European Medicines Agency

Executive Director
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Access-to-Documents Department
Via email to AskEMAATD@ema.europa.eu

25th February 2025

Subject: Urgent Request for Transparency on Comirnaty/Spikevax Vaccine Safety: Disclosure of the Common Technical Document

Dear Executive Director Cooke,
Dear Ms Gavriilidou,
Dear Mr Guyodo,

The European Medicines Agency (EMA) has a legal duty to ensure that pharmaceutical products meet the highest standards of safety underpinned by rigorous scientific support — an objective that aligns with the purpose of this urgent request for transparency due to reliable, independent and confirmed evidence of alarming quality defects of Comirnaty and Spikevax.

In unison with individual citizens throughout the European Union that have submitted an identical request to disclose the Common Technical Document (CTD) for both Comirnaty and Spikevax, the undersigned formally request access to these data on behalf of our organization.

Our organization values safety and transparency. We believe that the primary aim of a regulatory authority is to ensure the highest standards of drug safety and quality without compromising public health. In this context, we reaffirm our commitment to maintaining an open dialogue with EMA and express our willingness to engage further, given our influence on the substantial number of individuals submitting or withdrawing requests to disclose the CTD of Comirnaty and Spikevax.

Moreover, Comirnaty and Spikevax have served as the most critical medical countermeasures against the COVID-19 pandemic. Their significance was the foundation for Regulation 2022/123, which mandates EMA to uphold maximum transparency regarding its regulatory actions related to medical countermeasures, specifically outlined in Recitals 38, 40, 48, and 49.

In light of the above, pursuant to Regulation (EC) No 1049/2001, the undersigned, on behalf of our organization, formally request the immediate and unredacted disclosure of the CTD modules for Comirnaty and Spikevax, along with substantial additional data regarding the

Critical Quality Attributes (CQAs). All documents must be provided in their most current and officially active version at the time of release.

Priority in disclosure should follow this ranking:

1.) qPCR Assay for residual DNA measurement, or any other methods applied to quantify residual DNA for Spikevax and Comirnaty as further outlined in Procedure EMEA/H/C/005735/II/0202, 29th February 2024, including full laboratory data from the 236-batches to validate the results submitted to EMA.

2.) CTD Module 2 and 3, particularly regarding CQA (specifications, acceptance criteria, control procedures and analytical results regarding RNA integrity, dsRNA content, residual DNA levels, RNA sequence identity, RNA concentration, bioburden, pH balance, 5 ′-CAP structure, and Poly(A) tail composition for Comirnaty and Spikevax. With regard to Comirnaty Modules 3.2.S.2-3.2.S.7, please be aware of the re-relase under ASK-257127 and ASK-112278.

3.) CTD Modules 4 and 5 for Comirnaty and Spikevax.

Evidence for the overriding public interest

This request is justified by an overriding public interest, substantiated by publicly available evidence indicating potential harm to human health.

In 2023, independent scientists provided irrefutable proof of the SV40 promoter/enhancer, revealing BioNTech's intentional concealment of critical safety data. BioNTech only acknowledged the presence of the SV40 promoter/enhancer in the manufacturing process when confronted with undeniable evidence, making this a clear case of regulatory deception.

EMA continues to deflect the mounting evidence of excessive levels of residual DNA in Comirnaty and Spikevax, relying on qPCR methods that are unsuitable for accurately quantifying total residual DNA content. The lack of transparency regarding these methodologies directly impairs independent verification and undermines regulatory accountability.

The potential health risks posed by residual DNA encapsulated in LNPs necessitate rigorous scrutiny, as the extent of associated risks including but not exclusively related to genomic integration remain inadequately assessed. Consequently, EMA's assertion that residual DNA levels in batches comply with regulatory thresholds (see EMEA/H/C/005735/II/0202) must be validated through full disclosure of BioNTech's and Moderna's qPCR methodology.

In light of the available evidence of excessive residual DNA levels, full disclosure under the overriding public interest principle is essential to ensure a transparent, independently verifiable control method for accurately quantifying and characterizing residual DNA. This is particularly crucial for regulatory procedures where exclusive competence lies with the European Commission, leaving Member States without jurisdiction. European Union law guarantees a right to oversight and transparency, which is especially relevant when national authorities lack competence, as is the case with the centralised authorisation procedure.

Pending case T-623/22, concerning Comirnaty's Specific Obligation Number 1 and CTD Module 3.2.S.3, is currently before the European Court for the unlawful withholding of CQA data by EMA and BioNTech under the pretext of Confidential Commercial Information (CCI). As these data are integral to regulatory safety assessments, they do not qualify for CCI protection and must be disclosed under the overriding public interest principle established in EU jurisprudence. Given the direct implications for public health and regulatory compliance, this case necessitates full transparency.

The undersigned, on behalf of our organisation, asserts the prevailing public interest in disclosure of theses documents, as the European Court's ruling will be instrumental in affirming that regulatory safety data, including CQA, outweigh alleged commercial confidentiality claims, which are, in any case, protected by patents and market authorizations. In C-588/21, the EU Court of Justice reaffirmed that the rule of law necessitates free access to EU legislative standards, enabling individuals to ascertain their rights and verify whether regulated products comply with EU obligations. Under the final clause of Art. 4 para. 2 of Reg 1049/2001, an overriding public interest mandates disclosure of essential information—particularly where drug safety is at stake.

In light of this judgment and the pending case against your agency, EMA is legally obliged to release the requested CTD data without delay under Art. 7 of Reg 1049/01. Continued withholding of this critical information would violate EU transparency law and erode public trust in regulatory oversight.

The overwhelming public interest in this matter is confirmed through the substantial number of access requests on this behalf submitted to your agency from countries throughout Europe as long as CCI protections are maintained for these critical data. The weight of evidence and the undeniable health risks to vaccine recipients demand immediate, full disclosure. Any further obstruction by EMA would not only constitute regulatory negligence but also a wilful violation of EU transparency laws.

The public has a right to access critical safety data, and any continued resistance to disclosure will only deepen concerns about regulatory integrity and accountability. We trust that EMA will act in accordance with its legal obligations and prioritize public health over corporate interests. Furthermore, establishing a publicly accessible database for released documents, similar to the Commission’s EASE platform, would greatly reduce the administrative burden on EMA and the constant invocation of a business continuity plan.

Please acknowledge receipt of this letter and provide the undersigned with an individual ASK number to the email address stated above.

Sincerely,

Signed by the supporting group or organization.