EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Dr Silvia Behrendt
Director
Global Health Responsibility Agency

3 September 2025
EMA/286067/2025

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

Dear Dr Behrendt,

Subject: Reply of the European Medicines Agency in response to your correspondence dated 8 July 2025 and 21 August 2025 concerning the disclosure of certain documents for two COVID-19 vaccines

We are writing to you in response to your correspondence to the European Medicines Agency ("EMA" or the "Agency") dated 8 July 2025 and 21 August 2025, respectively. In the context of that correspondence, you ask EMA to immediately process your request of 17 February 2025 submitted under Regulation (EC) No 1049/2001 relating to the common technical documents ("CTD") for the dossiers of two COVID-19 vaccines, namely, Comirnaty and Spikevax (also referred to as, the "concerned COVID-19 vaccines").[1] Further, you request EMA to process all other pending requests that were submitted as part of the mass public request for access to documents relating to the concerned COVID-19 vaccines under the so-called "EMA Transparency Initiative" (the "mass public request").[2]

On 2 July 2025, EMA informed you that certain documents pertaining to your request for access to documents had already been published on its website.[3] Those documents correspond to clinical data emanating from Module 2.5 (relating to clinical overviews), Module 2.7 (relating to clinical summaries) and Module 5.3 (relating to the clinical study reports) for the concerned COVID-19 vaccines.

As regards the remaining scope of your request, EMA explained that, due to the very high interest expressed by members of the public in obtaining access to data related to the concerned COVID-19 vaccines, it would publish the requested documents on its website as part of an exceptional

1 Reference is made to the request for access to documents set out under the letter dated 17 February 2025, that you submitted to EMA on behalf of Global Health Responsibility on the same day, and registered under reference number ASK-267712.

2 For the purpose of the present letter, the reference to "mass public request" is intended to denote the extensive volume of requests for access to the CTD modules for Comirnaty and Spikevax that EMA has received since 13 February 2025.

3 As indicated in EMA's communication of 2 July 2025, said information has been published on the clinical data publication website of the Agency, which provides online access to clinical data for medicinal products for human use, including Comirnaty and Spikevax: https://clinicaldata.ema.europa.eu/web/cdp.

transparency initiative. As will be explained further below, a number of documents pertaining to your request have been published since that time.

By the present letter, EMA would like to provide: **first**, certain preliminary remarks in relation to EMA's commitment to transparency; **second**, clarifications concerning the handling of your request and the mass public request for access to documents concerning Comirnaty and Spikevax; and **third**, clarifications regarding the safety of the concerned COVID-19 vaccines.

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

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.[4] By conducting its work in a transparent manner, EMA actively strives to enhance public trust in its scientific opinions, recommendations and decisions.

More particularly, in the context of the COVID-19 pandemic and the subsequent public health emergency, it is important to recall that 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.[5] 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 vaccin*e".[6]

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.[7]

In view of the above, EMA firmly but respectfully disagrees with the position set out in your correspondence concerning the notion that EMA has engaged in the "*deliberate withholding of important EMA releases*" or any unlawful "*secrecy*" in order to prevent public scrutiny.[8]

As regards the claim that EMA has deliberately circumvented its transparency obligations under Regulation (EC) No 1049/2001, under section II of the present letter, EMA will provide clarifications on the handling of your request of 17 February 2025 and the mass public request. To this end, it will also further explain and define its position as regards why it has not handled your request under Regulation (EC) No 1049/2001.

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4 In this respect, see: the document titled, "Guide to information on human medicines evaluated by EMA (EMA/207532/2025) which provides, in 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.

5 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.

6 Available at: https://www.ombudsman.europa.eu/en/decision/en/149025.

7 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.

8 In this respect, reference is made to your email of 21 August 2025 to EMA.

II. The handling of your request of 17 February 2025 and the mass public request for access to documents concerning Comirnaty and Spikevax

(a) EMA's assessment of your request of 17 February 2025 and the mass public request for access to documents concerning Comirnaty and Spikevax

In your email of 8 July 2025, you expressly acknowledge the extensive volume of requests for access to documents that EMA has received since 13 February 2025 under Regulation (EC) No 1049/2001. Those requests are either identical or very similar in scope. In the context of the same email, you also acknowledge the existence of the activities of the North Group. Further, you criticise the manner in which EMA has handled your request and the mass public request.

Please be aware that between 13 February 2025 and 2 July 2025, **EMA has received over 2,100 individual requests for access to documents concerning the CTD modules for Comirnaty and Spikevax.** A review of those individual requests provides a clear indication that there is a high degree of overlap between the instructions provided on the website of the North Group under the auspices of the "EMA Transparency Initiative"[9] and the requests that have been submitted in relation to the foregoing documents.

In the context of this initiative, it is clear that members of the public have been encouraged to submit a request for access to documents under the relevant webpage of EMA. Therefore, it is our understanding that the mass public request and the high-volume of requests linked to the CTD modules for the concerned COVID-19 vaccines has been prompted by this initiative.

In assessing each of the individual applications corresponding to the mass access request, including your request, **we identified a total of more than 3,000 documents that were considered as falling within the scope of these requests**.[10]

For the purpose of illustrating the significant administrative workload entailed by the handling of these requests, we would like to note that in 2024, EMA released approximately 1,500 documents (for the entire reporting year) under the framework of Regulation (EC) No 1049/2001.[11]

It is our position that the processing of these requests (on an individual basis under Regulation (EC) No 1049/2001) would entail an unreasonable workload and could paralyse the proper functioning of EMA in a very substantial manner. Such processing would also be to the detriment of the principle of good administration in what regards the handling of other (non-related) requests for access to documents concerning other medicinal products submitted by different requesters, including but not limited to, academia, patients and consumers and healthcare professionals.[12]

In view, therefore, of the clear similarities between the scope of the extensive number of individual requests (including your request) that were submitted to EMA and the instructions set forth on the

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9 Available at: https://uploads.publishwall.si/publishwall_new/63120/files/67b086258faa3.pdf.

10 This figure does not encompass the documents that have been published on EMA's proactive clinical data publication website.

11 In this respect, reference is made to Annex 22 (relating to the Access to documents requests) to the annual report of the European Medicines Agency for 2024, page 119, which explains that EMA received a total number of 520 requests and released over 150,000 pages; available at: https://www.ema.europa.eu/en/documents/annual-report/annexes-2024-annual-report-european-medicines-agency_en.pdf.

12 Ibid, page 120, wherein, a more detailed overview of the affiliation of persons who submitted requests for access to documents in 2024 is set out.

North Group website, EMA contacted the organisation on 25 February 2025 in order to identify a single contact point for the mass public request. EMA did this with a view to finding a fair arrangement for the timely processing of the mass public request, on account of the extensive nature of the request and the time that would be required to ensure the individual handling of each of the requests under Regulation (EC) No 1049/2001. The organisation declined EMA's efforts to find an arrangement for the timely processing of the mass access request.

In light of the above considerations, EMA strongly disagrees with the claim made in your email of 8 July 2025 that, by virtue of its communication of 19 March 2025, EMA has effectively sought "*to deflect responsibility by blaming the North Group for not consolidating the requests into a single point of contact*". This communication was sent in an effort to provide reassurance that EMA has been using its best efforts to find a solution to address the mass public request in an efficient and timely manner, including by exploring the possibility to engage with the North Group as a single contact point for the mass public request.

Finally, as explained in our communication of 2 July 2025, EMA has and continues to take steps to facilitate a more timely disclosure of documents pertaining to the CTD modules for Comirnaty and Spikevax by means of proactive publication on its website. As indicated in thatcommunication, these documents will be published on the respective EMA webpages for Comirnaty[13] and Spikevax.[14] Under sub-section II(c) of the present letter, we would like to highlight the documents that have been published by EMA.

(b) The protection of commercial confidential information and personal data

In your email of 8 July 2025, you state that the disclosure of the requested documents pertaining to the CTD modules for Comirnaty and Spikevax should be processed "*without referring to Biontech or Moderna for the identification of commercially confidential information*" and that such consultation with the marketing authorisation holders "*would constitute a clear breach of the principle of institutional autonomy and legal accountability*".

EMA respectfully considers that this position is misplaced, insofar as it fails to take into account EMA's obligation to ensure 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 (EU) No 726/2004[15] and Regulation (EU) 2022/123.[16] 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. Therefore, EMA disagrees with any suggestion that it should refrain from consulting the concerned marketing authorisation holders in conducting this exercise.In view of the large volume of the

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13 The requested documents (excluding, clinical data) relating to Comirnaty are available on the following EMA webpage: https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty#exceptional-transparency-measures-77657.

14 Similarly, the requested documents (excluding, clinical data) relating to Spikevax are available on the following EMA webpage: https://www.ema.europa.eu/en/medicines/human/EPAR/spikevax#exceptional-transparency-measures-77652.

15 See, by analogy, Articles 13(3) and 80 of 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 (OJ 2004 L 136, p. 1).

16 See, in particular, Article 34(1) of Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, pp. 1-37).

documents requested, it is also relevant to note that consultation with the concerned marketing authorisation holders entails that they must be afforded the necessary time to review and provide comments on the disclosure of each of the requested documents.

Taking into account the above considerations, it is not permissible for EMA to disclose the requested documents without consulting the concerned marketing authorisation holders for the purposes of identifying commercially confidential information, as this would be at variance with EMA's obligation to ensure the protection of commercially confidential information.

Further, EMA would like to take this opportunity to recall that, in respect of the protection of personal data, it 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. Accordingly, each document (that has not been previously disclosed) must also be verified in order to ensure that personal data is not inadvertently disclosed.

On the basis of the above, EMA will continue to ensure that the requested documents are verified in order to safeguard the protection of any commercially confidential information and/or personal data contained in those documents.

(c) The documents relating to the CTD modules for Comirnaty and Spikevax that have been published to date

For completeness, under the present subsection of the letter, we would like to highlight the documents (without commercially confidential information and personal data) relating to the CTD modules for the concerned COVID-19 vaccines that have been incrementally published on the website of EMA since 30 June 2025.

As an initial remark, please be informed that the relevant documents containing the qPCR assay protocols and laboratory data for residual DNA quantification used in the assessment of Spikevax and Comirnaty have now been released.[17]

In the below table, EMA would like to highlight the (total) documents that have been published as of today.

Vaccine	(Sub-)Module	Type of data	Date of first publication on EMA's webpage
Comirnaty	2.3.S	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.P	Drug product	2 September 2025

[17] By its communication of 13 August 2025, EMA confirmed the publication of the relevant documents on the EMA webpage for Comirnaty.

Comirnaty	3.2.S.2.2	Description of manufacturing process	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
Spikevax	3.2.S.2.5	Process validation and/or evaluation	12 August 2025
Comirnaty	3.2.S.2.6	Manufacturing process development	17 July 2025
Comirnaty Spikevax	3.2.S.4.2	Analytical procedures	12 August 2025
Spikevax	3.2.S.4.2	Analytical procedures lonza visp	12 August 2025
		Analytical procedures sop 1020	
Spikevax	S.2.S.4.3	Validation of analytical procedures lonza_visp	12 August 2025
Spikevax	3.2.S.4.4	Batch analyses	12 August 2025
		batch analyses CX-024414	
Spikevax	4.2.2.3	Distribution	30 June 2025
Comirnaty Spikevax	4.2.3.2	Repeat-dose toxicity	30 June 2025
Comirnaty Spikevax	4.2.3.3.1	In vitro	30 June 2025
Comirnaty	4.2.3.3.2	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	12 August 2025
		Response to EMA request for supplementary information	

It should be noted that the above-listed documents have been published in parallel with the clinical data for Comirnaty and Spikevax that is made available on the clinical data publication website of EMA.[18]

III. **Additional considerations**

Under the present section, EMA would like to take this opportunity to provide some clarifications regarding the safety of the concerned COVID-19 vaccines.

[18] As also recalled at the outset of this letter, this information has been published on the clinical data publication website of EMA, which provides online access to clinical data for medicinal products for human use, including Comirnaty and Spikevax: https://clinicaldata.ema.europa.eu/web/cdphttps://clinicaldata.ema.europa.eu/web/cdp.

At the outset, it bears emphasising that the respective manufacturing processes for the concerned 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, 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 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.

One such test used by some researchers on the final product is the Qubit test. A recent study that looked at the Qubit test concluded that "*earlier published claims of 534-fold higher amounts of DNA impurities in vaccine mRNA products are not correct and a consequence of extraordinary high RNA and lipid concentrations. According to our data, gathered by applying different, orthogonal (different) methods, we provide evidence that the concentration of product-related DNA impurities in both approved mRNA vaccines, BNT162b2 (Comirnaty) and mRNA-1273 (Spikevax) coincide with the approved mRNA specifications*".[19]

In view of the above considerations, the "*severe drug safety concerns*" in respect of the concerned COVID-019 vaccines, which you cite in your correspondence of 8 July 2025, have not been substantiated.

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 to grant a marketing authorisation. In this respect, a watchful eye is maintained in respect of the medicinal products on the market and 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.

IV. Concluding remarks

By the present letter, EMA has provided additional explanations and clarifications concerning the handling of your request for access to documents pertaining to the CTD modules for Comirnaty and Spikevax and the mass public request, including the actions taken by the Agency in connection

[19] In this respect, see: Kaiser S, Kaiser S, Reis J, Marschalek R. Quantification of objective concentrations of DNA impurities in mRNA vaccines. Vaccine. 2025 March 21;55:127022. doi: 10.1016/j.vaccine.2025.127022. Epub ahead of print. PMID: 40120438.

with the requests in question. Further, we have also defined our position concerning the handling of your request of 17 February 2025 under Regulation (EC) No 1049/2001.

As mentioned at the outset of the letter, we remain committed to ensuring the transparency of our work, including the assessments performed by our scientific committees. The action taken to date in order to facilitate timely access to your request and the mass public request also demonstrates the strength of this continuing commitment.

We remain available for any further clarifications or information that could be helpful.

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