CASE AUTH/3746/2/23

COMPLAINANT v MODERNA

Allegations regarding promotion of Spikevax

CASE SUMMARY

This case was in relation to a Moderna presentation at the European Congress of Clinical Microbiology and Infectious Diseases in April 2022.

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**
Breach of Clause 11.2	**Promoting a medicine in a manner that was inconsistent with its SPC**

No Breach of Clause 11.1	**Requirement that a medicine must not be promoted prior to the grant of its marketing authorisation**
No Breach of Clause 15.6	**Requirement that promotional materials and activities must not be disguised**

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 a named, contactable complainant who described themself as a member of the public.

COMPLAINT

The complaint wording is reproduced below:

> "Off label data presented at a congress not sure if this was approved as promotional/non-promotional.
>
> - The date the meeting took place, Sunday 24 April 2022 1030–1050am
> - Venue including country, Pavilion 3, Exhibit Hall, FIL Lisbon, Portugal
> - Name of congress, 32nd European Congress of Clinical Microbiology and Infectious Diseases
> - Presenters, [name and location]

- Audience, HCPs [health professionals], Moderna staff and attendees of the congress as they were actively handing out invitations/meeting details to drive attendance

I suggest you request the slides presented as these are not available to me but in the recording I draw your attention to the fact that this was a Product Theatre type presentation and I would also confirm whether this was approved as a promotional or non-promotional activity as a part of the compliance checks as I don't think this was approved by a UK PMCPA Final Signatory and presented by a UK based physician.

Regarding the presentation audio;

- Please note the meeting title; **Clinical Perspectives on mRNA Vaccine Technology: Demonstrating Potential Through Pandemic Response** which suggests to me a balanced presentation covering mRNA vaccine technologies in a pandemic scenario.
- First 2 minutes or so covering the Moderna Spikevax clinical programme.
- COVE data presented for the Phase 3 data presented and a brief mention of the Pfizer data being confirmed.
- Spikevax efficacy communicated for the phase 3 and TeenCOVE
- Around 5;45 secs the data is described for subsets for Spikevax.
- Occupational data presented just after 6 mins and Spikevax efficacious across occupations.
- "Excellent efficacy" – 7 mins.
- Safety profile – original COVE study no deaths and similar AE [adverse event] profiles across both groups
- Spikevax safety around 9 mins
- Boosters to be required – just under 10 mins – data for boosting from Moderna studies
- 1025 moves on to CovBoost study – using half doses – used 100 mcg Spikevax and couldn't test 100 mcg Spikevax versus the Pfizer BioNTech 30 mg dose so used half dose 15 mg of BioNTech.
- 100 mcg Spikevax versus 15 mg Comirnaty (Pfizer BioNTech) – Off label
- 1235 – "Spikevax is the most immunogenic" – 1315 – Moderna was best at 100 mcg – 1350 then states Moderna took forward 50 mcg as booster dose
- Spikevax was the most reactogenic at 100 mcg 1450 – backed up by immunogenicity studies...

RWE [real word evidence] data discussed from around 15mins – 'Product Theatre' is mentioned at around 16 mins 10 secs on the recording – Summary covering PI [prescribing information], Dosing and indications.

The whole presentation is promotional in respect of promoting Spikevax rather than being a scientifically accurate and balanced presentation aligned [with] what I expected to hear at the presentation and it clearly communicated off label data given the dose for Moderna booster was confirmed as 50 mcg and 30 mcg for Pfizer BioNTech yet the data shared was for 100 mcg and 15 mcg respectively and claims made around being the most immunogenic is also supporting an off label claim."

When writing to Moderna, the PMCPA asked it to consider the requirements of Clauses 2, 5.1, 8.1, 8.2, 11.1, 11.2 and 15.6 of the Code.

MODERNA'S RESPONSE

The response from Moderna is reproduced below:

> "The event in question took place many months before Moderna UK became a member of the ABPI and accepted the jurisdiction of the PMCPA in January 2023. At the time 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 time 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. This would have materially impacted Moderna UK's decision as to when to join the ABPI. 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.
>
> Moderna UK received a complaint relating to this same event from the MHRA on 23 December 2022, which was also [sic] from an anonymous complainant. The scope of that complaint included the UK HCP's presentation in question in this case and also a table that appeared in the presentations of a US speaker and a Spanish speaker. Moderna UK responded to the MHRA on 19 January 2023. The MHRA did not uphold the complaint and closed the matter on 7 March 2023.
>
> The complainant has provided a recording of the UK HCP's presentation to the PMCPA. The complaint did not provide a recording to the MHRA and, as there was no official recording of the presentation during ECCMID, Moderna UK was not aware that a recording of the presentation existed when responding to the MHRA. It is unclear how the complainant has obtained this recording, particularly as consent was not obtained from the UK HCP presenting or any of the attendees to the recording of the presentation.
>
> We also note that the complainant indicates that they heard the presentation in person and that they are a member of the public. We note that only HCPs and not members of the public were permitted to attend ECCMID.

We understand that the PMCPA nonetheless requires Moderna UK to respond to this complaint.

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.

Clauses 11.1 and 11.2: The meeting in question took place on Sunday 24 April 2022 at 10:30–10:50am at the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Lisbon, Portugal. The attendees were international healthcare professionals totalling over 3,500 from more than 18 countries around the world, including the UK.

As an international event, Moderna's involvement was led by Moderna Tx Inc., our US parent company. The materials relating to ECCMID were approved internally to local Portuguese legal and code requirements. References in the symposium materials to the Spikevax product were to the product as licensed in Portugal, i.e., the EU approved SPC. Copies of the local SPC for all attendees, including Great Britain, were available to attendees on request. We enclose a copy of the GB and EU/NI SPCs that were current at the time of the meeting.

Moderna engaged the UK HCP in question to deliver a presentation. This UK HCP was selected as a speaker and engaged by Moderna based on their international reputation as a professor in immunology and infectious disease with particular expertise in generating pandemic-related real-world evidence. Moderna Biotech UK Limited contracted with the UK HCP's employing NHS hospital Foundation Trust and paid an honorarium of [amount stated] (excluding VAT) plus reasonable travel expenses to cover the UK HCP's time spent planning, drafting, preparing, and delivering the presentation.

We enclose a copy of the UK HCP's presentation entitled 'Clinical Perspectives on mRNA Vaccine Technology: Demonstrating Potential Pandemic Response', however, the speaker briefing materials requested are not available.

The meeting at which the presentation was delivered was open to all ECCMID attendees. ECCMID attendees from the UK were not specifically invited or targeted to attend. Moderna made information about the presentation available to all ECCMID attendees in the form of a handout and banner. We enclose a copy of the handout which was approved based on local Portuguese requirements. The handout was available to visitors at Moderna's booth and was distributed near the presentation room, and the banner was placed outside the room.

The complainant refers to various references in the UK HCP's presentation that that the complaint alleges promoted off-label data. The full, balanced transcript of the recording that you sent to us is enclosed.

In the presentation, the UK HCP provided his clinical perspective, which included data available in relation to Modern's EU and GB licensed product Spikevax. We acknowledge that the UK HCP's presentation contained data relating to a clinical study in which the booster dose of the Pfizer BioNTech product was half that of the primary

vaccination dose in the GB and EU SPCs, whereas for the Moderna product the booster dose used was the same as the primary vaccination dose in the GB and EU SPCs (though the booster dose subsequently licensed is half the primary dose).

The intention of including these references to clinical information in the presentation was to reference scientific information (already published in the Lancet) of genuine scientific interest for the attendees and relevant to different COVID-19 vaccine products and countries globally. This was of particular interest to healthcare professionals at that time as booster strategy was being considered as part of the national recommendations of many countries. The nature of the data was made clear in the presentation with a footnote that 'This data is not based on a randomized, head-to-head comparison study, and no comparative conclusions of vaccine efficacy and/or safety should be drawn'. The data was included in the presentation in the context of discussing the global pandemic response, as indicated in the presentation title.

We therefore do not believe that the inclusion of this information in the UK HCP's presentation at ECCMID constitutes promotion of an individual product, the Spikevax vaccine, to UK healthcare professionals outside the product's UK license.

Clause 15.6: The presentation was not promotional for the reasons explained above and therefore was not disguised promotional material.

Clause 8.1 and 8.2: The presentation was not promotional for the reasons explained above and therefore did not need to be certified. The complaint refers to the presentation not having been approved by a UK PMCPA Final Signatory. This is correct – the presentation was not approved 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.

Clause 5.1: Moderna UK does not believe that presentation in question failed to maintain high standards.

Clause 2: Moderna UK does not believe that presentation in question has brought discredit upon or reduced confidence in the pharmaceutical industry."

DECISION OF CASE PREPARATION MANAGER FOLLOWING RECEIPT OF MODERNA'S RESPONSE

"The PMCPA does accept complaints under the Code about matters which pre-date a company agreeing to comply with the Code and accept the jurisdiction of the PMCPA if such matters are covered by UK law. However, if a company would rather the matter be dealt with by the MHRA then the PMCPA would refer the complainant to the MHRA and explain that the activity occurred prior to the company agreeing to comply with the Code/accept the jurisdiction of the PMCPA. That a complaint about the same material/activity has already been assessed by the MHRA does not preclude the PMCPA from making its own assessment under the Code.

If you did agree for the complaint to be dealt with under the Code, as the activity in question pre-dated Moderna agreeing to abide by the Code, I would not take forward

the matter in relation to approval by a nominated signatory (Clauses 8.1 and 8.2) as this is a requirement of the Code but not of UK law."

Following receipt of the above information, Moderna confirmed its agreement for the case to be dealt with under the Code.

Bearing in mind the case preparation manager's decision, the Panel considered the requirements of Clauses 2, 5.1, 11.1, 11.2 and 15.6 of the Code.

PANEL RULING

The complaint related to a Moderna presentation at the European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) in Lisbon, Portugal, April 2022.

Moderna UK had received a complaint relating to this same meeting from the MHRA in December 2022, made by an anonymous complainant. According to Moderna, the scope of the complaint to the MHRA included the UK health professional's presentation in question, however, there was no recording provided by the complainant to the MHRA. The MHRA did not uphold the complaint. The Panel did not know what material was before the MHRA in that complaint nor what allegations were made by the complainant. There was no evidence before the Panel that the complaints made to the MHRA and the PMCPA were by the same complainant. Regardless, whether a complaint about the same material or activity had been assessed by the MHRA did not preclude the PMCPA from making its own assessment under the Code. The Panel would rule on the allegations against Moderna made by the complainant to the PMPCA in relation to the requirements of the Code and would only take account of the evidence by the complainant and respondent company that was provided to the PMCPA.

The Panel took account of Moderna's submission that the international meeting in question took place in Portugal and Moderna's involvement was led by Moderna Tx Inc, the parent company, headquartered in the US.

The first matter the Panel had to consider was whether the subject of the complaint was within the scope of the 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. Moderna submitted that the materials relating to ECCMID were approved to Portuguese legal and code requirements.

The Panel noted that Moderna Biotech UK Limited had contracted with the UK health professional speaker for the presentation at issue through their employing NHS hospital Foundation Trust.

The supplementary information to Clause 8.2 included that UK companies had responsibilities under the Code when UK delegates were supported and/or UK speakers were contracted to go to events/meetings outside the UK.

The Panel further noted that the supplementary information to Clause 8.2 included that when a pharmaceutical company based outside the UK arranges via a UK company for a UK speaker to present at an event/meeting to be held outside the UK, then that speaker's presentation materials do not need to be certified or examined by the UK, provided there are

no UK delegates and the UK company has no role whatsoever in relation to the event/meeting or the presentation.

The Panel noted Moderna's submission that attendees of ECCMID were health professionals totalling over 3,500 from more than 18 countries around the world, including the UK. The Panel took account of Moderna's submission that information about the presentation was available to all delegates, including in the form of a handout that was available to visitors of the Moderna booth and was also distributed at the congress. The Panel considered therefore that UK health professionals were, on the balance of probabilities, invited to the symposium.

While the Panel had no information before it regarding the role of the UK company at ECCMID or whether UK delegates were supported to attend the congress, nonetheless, bearing in mind Clause 8.2 as noted above, the Panel considered that the presentation was within the scope of the ABPI Code as it was delivered by a UK speaker to an audience that included UK health professionals.

In relation to the allegation that the presentation had not been approved by a "UK PMCPA final signatory", the Panel made no ruling on Clauses 8.1 and 8.2 as these had been removed by the case preparation manager following Moderna's response that the presentation occurred prior to the company agreeing to comply with the Code and accept the jurisdiction of the PMCPA as an ABPI member.

The Panel noted that the presentation at issue was 23 slides. Fifteen of the 23 slides were solely about Spikevax and included the Spikevax prescribing information. A further three slides included a comparison of Spikevax with other vaccines. There was also reference to Spikevax in the agenda slide.

The Panel noted that only four of the 23 slides, including the title slide, made no direct reference to Spikevax; the Panel was therefore concerned that Moderna had submitted that the presentation was not promotional. In the Panel's view, the presentation could not be seen as anything other than promotion of Spikevax. It included Spikevax prescribing information, which is obligatory information for promotional material. The Panel noted that the presentation was almost entirely about Spikevax and included numerous product claims, including the final slide prior to prescribing information, which stated:

> "Spikevax mRNA COVID-19 Vaccine highlights may include:
>
> - ✓ Immunostimulatory effects
> - ✓ Protective immunity
> - ✓ Relatively well tolerated"

The complainant provided an audio recording from the presentation. The Panel noted that the verbal presentation, as with the slides referred to above, was clearly promoting Spikevax. The presentation was almost entirely about Spikevax and included claims about the medicine, including claims vocalised by the speaker such as "excellent efficacy" and "staggeringly high efficacy in the elderly" and "the side effects are far less serious than COVID itself".

Noting its view that the presentation was clearly promotional for Spikevax, the Panel had to determine if it was disguised promotion as alleged.

The Panel considered that how the presentation was advertised to delegates was relevant in its determination of whether the presentation was disguised promotion of Spikevax. In that regard, the Panel noted that the complainant provided a photograph of a handout (material reference PT-COV-2200010 04/2022) which stated, "Please join us for a presentation" followed by "Clinical Perspectives on mRNA Vaccine Technology: Demonstrating Potential Through Pandemic Response". The handout further provided the details of the UK speaker and date and time of the meeting. At the bottom it stated "Brought to you by Moderna" with the name of the company provided in logo format.

The Panel noted that the complainant only provided a photograph of the front of the handout. According to material provided by Moderna, with the same reference number, the Spikevax prescribing information was on the reverse side of the handout.

The Panel considered that the Code did not require promotional material to be labelled as such, however, promotion must not be disguised.

The complainant and the speaker had referred to the presentation as a 'Product Theatre' and Moderna's electronic certificate gave the document name as 'ECCMID Commercial Product Theatre Slides'. The Panel understood that 'Product Theatre' was an established term to describe a session where pharmaceutical companies would present product information.

The Panel did not have before it all material that was used to advertise the presentation at issue. Nonetheless, the Panel considered that the handout provided by the complainant made clear that it was a Moderna-organised meeting and the inclusion of Spikevax prescribing information on the reverse of the handout would indicate to delegates that Spikevax would be discussed at the meeting. In that regard, the Panel considered, based on the material referred to by the complainant, that the promotional nature of the meeting was not disguised as alleged, and the Panel ruled **no breach of Clause 15.6**.

With regard to the allegation about the communication of off-label data, the Panel noted that Clause 11.1 stated that a medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply. Clause 11.2 stated that the promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its summary of product characteristics (SPC).

The Panel noted that at the time of the presentation in April 2022, Spikevax had a marketing authorisation in Great Britain (GB) and Northern Ireland (NI) and therefore the Panel ruled **no breach of Clause 11.1**.

The complainant alleged that the presentation "communicated off-label data given the dose for Moderna booster was confirmed as 50 mcg and 30 mcg for Pfizer BioNTech yet the data shared was for 100 mcg and 15 mcg respectively".

Noting the definition of promotion in Clause 1.17, the Panel considered that Moderna could not promote Pfizer BioNTech's medicine, and therefore the Panel considered the allegation in relation to off-label promotion with respect to Moderna's Spikevax only.

The Panel noted that the GB Spikevax SPC provided by Moderna (date of revision of the text 14/04/2022) stated:

> *"**Booster dose***
> *Individuals 18 years of age and older*
> A booster dose (0.25 mL, containing 50 micrograms mRNA, which is half of the primary dose) of Spikevax may be administered intramuscularly at least 6 months after the second dose in individuals 18 years of age and older."

The Panel noted that the wording in the EU SPC provided by Moderna (undated) had similar information about the booster dose and the age of the patient but differed regarding timing after completion of the primary series. Nonetheless, the dose of the booster, which was the subject of the allegation, was the same in both the GB and EU Spikevax SPCs provided by Moderna; the EU SPC was relevant to UK health professionals from Northern Ireland.

The Panel noted that the speaker stated in relation to boosting, "So the data you're going to see compares … 100 mcg of Moderna Spikevax with 15 micrograms of Pfizer."

In its response to the complaint, Moderna acknowledged that the presentation contained data relating to a clinical study in which the booster dose of the Pfizer BioNTech product was half that of the primary vaccination dose in the GB and EU SPCs, whereas for the Moderna product the booster dose used in the clinical study was the same as the primary vaccination dose in the GB and EU SPCs, however, the Moderna booster dose that was subsequently licensed was half the primary dose.

Noting the Panel's view above that the presentation was promotional, the Panel considered that presenting clinical data in which the booster dose used for Spikevax was 100 mcg when the EU and GB Spikevax SPCs referred to a booster dose of 50 mcg meant that Spikevax had been promoted in a manner that was inconsistent with its SPC and **a breach of Clause 11.2** was ruled.

The Panel noted that the approved presentation slides had speaker notes but that what the speaker verbally communicated, as evidenced through the recording, differed. Moderna stated that speaker briefing materials were not available.

There was no evidence before the Panel that the speaker had been briefed with regard to the prohibition of off-label promotion. Off-label promotion was not just prohibited in the Code but was prohibited by law across Europe. Moderna would have known from the slides approved that the data being presented included off-label information.

Moderna submitted that the intention of including this in the presentation was to reference scientific information, published in the Lancet, of genuine scientific interest for the attendees and relevant to different COVID-19 vaccine products and countries globally. Moderna further submitted that this data was of particular interest to health professionals at that time as booster strategy was being considered as part of the national recommendations of many countries. In that regard, the Panel considered that it was even more inappropriate to promote Spikevax off label as it could confuse the audience at a critical time.

The Panel noted that Moderna made claims in relation to the presentation of this off-label data, including the speaker stating: "So, you can see here in our trial, the Spikevax was the most immunogenic …", "So Moderna was the best in our trial at 100 mcg ..." and "So, from an immunogenicity point of view, Moderna was safe and effective as a heterologous booster in our small trial in the United Kingdom, and this led to the UK regulatory authorities choosing to use

Moderna and Pfizer as the dose to take forward into the third dose booster campaign". The Panel considered that to make such efficacy and safety claims based on a dose that was twice the licensed dose for the booster meant that Moderna had failed to maintain high standards and **a breach of Clause 5.1** was ruled.

The Panel noted that the presenter did subsequently mention the licensed Spikevax booster dose as part of their statement "Moderna chose 50 as their dose to take through as a licensed phase booster dose"; the 50 micrograms booster dose was reiterated when the speaker referred to the prescribing information. However, the Panel was particularly concerned that when discussing the Spikevax prescribing information the speaker stated, "The booster dose can be used in teenagers, but the children's data is not yet there and there's no approval yet for boosters in children". The Panel noted that both the GB and EU Spikevax SPCs stated that the booster was licensed for those 18 years of age and older. By referring to teenagers, the speaker misleadingly implied that a booster dose of Spikevax was licensed from age 13 onwards which was incorrect.

Taking everything into account, the Panel considered that the promotion of off-label information about dosage in association with claims such as "safe", "most immunogenic" and "the best", meant that Moderna had brought discredit upon and reduced confidence in the pharmaceutical industry and **a breach of Clause 2** was ruled.

Complaint received **27 February 2023**

Case completed **9 August 2024**