



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Prof Dr Jörg Matysik
Analytische Chemie
Universität Leipzig

30 July 2026
EMA/178057/2026

Sent by email only: [REDACTED]

Dear Prof Dr Matysik,

Subject: Reply of the European Medicines Agency in response to your correspondence of 26 May 2026 concerning the Transparency4Safety Initiative

We are writing to you in response to your correspondence to the European Medicines Agency (“EMA” or the “Agency”) of 26 May 2026.

In the context of that correspondence, you request the complete disclosure of certain documents concerning the common technical documents (“CTD”) modules for Comirnaty and Spikevax (the “concerned mRNA COVID-19 vaccines”). In addition, you request the disclosure of a significant number of additional documents related to mRNA/LPN vaccines, including Comirnaty and Spikevax. Furthermore, you claim (alleged) safety concerns with regard to said vaccines, request the triggering of an Article 20 referral procedure and identify several scientific points that, in your view, should be discussed in the meeting that the Agency offered to the Global Health Responsibility Agency (“GHRA”) in the context of the Agency’s correspondence with said organisation, or in a separate meeting.

I. Preliminary remarks in relation to EMA’s commitment to transparency

At the outset, EMA would like to put forward the following important preliminary remarks in relation to the Agency’s commitment to transparency, in particular in the context of the COVID-19 pandemic and the subsequent public health emergency.

As an agency of the European Union (“EU”) responsible for the scientific evaluation and supervision of medicinal products, ensuring a high degree of transparency is at the cornerstone of EMA’s work.¹ By conducting its work in a transparent manner, EMA actively strives to enhance public trust in its scientific opinions, recommendations and decisions.

¹ In this respect, see: the document “Guide to information on human medicines evaluated by EMA (EMA/207532/2025)” which provides, in the relevant part, an overview of the different types of information concerning centrally and non-centrally authorised medicinal products for human use that EMA publishes on its website; available at: https://www.ema.europa.eu/en/documents/other/guide-information-human-medicines-evaluated-european-medicines-agency-what-agency-publishes-when_en.pdf.



More particularly, in the context of the COVID-19 pandemic and the subsequent public health emergency, EMA adopted a number of measures in order to maximise the transparency (and publicity) of its regulatory activities concerning the scientific evaluation of COVID-19 vaccines and therapies.² This included the proactive publication of (non-confidential) information on the safety and efficacy of those vaccines and therapies. In specific relation to Comirnaty, this finding was acknowledged by the European Ombudsman in her decision of 10 November 2021 in case 1458/2021/MIG, wherein she noted that “*EMA has proactively published extensive (non-confidential) information not only on the safety and efficacy but also on the quality of the vaccine*”.³

Further, as result of the entry into force of Regulation (EU) 2022/123, a reinforced framework for the enhanced transparency standards and measures has been established, which builds on the transparency standards and measures (proactively) adopted by EMA during the COVID-19 pandemic.⁴

The above outlines the strong commitment of the Agency to ensuring the full transparency of its activities, including the ongoing proactive publication of documents pertaining to the CTD modules for Comirnaty and Spikevax.

II. As regards your request for the complete disclosure of certain documents concerning the CTD modules for Comirnaty and Spikevax

In your letter, you refer to several access to documents requests submitted to the Agency in 2022 under Regulation (EC) No 1049/2001⁵ regarding the CTD modules for the concerned mRNA COVID-19 vaccines. In this respect, you note that “*parts of these requests have since been processed*” but that the Agency has either not yet made available, or has disclosed only with extensive redactions, some of the requested documents. In addition, you criticise the handling by EMA of the mass access request initiated in 2025 (initially so-called “EMA Transparency Initiative”) because “[a]s of today, only re-releases of redacted CTD documents have been made available as “exceptional transparency measures” without any procedural safeguards of the requesters.”

First, we would like to emphasize that all the access to documents requests under Regulation (EC) No 1049/2001 identified in your letter are duly processed by the Agency and subsequently closed where relevant. Where the Agency provided the requested documents with redactions, the reasons for such redactions were duly explained in the corresponding decisions adopted by the Agency in the context of said requests.

Furthermore, with regard to the mass access request of 2025, we would like to explain that some of the requested documents regarding the CTD modules for the concerned mRNA COVID-19 vaccines have already been published on EMA’s clinical data website⁶ as part of the above-referred transparency measures. Those documents correspond to clinical data emanating from Module 2.5

² In this respect, see: the document titled “EMA transparency measures for medicines addressing public health emergencies (EMA/244151/2020)”; available at: https://www.ema.europa.eu/en/documents/other/ema-transparency-measures-medicines-addressing-public-health-emergencies_en.pdf.

³ Available at: <https://www.ombudsman.europa.eu/en/decision/en/149025>.

⁴ In this respect, see: recital 49 of Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.

⁵ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

⁶ The clinical data publication website of the Agency provides online access to clinical data for medicinal products for human use, including Comirnaty and Spikevax: <https://clinicaldata.ema.europa.eu/web/cdp>.

(relating to the clinical overview), Module 2.7 (relating to the clinical summary) and Module 5.3 (relating to the clinical study reports) for Comirnaty and Spikevax.

In relation to the remaining scope of the CTD modules, due to the very high interest expressed by members of the public in obtaining access to data related to the concerned mRNA COVID-19 vaccines, EMA is publishing them incrementally, also by means of its proactive publication on the respective EMA webpages for [Comirnaty](#) and [Spikevax](#).

In this regard, please note that between 13 February 2025 and 2 July 2025, EMA received over 2,100 individual requests for access to documents concerning the CTD modules for Comirnaty and Spikevax as part of the EMA Transparency Initiative. In assessing each of the individual applications corresponding to the mass access request, we identified a total of more than 3,000 documents that were considered as falling within the scope of these requests (this figure does not encompass the documents that have been published on EMA's proactive clinical data publication website).

As we trust that you can appreciate, the processing of these requests individually would potentially delay the release of the documents requested and entail a disproportionate amount of workload which could significantly disrupt the proper functioning of EMA. Further, such processing would compromise EMA's adherence to the principle of good administration in what regards the processing of other unrelated requests for access to documents submitted by different requesters.

Therefore, the Agency is disclosing the concerned documents by means of its proactive publication on the respective EMA webpages for Comirnaty and Spikevax and that, due to the high-volume of the documents at issue, the exercise remains ongoing.

In addition, we would like to respectfully note that your claim that “[a]s of today, only re-releases of redacted CTD documents have been made available as “exceptional transparency measures” without any procedural safeguards of the requester” is incorrect, as the Agency has published (and continues to publish) documents concerning the CTD modules for Comirnaty and Spikevax that have not been previously disclosed as part of access to documents requests submitted to EMA under Regulation (EC) No 1049/2001.

For your reference, please find annexed to this correspondence a table listing the documents that EMA has published since 30 June 2025 until today on its respective webpages for Comirnaty and Spikevax.

Second, in connection with your request for the full disclosure of the requested documents pertaining to the CTD modules for the concerned mRNA COVID-19 vaccines, without any redactions, please note that this request fails to take into account EMA's obligations to ensure the protection of commercially confidential information and personal data in accordance with the applicable legislation, as explained below.

While the Agency is firmly committed to ensuring the timely publication of the relevant documents and to ensure the full transparency of the Agency's activities, this publication is subject to the Agency's obligation to protect commercially confidential information and personal data.

Concerning the protection of commercially confidential information, this obligation derives from Article 339 of the Treaty on the Functioning of the European Union (“TFEU”), as well as other

key pieces of secondary legislation, including Regulation (EC) No 726/2004⁷ (by analogy, Articles 13(3) and 80) and Regulation (EU) 2022/123 (in particular, Article 34(1)). Further, in view of the fact that the requested documents emanate from third-parties, EMA is bound to consult the concerned marketing authorisation holders in relation to documents that have not been previously disclosed by EMA.

On this note, we would like to further draw your attention to the judgment of the General Court in Case T-623/22, *SD v EMA*. Aside from finding that vaccine data submitted by a marketing authorisation (“MA”) holder may be regarded as commercially confidential and hence not subject to generalised access, the Court also rejected the argument that a decision to protect (on reasoned grounds) vaccine data submitted by a MA holder cannot lead to the conclusion that the Agency has compromised its public service mission, its mandate and its powers. In that regard, the General Court also (correctly) observed that “[c]ompliance with the criteria laid down in Directive 2001/83 for the grant of a MA for the Comirnaty vaccine had also been verified, as is apparent from the numerous assessment reports published on the EMA’s website”.⁸

As regards the protection of personal data, EMA is precluded from disclosing the requested documents without verifying the possible existence of personal data and safeguarding the rights of the holders of that data in accordance with Regulation (EU) 2018/1725.⁹ Accordingly, each document (that has not been previously disclosed) must be verified in order to ensure that personal data is not inadvertently disclosed.

Taking into account the above considerations, please note that it is not permissible for EMA to disclose documents that may contain commercially confidential information and/or personal data.

III. As regards your request for the disclosure of a significant number of additional documents related to mRNA/LPN vaccines

Under sections 1, 2, 3 and 4 of your letter, you request the full disclosure of an extensive volume of documents regarding mRNA/LPN vaccines, including but not limited to Comirnaty and Spikevax. In this regard, we would like to make the following observations.

First, it bears clarifying that several of the requested documents have already been disclosed by EMA. For example, this is the case of the documents concerning module 2.3.P.1 entitled “*Description and Composition of the Drug Product*”, module 3.2.P.2.3 entitled “*Manufacturing Process Development*” and module 3.2.P.3.3 “*Description of Manufacturing Process and Process Controls*” for Comirnaty, requested under section 4.1 of your letter.

For the reasons set out in Section II above, the Agency has published these documents in a redacted form, in full compliance with its legal obligation to protect commercially confidential information and personal data. As explained *supra*, the Agency cannot publish documents without redacting such information, as doing so would constitute a violation of the Agency’s legal obligations.

⁷ 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.

⁸ In this respect, see: judgment of the General Court of 19 November 2025 in *SD v EMA*, T-623/22, EU:T:2025:1035, paragraph 126.

⁹ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC.

Second, in view of the particularly broad scope of your requests, you are kindly invited to consider defining the scope with more precise and specific parameters (e.g. clearly identifying specific medicinal products) and indicating a priority order. These clarifications will facilitate the proper and efficient processing of your requests.

Furthermore, we would also like to kindly ask that you submit your requests through the Agency's dedicated electronic form available on the EMA website,¹⁰ for efficient and faster handling of your requests, and for traceability purposes.

IV. Clarifications regarding (alleged) safety concerns in respect of Comirnaty and Spikevax

Under the present section, EMA would like to provide several important clarifications regarding the safety of the concerned mRNA COVID-19 vaccines, especially concerning the manufacturing process and batch release of these medicinal products.

At the outset, it bears emphasising that the respective manufacturing processes for the concerned mRNA COVID-19 vaccines must be carefully designed and controlled to ensure safe and acceptable levels as per the approved terms of the respective marketing authorisation.

To that end, the quality of every batch of a COVID-19 vaccine is checked before it is released for use in the EU. Only batches that comply with EMA and the European Commission's approved quality specifications, as per the terms of the marketing authorisation, can be used in the EU. In addition, it is relevant to note that an official medicines control laboratory ("OMCL") of a national competent authority must check the results of all of the vaccine release testing performed by each marketing authorisation holder before any of the vaccines batches made can be released.

In this connection and concerning the alleged claims on the residual DNA in mRNA COVID-19 vaccines, we would like to underscore that, to date, EMA has not seen any reliable scientific evidence of DNA exceeding approved levels for either of the concerned mRNA COVID-19 vaccines.

EMA is aware that some researchers have claimed that levels of residual DNA in mRNA COVID-19 vaccines exceed approved levels. It is our understanding that these claims are however based on results from unvalidated tests.

As DNA is only used during the manufacture of the active substance, it is important to test the active substance itself. Some researchers have instead tested the final product (which includes excipients) and have obtained incorrect results because of interference from excipients.

We would like to highlight that, to date, EMA has not seen any reliable scientific data demonstrating safety concerns capable of overturning the current positive risk-benefit balance for Comirnaty and Spikevax.

Finally, we would like to reassure you that the work of EMA, acting through its scientific committees, does not end with the decision of the European Commission ("Commission") to grant

¹⁰ 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>.

a marketing authorisation. In this respect, EMA's committees are constantly active in monitoring their safety and efficacy, and any change to the side effect profile. This latter activity is conducted through pharmacovigilance.

V. In connection with your request for an Article 20 referral procedure

The Agency understands that, in your letter, you are requesting EMA to initiate, or to advise the Commission to initiate, a referral procedure under Article 20 of Regulation (EC) No 726/2004 ("Article 20 referral") for Comirnaty and Spikevax.

As an initial remark, we would like to clarify that Article 20 referrals shall be initiated by the Commission, and 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 are fulfilled in respect of one or more centrally authorised medicines.

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 the following: *"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."*

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 mRNA COVID-19 vaccines.

VI. As regards the meeting that was offered by the Agency to GHRA

In your letter, you identify several scientific points that, in your view, should be discussed in the meeting that the Agency offered to GHRA in the context of the Agency's correspondence with said organisation, or in a separate meeting.

In this regard, we would like to clarify that the meeting offered by EMA to GHRA in the context of the Agency's correspondence with said organisation took place on 2 July 2026, in person only, at EMA's premises in Amsterdam. The meeting was only open to GHRA's representatives and it was not livestreamed.

As notified to GHRA in advance, the scope of the meeting was to discuss several of GHRA's requests for the disclosure of documents which are connected to the "Transparency4Safety" Initiative but also to other topics concerning other requests submitted by GHRA. Accordingly, no scientific matters regarding mRNA/LPN vaccines were discussed at said meeting.

Furthermore, please note that in view of the scope of the meeting, the Agency was represented therein solely by EMA staff members involved in measures related to transparency; no representatives of the Paul-Ehrlich-Institute (PEI), EMA scientific committees and EMA Product Leads were present at the meeting.

Should you wish to obtain information on the discussions held at that meeting, please kindly contact GHRA.

Furthermore, please note that, at present, the Agency does not plan to schedule another meeting to discuss the claims raised in the context of the “Transparency4Safety” Initiative. Should this change in the future, please rest assured that we will inform you accordingly.

VII. Concluding remarks

As a final remark, the Agency would like to reiterate its firm commitment to ensuring the full transparency of the Agency’s activities, including the continued publication of all documents pertaining to the CTD modules for Comirnaty and Spikevax, subject to EMA’s obligation to ensure the protection of commercially confidential information and of personal data.

We would also like to reassure you that the Agency, through its scientific committees, is continuously monitoring the safety and efficacy of medicinal products placed on the Union, and any change to the side effect profile.

Sincerely,



Emer Cooke
Executive Director

Annex

Table listing the documents published by EMA since 30 June 2025 on its respective webpages for Comirnaty and Spikevax.

Vaccine	Sub-module	Type of data	Date of first publication on EMA's webpage
Comirnaty	2.3.S 2.3.P	Drug substance	25 July 2025
Comirnaty	2.6.4	Pharmacokinetics (non-clinical) written summary	30 June 2025
Comirnaty	2.6.5	Pharmacokinetics (non-clinical) tabulated summary	30 June 2025
Comirnaty	3.2.A	Appendices	27 August 2025
Comirnaty	3.2.S.4.1 3.2.S.4.2	Specification Analytical procedures	2 September 2025
Comirnaty	3.2.S.2.6	Manufacturing Process Development	17 July 2025
Comirnaty	3.2.S.2.3	Control of materials	17 July 2025
Comirnaty	3.2.S.2.4	Controls of critical steps and intermediaries	17 July 2025
Comirnaty	3.2.S.2.2	Description of Manufacturing Process and Process Controls	17 July 2025
Comirnaty	3.2.S.2.2	Description of Manufacturing Process and Process Controls	25 July 2025
Comirnaty	3.2.S.2.3	Control of Materials	25 July 2025
Comirnaty	2.3.S.1	General Information	25 July 2025
Comirnaty	2.3.P.1	Description and Composition of the Drug Product	25 July 2025
Spikevax	3.2.P.1	Description and Composition of the Drug Product (name, dosage form)	20 August 2025
Spikevax	3.2.P.2.1	Components of the Drug Product (name, dosage form)	20 August 2025
Spikevax	3.2.P.2.2	Drug Product (name, dosage form)	20 August 2025
Spikevax	3.2.P.2.3	Manufacturing Process Development (name, dosage form)	20 August 2025
Spikevax	3.2.P.2.4	Container Closure System (name, dosage form)	20 August 2025
Spikevax	3.2.P.2.5	Microbiological Attributes (name, dosage form)	20 August 2025
Spikevax	3.2.P.2.6	Compatibility (name, dosage form)	20 August 2025
Spikevax	3.2.P.3.1	Manufacturer(s) (name, dosage form)	20 August 2025
Spikevax	3.2.P.3.2	Batch Formula (name, dosage form)	20 August 2025
Spikevax	3.2.P.3.3	Description of Manufacturing Process and Process Controls (name, dosage form)	20 August 2025
Spikevax	3.2.P.3.4	Controls of Critical Steps and Intermediates (name, dosage form)	20 August 2025

Spikevax	3.2.P.3.5	Process Validation and/or Evaluation (name, dosage form)	20 August 2025
Spikevax	3.2.P.5.1	Specification(s) (name, dosage form)	20 August 2025
Spikevax	3.2.P.5.2	Analytical Procedures (name, dosage form)	20 August 2025
Spikevax	3.2.P.5.3	Validation of Analytical Procedures (name, dosage form)	20 August 2025
Spikevax	3.2.P.5.4	Batch Analyses (name, dosage form)	20 August 2025
Spikevax	3.2.P.5.5	Characterisation of Impurities (name, dosage form)	20 August 2025
Spikevax	3.2.P.5.6	Justification of Specification(s) (name, dosage form)	20 August 2025
Spikevax	3.2.P.8.1	Stability Summary and Conclusion (name, dosage form)	20 August 2025
Spikevax	3.2.P.8.3	Stability Data (name, dosage form)	20 August 2025
Spikevax	3.2.S.2.5	Process validation and/or evaluation	12 August 2025
Spikevax	3.2.S.4.2	Analytical procedures Analytical procedures lonza visp Analytical procedures sop 1020	12 August 2025
Spikevax	S.2.S.4.3	Validation of analytical procedures lonza_visp	12 August 2025
Spikevax	3.2.S.4.4	Batch analyses CX-024414	12 August 2025
Comirnaty	3.2.P.2.3	Manufacturing Process Development	20 August 2025
Spikevax	4.2.2.3	Distribution	30 June 2025
Comirnaty	4.2.3.2	Repeat-dose toxicity	30 June 2025
Spikevax	4.2.3.2	Repeat-dose toxicity	30 June 2025
Spikevax	4.2.3.3.1	In vitro	30 June 2025
Spikevax	4.2.3.3.1	In vivo (including supportive toxicokinetics evaluations)	30 June 2025
Comirnaty	4.2.3.5.1	Fertility and early embryonic development	30 June 2025
Spikevax	4.2.3.7.2	Immunotoxicity	30 June 2025
Comirnaty	4.2	Residual DNA characterisation report Response to EMA request for supplementary information	12 August 2025
Comirnaty	3.2.P.6	Reference Standards or Materials	11 September 2025
Comirnaty	3.2.P.7	Container closure system	11 September 2025
Comirnaty	3.2.P.8.1	Stability Summary and Conclusion (name, dosage form)	11 September 2025
Comirnaty	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment (name, dosage form)	11 September 2025

Comirnaty	3.2.P.8.3	Stability Data (name, dosage form)	11 September 2025
Spikevax	2.4	Non-clinical overview	9 October 2025
Comirnaty	2.4	Non-clinical overview	9 October 2025
Spikevax	2.6	Non-clinical summary	28 November 2025
Comirnaty	2.6	Non-clinical summary	28 November 2025
Comirnaty	3.2.S.2.1	Manufacturer(s) (name, manufacturer)	19 December 2025
Comirnaty	3.2.S.2.5	Process Validation and/or Evaluation (name, manufacturer)	19 December 2025
Comirnaty	3.2.S.2.6	Manufacturing Process Development (name, manufacturer)	19 December 2025
Comirnaty	3.2.S.4.2	Analytical Procedures (name, manufacturer)	19 December 2025
Comirnaty	3.2.S.4.3	Validation of Analytical Procedures (name, manufacturer)	19 December 2025
Comirnaty	3.2.P.1	Description and Composition of the Drug Product (name, dosage form)	19 December 2025
Comirnaty	3.2.P.2.3	Manufacturing Process Development (name, dosage form)	19 December 2025
Comirnaty	3.2.P.3.1	Description and Composition of the Drug Product (name, dosage form)	19 December 2025
Comirnaty	3.2.P.3.2	Batch Formula (name, dosage form)	19 December 2025
Comirnaty	3.2.P.3.3	Description of Manufacturing Process and Process Controls (name, dosage form)	19 December 2025
Comirnaty	3.2.P.8.3	Stability Data (name, dosage form)	19 December 2025
Comirnaty	2.3.S	Drug substance	30 January 2026
Spikevax	2.3.S	Drug substance	30 January 2026
Comirnaty	2.3.S	Drug substance	27 February 2026
Spikevax	2.3.S	Drug substance	27 February 2026
Comirnaty	2.3.S	Drug substance	31 March 2026
Spikevax	2.3.S	Drug substance	31 March 2026
Comirnaty	2.3.S	Drug substance	29 April 2026
Spikevax	2.3.S	Drug substance	29 April 2026

Comirnaty	2.3.S	Drug substance	28 May 2026
Spikevax	2.3.S	Drug substance	28 May 2026
Comirnaty	2.3.S	Drug substance	30 June 2026
Spikevax	2.3.S	Drug substance	30 June 2026