CASE AUTH/3789/7/23 ***NO BREACH OF THE CODE***

COMPLAINANT v MODERNA

Allegations regarding e-consent and communications

CASE SUMMARY

This case was in relation to a presentation which described a regional level proposal for seeking consent from health professionals to receiving medical, scientific information.

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 the marketing authorisation**
No Breach of Clause 5.1	**Requirement to maintain high standards at all times**
No Breach of Clause 5.6	**Requirement that material should only be provided or made available to those groups of people whose need for or interest in it can reasonably be assumed. Material should be tailored to the audience to whom it is directed.**
No Breach of Clause 15.5	**Requirement that the telephone, text messages, email, faxes, automated calling systems, and other digital communications must not be used for promotional purposes, except with the prior permission of the recipient**
No Breach of Clause 15.6	**Requirement that promotional material 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 was received from an anonymous, non-contactable complainant about Moderna.

COMPLAINT

The complaint wording is reproduced below:

> "I attach a presentation which was communicated and I believe approved for non-promotional use by MSLs across Europe, including the UK - and is clearly a proactive process. in addition, the position of [two named senior Moderna employees] was that the

company would be proactive in communicating preprint data even though it is non-peer reviewed nor meant to be used to guide clinical decision making. Additionally, this process appears to give modern a carte-blanche to send any data they wish which is different from other platforms where users specify areas of interest. Therefore, I believe this clearly breaches the PMCPA code regarding non-promotional activities, maintaining high professional standards and even potentially (depending on a review of what has been sent proactively) off-label promotion. Please investigate."

When writing to Moderna, the PMCPA asked it to consider the requirements of Clauses 2, 3.1, 5.1, 5.6, 15.5 and 15.6 of the 2021 Code.

MODERNA'S RESPONSE

The response from Moderna is reproduced below:

"The presentation submitted by the complainant is dated November 2021, which is before Moderna UK became a member of the ABPI and accepted the jurisdiction of the PMCPA in January 2023. In 2021, 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 matter.

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.

We enclose a copy of the presentation in question and the SPC [summary of product characteristics] for Spikevax.

The presentation referred to in the complaint does not relate to using digital communications to UK HCPs [healthcare professionals] for promotional purposes, rather it describes a regional level proposal for seeking consent from HCPs to receiving medical, scientific information (which in practice is then checked against local requirements before being used in a specific market).

Moderna UK had no involvement in the creation of this presentation and neither the presentation nor the process described in it were used by Moderna in relation to the UK market.

As requested, we also enclose a copy of Moderna's Global SOP on Scientific Communications. In addition, UK activities and materials are reviewed in line with the ABPI Code requirements. We do not have an SOP specifically on collecting promotional consent as Moderna does not send promotional materials directly.

Clause 15.5 and 15.6: The complainant has not provided any information showing that Moderna has used digital communications for promotional purposes with UK HCPs without the prior permission of the recipient, nor that Moderna has sent disguised promotional material.

As explained above, the presentation referred to in the complaint does not relate to using digital communications to UK HCPs for promotional purposes, rather it describes a regional level proposal for seeking consent from HCPs to receiving medical, scientific information (which in practice is then checked against local requirements before being used in a specific market).

In the UK, prior to sending digital communications for promotional purposes (or for medical, scientific purposes) to UK HCPs Moderna would obtain the prior permission of the recipient, in line with both the ABPI Code and UK data privacy and electronic communications legislation. In practice, Moderna UK does not send promotional digital communications to UK HCPs directly, rather promotional content that has been approved internally is distributed via third parties with the appropriate consents in place such as [two named websites for medical news and information].

Clause 3.1: The complainant has not provided any information showing that Moderna promoted a medicine prior to the grant of a marketing authorization. The complainant specifically alleges that Moderna's position was that the company would be proactive in communicating non-peer reviewed preprint data but again the complainant has not provided any information showing this. Moderna UK follows the ABPI Code and does not proactively communicate preprint data to HCPs.

Clause 5.6: The complainant has not provided any information showing that any material was made available by Moderna to UK HCPs without a need for or interest in it, or that was not tailored to the audience to whom it was directed. The process set out in the presentation is not used by Moderna UK or with UK HCPs. As mentioned above, Moderna only distributes content to UK HCPs via third parties with the appropriate consents in place.

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

Clause 2: Moderna UK has not breached the ABPI Code and so has not brought discredit upon or reduced confidence in the pharmaceutical industry."

Request for further information from the Panel

Moderna's response, following a request for further information, is reproduced below:

> "Only a single version of the Scientific Exchange Policy (SEP) exists. Following consultation with both internal teams and external consultants with relevant historical knowledge, it was confirmed that the "v2" designation in the document's footer was the result of a technical issue encountered during the original approval process. The initial version of the policy was approved on 4 November 2022, but due to a system error, a named employee had to resubmit the document for approval. Consequently, the system assigned the policy as "version 2" despite no substantive amendments to the content.
>
> The Scientific Exchange Policy was hence formally launched on 9 November 2022, at which time all internal and external material owners received appropriate training. The document labelled as "version 2" is the only extant version, and no earlier version exists beyond the draft that was affected by the afore mentioned technical issue."

PANEL RULING

The Panel noted Moderna's explanation that in November 2021 (the date on the presentation which was submitted to support the complaint), 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 further explained that in 2021, 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.

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 prior to the grant of the marketing authorisation, then the complaint would be considered in the usual way. The Panel noted the role of Moderna's regional affiliate in this matter. 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 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. Following a request for further information the Panel considered that the copy of the Scientific Exchange Policy submitted by Moderna was the version which was current at the time of the complaint.

The complaint related to a presentation which the complainant believed was approved for non-promotional use by MSLs (Medical Scientific Liaison) in Europe, including the UK, and was a pro-active process. They alleged that two named senior Moderna employees had communicated that Moderna would be proactive in communicating pre-print data even though it was not peer reviewed. It was alleged that this process meant Moderna had the freedom to

send any data they wished and that depending on the material provided, this could constitute off-label promotion.

The Panel noted Moderna's submission that the presentation at issue "describes a regional level proposal for seeking consent from HCPs to receiving medical, scientific information (which in practice is then checked against local requirements before being used in a specific market)". Moderna further submitted that it had not used the presentation, nor the process described in it, in relation to the UK market.

The presentation titled, "E-concent management – Manual process", dated November 2021, consisted of four slides including the title slide. The second slide showed a flow diagram setting out a process for undefined employees to call health professionals to ask if the health professionals wished to opt into/out of receiving communication from Moderna and updating GoogleApp, according to the health professionals' response. The first action box in the flow diagram stated, "Moderna pro-actively call HCP to request opt-in*". The asterisk was defined in a footnote at the bottom of the slide and stated "*Proposed verbatim on page 10 (if Moderna resource has an established relationship with an HCP, he may use usual channel of communication (eg e-mail) to pro-actively request the e-consent)". Where a health professional accepts opt-in, the action box stated, "Inform HCP that a confirmatory e-mail will be sent, Confirm e-mail address, Send confirmatory e-mail**". The double asterisk was again defined in a footnote at the bottom of the slide and stated, "** Proposed e-mail text on page 11". The Panel noted that both footnotes referred to 'pages 10 and 11', respectively. The footnotes did not appear to correspond with the content in pages 10 and 11 of the Scientific Exchange Policy, as submitted by Moderna. The footnotes appeared to correspond with the titles of slides 3 and 4 of the presentation at issue, however these slides made no reference to 'pages 10 and 11'. The content of the information referred to in the footnotes was therefore unclear to the Panel.

The third slide set out the "proposed verbatim" wording for the proactive call with health professionals to request opt-in, which stated: "Would you be interested to be contacted via email and telephone by Moderna to receive relevant regular scientific, medical information about the products and services offered by Moderna? This could include invitations to medical educational events or webinars and information on opportunities for scientific and medical engagements. If you provide your consent, you agree with the related processing of your personal data and to be contacted by Moderna Switzerland and Moderna group companies in Europe, UK, and the USA. The exact group companies will be confirmed to you in a confirmation email that will be sent shortly after our telephone conversation. You can of course withdraw your consent at any time with effect for future".

The Panel noted that on responding 'no', the caller would thank the health professional and terminate the call; on responding 'yes', the process for e-mail confirmation of the consent, was explained.

The fourth and final slide provided the information included in the confirmatory opt-in e-mail that would be sent to a health professional should they accept opt-in.

In relation to role of the MSLs the Panel noted the purpose of the Scientific Exchange Policy was documented as "guiding principles at a global/regional level on appropriate Scientific Exchange activities and communications to ensure that all such activities and communications contribute scientific, medical and/or clinical value to patient care through Moderna Products", and that the policy was designed to be "supplemented by local guidelines, to ensure that these

activities and communications comply with all applicable laws, regulations, guidance, and industry best practices". The policy stated that "All Scientific Exchange communications and activities must be objective, balanced, based on prevailing scientific and medical standards, non-promotional, truthful and non-misleading" and "must be distinguishable from Promotional Communications". Proactive Scientific Exchange with Individual Healthcare Professionals was described as involving "epidemiology, burden of disease, approved/authorized Moderna Products, is consistent with product labelling and uses MRC (Medical review Committee) approved materials".

The Panel noted that the complainant bore the burden of proof and, on balance, and based on the limited material and information before it, did not consider that the presentation at issue meant that Moderna had the freedom to send any data they wished and that depending on the material provided, could constitute off-label promotion, or that Moderna had been proactive in the communication of pre-print data, as alleged. The Panel ruled **no breach of Clauses 2, 3.1, 5.1, 5.6, 15.5 and 15.6** of the Code accordingly.

Complaint received **3 July 2023**

Case completed **11 September 2024**