. The case in point is regarding presentation of Puranik et al data in which there are three graphs but Moderna removed the central data to support a misleading inference of superior VE [(vaccine effectiveness)] for their vaccine versus the mRNA competitor. To date this publication has not appeared as a peer-reviewed manuscript and believe this data (slide 10 and also 11 – where there was a requirement to include design and another slide – these are also attached) was presented to the JCVI by [regional medical affairs employee] in an attempt to gain more contract sales in the UK.

> I attach some supporting materials including a presentation made to a group of Spanish organizations by [regional medical affairs employee] where it is clearly data cherry picking but the presentations in the UK were kept highly secretive and delivered by [regional medical affairs employee] only – I do believe, however, they would have been shared with JCVI and should be available with approval codes and process etc from Moderna."

When writing to Moderna, the PMCPA asked it to consider the requirements of Clauses 5.1, 6.1, 6.2, 6.3 and 8.1 of the 2021 Code.

MODERNA'S RESPONSE

The response from Moderna is reproduced below:

> "We have reason to believe that the complainant is a former contractor [details provided].
>
> The presentation submitted by the complainant is dated 7 October 2021 (it was originally planned for 27 September 2021 as indicated on the title slide but then rescheduled at the request of [a group of Spanish organisations]) which was before Moderna UK became a member of the ABPI and accepted the jurisdiction of the PMCPA in January 2023. At the date of the presentation, Moderna UK did not yet have in place internal procedures that reflected all aspects of the ABPI Code and was not required to, as Moderna UK was not at that time an ABPI member and had not voluntarily committed to comply with the ABPI Code.
>
> While Moderna UK accepted the jurisdiction of the PMCPA from the date of joining the ABPI, we do not agree that Moderna UK can reasonably be expected to have been in compliance with the ABPI Code requirements prior to becoming an ABPI member. The Complaints Procedure in the ABPI Code refers to a complaint being where the Director of the PMCPA receives information from which it appears that a company may have contravened the ABPI Code. As the ABPI Code did not apply to Moderna UK at the date of the presentation in question, it is not possible for Moderna UK to have contravened the ABPI Code in relation to this presentation.
>
> If the PMCPA's position is that the ABPI Code does apply retrospectively to all members on joining the ABPI, this needs to be made clear to companies before they decide to join. In the absence of any indication of such retrospective application in the ABPI Code, Moderna UK had a reasonable and legitimate expectation that all activities prior to the date of joining the ABPI would not retrospectively be required to have complied with the ABPI Code.
>
> Subject to the points raised above, we have set out below our response to the matters in the complaint below with reference to the specific clauses of the Code referenced in your letter.
>
> The main presentation included in the complaint is a presentation approved by our global parent company, Moderna, Inc. (as can be seen by the approval code on the document starting "MED-US…"), which was delivered to [a group of Spanish organisations] in 2021. The meeting was requested by [a representative of the group of

Spanish organisations]. The meeting was arranged by [the group of Spanish organisations'] Secretariat, which decided the attendees (members of the Vaccines Working Party) with no input from Moderna. Moderna did not have access the list of attendees to this meeting.

The meeting was requested by [the group of Spanish organisations] in order for [the group of Spanish organisations] to be updated on the most recent data as at the time they were in the process of updating their COVID-19 vaccination guidelines, which had been developed earlier in the pandemic.

Similarly, the other two sets of slides submitted by the complainant were also approved by our global parent company, Moderna, Inc. (again, as can be seen by the approval code on one set starting "MED-US…" and on the other set "MED-CA…" for Canada) and date from 2021. Moderna UK was not involved in these slides and the complainant has not provided any information showing that they were used with UK HCPs.

As requested, we enclose a copy of the presentation slides and the SPC for Spikevax.

The complainant has also provided a copy of a pre-print and has not provided any information that it was used by Moderna UK or with UK HCPs.

The complainant states that this pre-print publication authored by Puranik et al has not appeared as a peer-reviewed manuscript. That information is not accurate. A more mature study was published by Dr Puranik et al in 2022 (Puranik et al 2022; [DOI link provided]), which compared retrospectively protection against symptomatic infection conferred by mRNA-1273 and BNT162b2 at Mayo Clinic sites from December 2020 to September 2021.

[Regional medical affairs employee] is a [non-UK] HCP employed by Moderna [non-UK country]. [Regional medical affairs employee] delivered the presentation to the [group of Spanish organisations] meeting virtually as social distancing restrictions were still in place at the time.

Clause 6.1, 6.2 and 6.3: The complainant alleges that Moderna presented the Puranik et al data in the [group of Spanish organisations] presentation in a misleading way and in presentations by [regional medical affairs employee] to the UK JCVI, and describes such presentations as "highly secretive", but again has provided no evidence of this.

[Regional medical affairs employee] did make a number of presentations to the JCVI during the pandemic in 2021 and 2022, at the request and invitation of the JCVI to provide up to date scientific information relating to vaccine and booster development, which given the circumstances of the pandemic and developments at the time were of a confidential nature (as is usual with any presentation made to a National Immunization Technical Advisory Group such as the JCVI and was also at the JCVI's express request for confidentiality). We attach a copy of those presentations and would ask that they are kept confidential by the PMCPA.

The data presented by [regional medical affairs employee] was accurate, balanced, fair, objective, unambiguous, up-to-date, and not misleading. Specifically:

- The comment made by the complainant refers specifically by the publication by Dr Puranik et al in the pre-print portal medrxiv ([URL provided]).
- Both in the abstract and during the discussion in this manuscript, Dr Puranik focused on the ability of vaccines to prevent SARS-CoV-2 infection and COVID-19 associated hospitalization.
- In line with the authors' discussion of their results, the slides summarizing the study by Puranik et al 2021 in the presentations to [the group of Spanish organisations] (7 October 2021) and the JCVI (7 September 2021) focused on the outcomes mentioned above.
- The selected graphs were not modified at all and originated from Figures 1 and 2 in the manuscript. The table on slide #12 in the presentation to the JCVI (7 September 2021) was modified from Table 3 in the manuscript to exclude data referring to the incidence rate of breakthrough infections in individuals vaccinated with BNT162b2 as the focus of the slide was to describe the ability of mRNA-1273 to prevent breakthrough SARS-CoV-2 infections. No comparative statement was included in this table. The table on slide #13 was modified from Table 5 in the manuscript in order to focus on vaccine effectiveness on or after 14 days following the second dose across the entire study period. The parts of the table excluded corresponded to vaccine effectiveness 1-7 days following the first dose (incomplete primary schedule) or following the 2nd dose but in July only.

The complainant also claims that there was "data cherry picking" in the presentations to the [group of Spanish organisations] and JCVI. Again, this is not correct. At the time the presentations took place, the Mayo Clinic Health System and the Qatari health authorities were the first to publish methodologically sound comparative data between different COVID-19 vaccines. Subsequent presentations to the JCVI included summaries of the main publications on comparative effectiveness to date, primarily in major peer-reviewed journals:

- The presentation made to the JCVI on 18 November 2021 included additional comparative effectiveness data generated by the US CDC, the Swiss Federal Office of Public Health, the Massachusetts General Hospital, and a Swedish nationwide cohort study, which were published shortly after the publications from the Mayo Clinic Health System and Qatar.
- The presentation made to the JCVI on 21 January 2022 highlighted three well designed comparative RWE studies. Two of them published in The New England Journal of Medicine and the third one, the first trial-emulation study conducted in the US Veterans cohort published in a pre-print portal (this study has been later published in major peer-reviewed journal). It also included data from the first study comparing the clinical effectiveness of both mRNA vaccines in the heterologous booster, which was conducted in Singapore.
- The presentation made to the JCVI on 7 July 2022 highlighted comparative effectiveness data generated and published by the UK HSA and the UK's COV-BOOST study group, data from a Spanish nationwide population registry published in The Lancet Infectious Diseases, and from the US Veterans Administration Healthcare System published in Clinical Infectious Diseases.

The complainant also alleges that the presentations to the JCVI were made in trying to gain more contract sales in the UK. This is inaccurate as the JCVI played no role in the

contract between Moderna and the UK government and that contract was already in place prior to the dates the presentations requested by the JCVI took place.

The slides presented to the JCVI by [regional medical affairs employee] were approved at global level by Moderna, Inc.; Moderna UK was not an ABPI member at that time, so Moderna UK did not have, and was not required to have, a PMCPA signatory.

For completeness, in 2021 Moderna received similar anonymous internal complaints, one relating to the [group of Spanish organisations] presentation and two to a JCVI presentation. The complaints were investigated internally, with the complaint relating to the [group of Spanish organisations] presentation resulting in the addition of clarifications to Moderna's Med Affairs SOP and the complaints relating to the JCVI presentation resulting in the correction of a typo in relation to a mRNA-1273 dose figure quoted going forward.

Clause 8.1: The [group of Spanish organisations] presentation and the JCVI presentations were not promotional. They were labelled as confidential and for the sole purpose of informing the requesting body's discussions about COVID-19 vaccination.

They were not certified by a UK PMCPA Final Signatory as Moderna UK was not an ABPI member at that time and so Moderna UK did not have, and was not required to have, a PMCPA signatory. In any event, the [group of Spanish organisations] presentation was not used in the UK or with a UK HCP audience.

Clause 5.1: Moderna UK has not breached the ABPI Code and has maintained high standards.

We hope this addresses the points raised in the complaint and your letter. If you have any questions, please do not hesitate to contact me."

PANEL RULING

The Panel noted Moderna's submission that at the date of the presentation at issue, Moderna UK was neither a member of the ABPI nor was it on the list of non-member companies that had agreed to comply with the Code and accept the jurisdiction of the PMCPA. Moderna subsequently became a member of the ABPI in January 2023. 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 the promotion of a medicine in a misleading way, then the complaint would be considered in the usual way.

The Panel noted that the complainant was anonymous and non-contactable and had provided limited information. 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.

The Panel considered that the complaint comprised four allegations and considered each in turn.

Allegation 1: Misleading use of data

The Panel noted the complainant's allegation regarding "misleading use of scientific data from preprint publications to infer benefits versus a competitor and manipulation of images as they were originally presented to augment this inference". The complainant referred specifically to data from Puranik et al. and provided a copy of the preprint paper. The complainant alleged that there were "three graphs but Moderna removed the central data to support a misleading inference of superior VE [vaccine effectiveness] for their vaccine versus the mRNA competitor".

The complainant provided a copy of a presentation titled "Overview of Latest Clinical Data – Moderna COVID-19 Vaccine Program" dated 27 September 2021 and subtitled "Meeting with [group of Spanish organisations]", two further PowerPoint files, each consisting of two slides and presenting data from a particular study: Puranik et al. 2021 and Tang et al. 2021, and a copy of the Puranik et al. 2021 preprint paper.

The Panel noted Moderna's submission that the presentation provided by the complainant (dated 27 September 2021) had been approved by the global parent company and delivered to [the group of Spanish organisations]. The Panel's comments on this presentation are given in relation to allegation 4, below.

The Panel accepted Moderna's submission that the other two sets of slides provided by the complainant were also approved by the global parent company, with no involvement from Moderna UK, and that the complainant had not provided any information showing they were used with UK health professionals or other relevant decision makers. The Panel did not consider that the complainant had made out an allegation in relation to these slides and made no comment on them.

The complainant made reference to the same data being presented to the Joint Committee on Vaccination and Immunisation (JCVI) in the UK. Moderna submitted that a number of presentations were made to the JCVI in 2021 "at the request and invitation of the JCVI to provide up-to-date scientific information relating to vaccine and booster development". The Panel noted that one of the presentations provided by Moderna (dated 7 September 2021) contained slides similar in content to those provided by the complainant. The presentation was titled "Overview of the latest clinical data – Moderna COVID-19 vaccine program" and included updates from the COVE trial, real world efficacy data of mRNA-1273 COVID-19 vaccine, studies of booster (3rd) doses and paediatric update. Two of the 38 slides, titled "Analysis of the Mayo Clinic database validates the utility of mRNA-1273 in preventing breakthrough infections", contained data and graphs referenced to the Puranik et al. 2021 paper. The first slide included two graphs and a table; the second slide included a repeat of one of the graphs on the previous slide, a table of data and some bullet pointed text.

The Panel noted that Puranik et al. was a retrospective observational study comparing the effectiveness of two mRNA vaccines for COVID-19 in the Mayo Clinic Health System during periods of Alpha and Delta prevalence. Vaccine effectiveness was measured by rates of infection and rates of COVID-19 associated hospitalisation, ICU admission or death between vaccinated and unvaccinated individuals.

Noting the complainant's specific allegation related to the graphs, the Panel compared the graphs presented in Moderna's slides to those in the Puranik et al. paper. The first graph in Moderna's slides corresponded to Figure 1b in the Puranik et al. paper; the Panel could find no difference between the two graphs. The second graph in Moderna's slides corresponded to Figure 2c in the Puranik et al. paper; the Panel could find no difference between the two graphs. The Panel therefore ruled **no breach of Clause 6.3** of the 2021 Code.

The Panel noted that the two tables of data in Moderna's slides did not perfectly match those in the Puranik et al. paper: the first corresponded to Table 3 of the Puranik et al. paper but omitted three of the columns; the second corresponded to only one of the three sections of Table 5 of the paper (omitting two of the three time periods). The Panel took account of Moderna's submission that the modifications to the first table were to exclude data referring to the incidence rate of breakthrough infections in individuals vaccinated with BNT162b2, as the focus of the slide was to describe the ability of mRNA-1273 to prevent breakthrough SARS-CoV-2 infections and that no comparative statement was included. The modifications to the second table were to focus on vaccine effectiveness on or after 14 days following the second dose across the entire study period.

The Panel noted that the complainant bore the burden of proof. Given the evidence before it, the Panel did not consider that the complainant had established the Puranik et al. data had been used in a misleading way. The Panel therefore ruled **no breach of Clause 6.1** of the 2021 Code.

Allegation 2: Using data from a publication that was not a peer-reviewed publication

The Panel noted the complainant's statement that the Puranik et al. data referred to in allegation 1 "has not appeared as a peer-reviewed manuscript". The complainant's allegation on this point was unclear but the Panel considered that the complainant was most likely concerned about Moderna presenting data from a publication that had not been peer reviewed and might contain findings that could potentially be invalidated later.

The Panel noted that the version of the Puranik et al. paper that was provided by the complainant was dated 21 August 2021. It included the following statement at the bottom of first page: "NOTE: This preprint reports new research that has not been certified by peer review and should not be used to guide clinical practice".

The Panel noted Moderna's submission that a more mature study was published by Puranik et al. in 2022. However, the Panel noted that this peer-reviewed paper was published after the dates of the presentations (to the group of Spanish organisations and to the JCVI) mentioned in the complaint.

The Panel noted Moderna's submission that both the [group of Spanish organisations] and JCVI presentations were made in response to requests to be updated with the most recent data during the COVID-19 pandemic. A summary of the Puranik et al. data was included in the "real world efficacy data of mRNA-1273 COVID-19 vaccine" section of the presentation. Summaries for four other real world evidence studies were also included in this section and slide 18 listed 20 real world evidence studies on mRNA-1273. The Panel noted that the slides containing the Puranik et al. data clearly stated that peer review was pending.

The Panel noted the unusual circumstances during the COVID-19 pandemic and the urgent demands of the medical and scientific communities to be updated with data as it was emerging. The Panel considered that, at the time the presentations were made, health professionals and other relevant decision makers would have been aware of increased preprints of data. Noting that the slides clearly stated that peer review was pending, the Panel concluded the Puranik et al. data was not presented in a misleading way and that it was not incapable of substantiation at the time the presentation was made and ruled **no breaches of Clauses 6.1 and 6.2**.

Allegation 3: Presenting data to the Joint Committee on Vaccination and Immunisation (JCVI) in an attempt to gain more contract sales in the UK

The Panel noted the complainant's allegation that: "this data (slide 10 and also 11 – where there was a requirement to include design and another slide – these are also attached) was presented to the JCVI by [regional medical affairs employee] in an attempt to gain more contract sales in the UK".

The Panel noted Moderna's submission that the JCVI played no role in the contract between Moderna and the UK government and that the contract was already in place prior to when the presentations requested by the JCVI took place.

The Panel noted that the complainant bore the burden of proof and had provided no details or evidence in relation to this allegation. The Panel therefore ruled **no breach of Clause 5.1** of the 2021 Code.

Allegation 4: Cherry picking in relation to data presented to a group of Spanish organisations

The complainant alleged that "a presentation made to a group of Spanish organisations" was "clearly data cherry picking".

The Panel noted Moderna's submission that:

- the presentation provided by the complainant (dated 27 September 2021) had been approved by Moderna's global parent company
- the presentation was delivered to [the group of Spanish organisations] in 2021
- [The group of Spanish organisations] requested and arranged the meeting and decided the attendees with no input from Moderna
- the presentation was delivered virtually by a non-UK health professional employed by Moderna [non-UK country]
- the complainant did not provide any evidence that the presentations were made to UK health professionals

The Panel considered that there was no evidence that this allegation had a UK nexus: Moderna UK was not involved in creating or approving the presentation, which was delivered by a non-UK employee to a group of non-UK organisations. The Panel therefore determined that the subject matter of this allegation fell outside the scope of the Code and ruled **no breach of Clause 6.1** of the 2021 Code.

Certification requirements

In relation to the requirements of Clause 8.1, the Panel noted Moderna's submission that the presentations at issue were not promotional and were made for the purpose of informing the requesting body's discussions about COVID-19 vaccination. The Panel also noted Moderna's submission that the presentations were not certified by a "UK PMCPA Final Signatory" as Moderna UK was not an ABPI member at that time. The Panel did not determine whether the presentations at issue were promotional. Additionally, since Moderna only became an ABPI member company from January 2023, the Panel concluded that the certification requirements outlined in Clause 8.1 were not applicable to Moderna prior to that date, and therefore, the Panel could make no ruling in this regard.

Complaint received **4 July 2023**

Case completed **31 October 2024**