EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Dr Silvia Behrendt
Director
Global Health Responsibility Agency

10 June 2026
EMA/134526/2026

Sent by email only: silvia.behrendt@ghra.ngo

Dear Dr Behrendt,

Subject: Reply of the European Medicines Agency in response to your follow-up correspondence dated 10 April 2026 concerning the disclosure of certain documents for two COVID-19 mRNA-vaccines

We are writing to you in response to your follow-up correspondence to the European Medicines Agency ("EMA" or the "Agency") dated 10 April 2026. In that correspondence, you request the Agency to prepare the necessary documents, including a scientific opinion, for the launching of a referral procedure under Article 20 of Regulation (EC) No 726/2004[1] in respect of Comirnaty and Spikevax (the "concerned COVID-19 vaccines") and "*any other centrally authorised modRNA-LNP medicinal products for infectious diseases*". In addition, you ask for the disclosure of additional documents on Comirnaty and Spikevax under Regulation (EC) No 1049/2001 and reiterate your previous claims on the requests for the complete disclosure of the common technical documents ("CTD") modules for the dossiers of the concerned COVID-19 vaccines. Further, you submit several requests regarding the meeting offered by EMA in its letter dated 13 February 2026.

At the outset, we would like to respectfully highlight that, in your letter, you reiterate several claims raised in your previous correspondence, including on the request for the full disclosure of the CTD modules for the dossiers of Comirnaty and Spikevax under the so-called "EMA Transparency Initiative", alleged safety issues concerning said vaccines and the public register of documents already subject to a request for access to documents. The Agency has expressed in detail its position on these matters in our previous communications, including in our letters dated 3 September 2025, 3 December 2025 and 13 February 2026. Accordingly, for the avoidance of repetition, EMA will refrain from reiterating again its position on these points.

I. In relation to your request for a referral procedure under Article 20 of Regulation (EC) No 726/2004

In your correspondence, you request EMA to prepare and submit to the European Commission ("Commission") a "*reasoned opinion requesting the Commission to initiate an Article 20 procedure under Regulation 726/2004 in respect of Comirnaty and Spikevax (and, where*

[1] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency.

applicable, any other centrally authorised modRNA-LNP medicinal products for infectious diseases)." In support of your request, you submit two claims: under the **first claim**, you note that there is *"substantive evidence of plausible mechanisms of harm arising from the regulatory failures that Comirnaty and Spikevax were not correctly assessed and controlled in accordance with their actual gene-therapy-relevant mode of action*" as per Regulation (EC) No 1394/2007[2]; and under the **second claim**, you submit that there is *"an exceptional volume of pharmacovigilance safety signals recorded in the Union pharmacovigilance system as well as peer-reviewed literature describing plausible mechanisms of harm.*"

As an initial remark, we would like to clarify that referral procedures under Article 20 of Regulation (EC) No 726/2004 ("Article 20 referrals") shall be initiated by the Commission only where a Member State or the Commission considers that at least one of the grounds set out in said provision for triggering the referral[3] are fulfilled in respect of one or more centrally authorised medicines. In this respect, please be informed that, to date, no concerns justifying the initiation of an Article 20 referral have been identified by a Member State or the Commission for the concerned COVID-19 vaccines or "*any other centrally authorised modRNA-LNP medicinal products for infectious diseases*".

With regard to the two claims set out in your letter in support of your request, we would like to put forward the following observations.

In connection with the **first claim**, it bears reiterating that, as already explained in detail in our previous correspondence, there is no reliable evidence demonstrating the existence of safety issues capable of overturning the positive risk-benefit balance of the concerned COVID-19 mRNA-vaccines.

Further, as regards your reference to alleged "*regulatory failures*" insofar as "*Comirnaty and Spikevax were not correctly assessed and controlled in accordance with their actual gene-therapy-relevant mode of action*", we would like to clarify that said vaccines do not meet the definition of "gene therapy medicinal product" as set out in Part IV of Annex I to Directive 2001/83/EC[4] or of "advanced therapy medicinal product" as per Regulation (EC) No 1394/2007.[5] Consequently, they cannot be classified as such. More importantly, Part IV of Annex I to Directive 2001/83/EC

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2 Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004.

3 More concretely, according to Article 20(1) of Regulation (EC) No 726/2004, the reasons that justify the triggering of an Article 20 referral are: "*where the supervisory authorities or the competent authorities of any other Member State are of the opinion that the manufacturer or importer established within the Union territory is no longer fulfilling the obligations laid down in Title IV of Directive 2001/83/EC*", "*where a Member State or the Commission considers that one of the measures envisaged in Titles IX and XI of Directive 2001/83/EC should be applied in respect of the medicinal product concerned or where the said Committee has delivered an opinion to that effect in accordance with Article 5 of this Regulation.*"

4 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

5 The term "gene therapy medicinal product" is defined as "*a biological medicinal product which has the following characteristics: (a) it contains an active substance which contains or consists of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence; (b) its therapeutic, prophylactic or diagnostic effect relates directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence. Gene therapy medicinal products shall not include vaccines against infectious diseases*"; and the term "advanced therapy medicinal product" is defined as "*any of the following medicinal products for human use: - a gene therapy medicinal product as defined in Part IV of Annex I to Directive 2001/83/EC, - a somatic cell therapy medicinal product as defined in Part IV of Annex I to Directive 2001/83/EC, - a tissue engineered product as defined in point (b).*"

explicitly clarifies that "*Gene therapy medicinal products shall not include vaccines against infectious diseases*".

Therefore, vaccines authorised against infectious diseases, including Spikevax and Comirnaty, are not gene therapy medicinal products and, accordingly, the specific provisions on assessment and control of advance therapy medicinal products do not apply to these medicines.

In view of the above, your claim that there is "*substantive evidence of plausible mechanisms of harm arising from the regulatory failures that Comirnaty and Spikevax were not correctly assessed and controlled in accordance with their actual gene-therapy-relevant mode of action*" is manifestly incorrect.

As regards your **second claim**, we would like to put forward several important clarifications on the significance and assessment of suspected adverse reactions reported in Eudravigilance, which are distinct from safety signals, as explained below.

EMA carries out routine screenings of the suspected adverse reactions that are reported in Eudravigilance and other sources in order to identify potential safety signals. Where identified, potential safety signals are first subject to a signal validation process and, if validated, they undergo a signal confirmation process.[6] The decision to validate and/or confirm safety signals is based, for example, on the level of evidence, clinical relevance and whether the relevant adverse reaction is already adequately reflected in the product information of the medicine.

Subsequently, confirmed safety signals are referred to the Pharmacovigilance Risk Assessment Committee ("PRAC"), for assessment.[7]

Therefore, suspected adverse reactions to medicines reported in Eudravigilance do not constitute (confirmed) safety signals. Also, the report of suspected adverse reactions for a medicine does not automatically confirm the presence of safety issues meriting regulatory actions against the concerned medicine.

In view of the above considerations, your claim that an exceptional volume of pharmacovigilance safety signals recorded in the Union pharmacovigilance system as well as peer-reviewed literature describe plausible mechanisms of harm for the concerned vaccines is also manifestly incorrect. As noted above, to date, the Member States and the Commission have not identified any safety concerns deriving from the signal management process justifying the triggering of an Article 20 referral for the concerned COVID-19 mRNA-vaccines or other "*authorised modRNA-LNP medicinal products for infectious diseases*."

II. In relation to your additional request for the disclosure of documents under the so-called "Transparency4Safety"

In your correspondence, you also request access to an extensive number of documents regarding the concerned COVID-19 mRNA-vaccines. In view of the large volume of documents requested,

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6 For more information on safety signal validation and confirmation, please see Module IX of the Guideline on good pharmacovigilance practices (GVP), available at: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-module-ix-signal-management-rev-1_en.pdf.

7 Detailed information on the Union signal management process can be found on the dedicated EMA webpage on signal management, available at: https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/signal-management.

we invite you to narrow down the scope of your request to a more manageable number of documents and to submit the request through the Agency's dedicated electronic form on the EMA's website,[8] to facilitate the proper and efficient processing of your request.

We would welcome the opportunity to address this matter in the context of the meeting proposed by EMA in its letter dated 13 February 2026.

III. In relation to the meeting proposed by the Agency in its letter dated 13 February 2026

At the outset, we would like to thank you for accepting the meeting proposed by EMA in its letter of 13 February 2026. Under the present section, we would like to make a number of clarifications concerning your requests for said meeting.

First, regarding the scope of the meeting, we would like to clarify that the Agency proposed the meeting in question to discuss your request for the disclosure of a comprehensive and structured overview of the CTD modules for the dossier of the concerned COVID-19 vaccines and various versions thereof held by the Agency, and your request for all disclosures made by the Agency under Regulation (EC) No 1049/2001 from 1 January 2025 onwards. Additionally, as noted above, the Agency would like to take this opportunity to also clarify the intended scope of the request referred to in the section entitled "*Extended Transparency4Satefy request*" of your correspondence dated 10 April 2026, in view of the high volume of documents involved in such request.

As regards your proposal to discuss during the meeting the "*the minimum technical and procedural prerequisites required for a scientifically conclusive resolution of the most urgent harm-to-human-health issues*" as per the sessions suggested in your letter, we would like to reiterate that the Agency has already explained on multiple occasions its position on your claims on alleged safety concerns of the concerned COVID-19 mRNA-vaccines. Therefore, please be informed that the Agency respectfully declines your proposal and will not discuss during the meeting scientific matters regarding the concerned COVID-19 mRNA-vaccine.

In view of the scope of the meeting, the Agency will be represented therein solely by EMA staff members involved in measures related to transparency, including members from the Agency's Access to documents, Communication and Legal teams; no representatives of the Paul-Ehrlich-Institute (PEI), EMA scientific committees and EMA Product Leads will be present at the meeting. Further, please note that, considering the topics for discussion, the invitation to the meeting is limited only to representatives of the Global Health Responsibility Agency.

Furthermore, please be informed that the Agency will accommodate your request to hold the meeting in person at its premises in Amsterdam, but the meeting will not be livestreamed. In this connection, please also be informed that EMA is not in a position to cover any expenses incurred for your attendance to such meeting.

Finally, please note that it has not been possible to organise such meeting in May. The Agency is identifying suitable dates for early July and will contact you shortly by email to share the proposed dates and confirm your availability.

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8 The EMA dedicated electronic form for submission of requests for access to documents is available at: https://www.ema.europa.eu/en/about-us/contacts-european-medicines-agency/send-question-european-medicines-agency.

IV. Concluding remarks

We trust that this letter has addressed the additional points raised in your correspondence dated 10 April 2026. In addition, it recapitulates the Agency's position on the claims raised in your previous correspondence, which have been addressed in detail in EMA's previous communications.

Once again, thank you for accepting the meeting proposed by EMA and we look forward to a fruitful discussion during said meeting.

Sincerely,

Emer Cooke
Executive Director

Copy: Ms Tereza Mandjukova, European Ombudsman;
Ms Georgia Gavriilidou, Head of Legal Department; and
Ms Anne-Sophie Henry-Eude, Head of Transparency Department