Transparency4Safety Initiative
Slovak Republic and Czech Republic

Ms Emer Cooke
Executive Director
European Medicines Agency

Copy:
European Ombudsman

Subject: Open letter – Transparency4Safety Initiative – report by Slovak and Czech experts on overriding public interest, request for access to CTD and urgent regulatory meeting with the EMA regarding Comirnaty, Spikevax and related mRNA products

Bratislava, June 8th, 2026

Dear Executive Director Cooke,

We address you with respect as physicians, scientists, and public health experts from Slovakia, the Czech Republic, and Austria.

The undersigned are part of the Transparency4Safety Initiative and support its requests, which have remained pending before the EMA since February 2025, for meaningful transparency, unredacted access to the relevant regulatory dossier, and a dedicated scientific dialogue on centrally authorised mRNA products, including Comirnaty and Spikevax.

In this context, we have recently held a scientific expert conference and adopted specific conclusions regarding unresolved issues concerning the quality of COVID-19 mRNA vaccines, batch safety, pharmacovigilance, access to regulatory and vaccination data, independent research on morbidity and mortality, and the need for scientific re-evaluation. These conclusions are hereby submitted to the EMA as a report of overriding public interest and as further scientific justification for disclosure, re-assessment, and regulatory action.

For legal clarity, each signatory formally adopts and submits the original Transparency4Safety request for access to documents as their own individual request under Regulation (EC) No 1049/2001. This request is made in the individual legal capacity of each signatory and must therefore be assessed as an exercise of participant-specific fundamental rights, rather than dismissed as a collective or mass submission.

Each signatory expressly invokes their individual and directly enforceable rights of access to Union documents under Article 15 TFEU, Article 42 of the Charter of Fundamental Rights of the European Union, and Regulation (EC) No 1049/2001, as well as the Union's obligation to ensure a high level of protection of human health under Article 168 TFEU and Article 35 of the Charter. We further invoke the precautionary principle as a binding principle of EU law, requiring timely, transparent, and preventive regulatory measures where scientifically plausible risks to human health have been raised and remain unresolved.

We request that our procedural rights be duly respected. We note with serious concern that since February 2025 the Transparency4Safety request has not been processed through a properly reasoned, legally compliant, and participant-specific access procedure. The limited or redacted materials that have so far been disclosed are insufficient for a scientifically reproducible assessment

of quality, safety, pharmacology, toxicology, clinical benefit-risk balance, and issues related to batch variability.

The undersigned therefore request the immediate and unredacted disclosure of the marketing authorisation dossiers and CTD modules for Comirnaty and Spikevax on the basis of overriding public interest in independent scientific verification and the protection of public health. Where necessary for the purposes of scientific re-evaluation, this request also extends to other mRNA vaccine products authorised within the European Union.

For legal certainty, we recall that the original request included the following:

1. qPCR testing for the measurement of residual DNA, or any other method used for quantification of residual DNA for Spikevax and Comirnaty, as specified in procedure EMEA/H/C/005735/II/0202 of 29 February 2024, including full laboratory data from 236 batches submitted to the EMA;
2. CTD Modules 2 and 3, particularly in relation to Critical Quality Attributes (CQAs), including specifications, acceptance criteria, control procedures, and analytical results concerning RNA integrity, dsRNA content, residual DNA levels, RNA sequence identity, RNA concentration, biological burden, pH balance, 5' cap structure, and poly(A) tail composition for Comirnaty and Spikevax;
3. With respect to Comirnaty, Modules 3.2.S.2–3.2.S.7, including previously redacted documents under ASK-257127 and ASK-112278;
4. CTD Modules 4 and 5 for Comirnaty and Spikevax, insofar as they are necessary for independent scientific assessment of quality, safety, pharmacology, toxicology, and clinical benefit-risk evaluation.

The conference conclusions set out below are submitted as a specific report of overriding public interest within the framework of the Transparency4Safety Initiative. In the specific case of the undersigned experts, they demonstrate why the requested documents must be disclosed in an unredacted form: the exception of overriding public interest shall apply, because independent scientific verification, reproducibility, and the protection of public health are not possible on the basis of redacted CTD materials or selectively disclosed regulatory summaries.

Reports of overriding public interest submitted within the Transparency4Safety framework constitute the evidentiary basis for applying this exception. Our conference conclusions demonstrate specific scientific concerns requiring measures at both national and European level, and translate them into corresponding implications for the EMA and its committees. They therefore support the existing request for disclosure of CTD documentation, as well as further requests for regulatory data, pharmacovigilance evidence, and scientific re-evaluation. Transparency is essential for any credible independent re-evaluation of Comirnaty, Spikevax, and related mRNA products.

Independent batch quality control

At the national level, the conference calls for immediate independent quality control of batches of mRNA vaccines used in the Slovak Republic and the Czech Republic. This control must include analysis of composition, detection of undeclared micro- and nano-particles including DNA, and assessment of morphological and chemical stability. It must be performed using validated, reproducible, and mutually independent analytical methods capable of detecting biologically relevant residual materials, including longer DNA fragments.

The analysis by the Slovak Academy of Sciences cannot be considered conclusive evidence of vaccine safety, insofar as fundamental methodological criticism remains unresolved, including questions concerning the ability to detect longer biologically significant DNA fragments, validation of extraction efficiency, and the absence of multiple independent analytical methods.

At the EMA level, these unresolved analytical issues require disclosure of the underlying regulatory, manufacturing, and quality control data. The EMA, CHMP, and PRAC must assess whether the relevant control strategy, specifications, analytical methods, and batch release data were sufficient to exclude clinically relevant risks arising from residual DNA, undeclared particulate matter, chemical instability, or batch variability.

Batch-level transparency and access to vaccination data

At the national level, the conference calls for the publication of anonymised vaccination and outcome data enabling independent assessment by year of birth, sex, month and year of vaccination, vaccine product, batch, month of death, and cause of death, in compliance with applicable data protection rules. Furthermore, it calls for the publication of suspected adverse events by date of occurrence, vaccine type, batch, and date of reporting, the publication of incidence of adverse events by batch, and the restoration of access to vaccination records, including COVID Pass data for patients and physicians.

These national requirements are necessary for the identification of persons exposed to higher-risk batches, for targeting diagnostic and early therapeutic interventions, and for identifying batches for which no serious adverse events have been reported, if the data support such reassurance.

At the EMA level, this implies that pharmacovigilance and quality signals linked to batches must not remain fragmented at national level. The EMA and PRAC must require, aggregate, and evaluate data on batch-related adverse events, quality deviations, manufacturing changes, and exposure data across Member States. If existing EMA guidelines or practice do not ensure detection of batch-level signals and publicly verifiable scientific assessment, the EMA must explain this gap and remedy it through updated pharmacovigilance and transparency requirements.

Active safety monitoring and regulatory oversight

At the national level, passive pharmacovigilance is insufficient. Conference participants call for systematic long-term monitoring of effectiveness and safety, active monitoring of selected vaccinated cohorts, structured investigation of adverse events, assessment of individuals exposed to higher-risk batches, and physical inspections by the State Institute for Drug Control and other competent authorities.

National authorities must be able to link the exact vaccine product and batch administered to each patient with suspected adverse events, relevant health outcomes, and mortality data. Regulatory oversight must include verification of batch documentation, storage and distribution chains, reported quality deviations, and patterns of adverse events by batch.

At EMA level, PRAC must assess whether passive reporting alone is adequate for products administered at population scale where batch-specific and quality concerns have been raised. EMA and relevant committees must require full data on quality, manufacturing, and pharmacovigilance by batch, evaluate the need for additional risk minimisation or signal-detection procedures, and make relevant CTD and pharmacovigilance evidence available in a form enabling independent verification.

Independent research on morbidity and mortality

At the national level, independent studies of morbidity and mortality in temporal association with COVID-19 vaccination are required, including comparison of vaccinated and unvaccinated groups. Data from the Slovak population for the years 2020 to 2025 should be analysed according to vaccination status, vaccine type, time of administration, and exposure to batch. Anonymised individual data must be made available to qualified independent researchers under appropriate protective conditions.

At EMA level, these findings and datasets are directly relevant for periodic benefit–risk assessment, signal detection, and regulatory reassessment. EMA and PRAC must specify which epidemiological, pharmacovigilance, and real-world data are required from Member States for reassessment of the benefit–risk balance, and ensure that such evidence is taken into account in any procedure under Article 20 or related pharmacovigilance assessment.

Preventive measures and clinical monitoring

At the national level, the conference calls for programmes for individuals exposed to higher-risk batches and for individuals with health problems occurring in temporal association with COVID-19 vaccination. Patients should be informed of their relevant level of risk. In preventive check-ups and general medical practice, attention should be paid to symptoms and diseases occurring in temporal association with vaccination.

If medically indicated, vaccinated individuals should have access once or twice per year to examinations of potentially relevant risk factors, including persistent S-protein in serum and defined inflammatory, haemocoagulation, immunological, hormonal, and oncological parameters. These may include serum S-protein, anti-PF4 antibodies, D-dimers, platelet count, cardiac markers (troponins, natriuretic peptide NT-proBNP, screening measurement of arterial elasticity), CRP, IL-6, ferritin, creatinine, urea, fasting glucose, specific IgG4, endocrine or pituitary parameters, and selected tumour markers.

At EMA level, PRAC and CHMP must assess whether product information, risk management plans, post-authorisation safety studies, and pharmacovigilance guidelines adequately take into account persistent antigen expression, and immunological, haemocoagulation, inflammatory, endocrine, or batch-related concerns. If such monitoring is absent or insufficient, EMA must request appropriate updates to risk management, post-authorisation studies, safety communication, and, where legally required by circumstances, temporary risk minimisation measures.

Institutional, regulatory and legal implications

At the national level, the conference supports the re-establishment of national institutes for sera and vaccines in order to strengthen independent control capacity, quality assessment, and resilience of public health. It also calls for a review of compliance with applicable legislation and regulatory procedures, including pharmacovigilance, manufacturing controls, and transparency obligations. If errors or regulatory deficiencies are confirmed, mechanisms for compensation for defective batches and affected patients must be examined.

At EMA level, the relevant question is whether the centralised authorisation and post-authorisation control system has sufficiently ensured independent verification of product quality and safety. EMA and relevant committees must assess whether the regulatory dossier contains sufficient evidence on batch consistency, impurity profile, residual DNA, RNA integrity, parameters related

to LNPs, validation of analytical methods, and clinical benefit–risk balance. Any identified deficiencies must lead to appropriate regulatory actions, including under Article 20 of Regulation (EC) No. 726/2004 and Article 116 of Directive 2001/83/EC, where legal conditions are met.

Public health context and open scientific discussion

At the national level, future emergency measures must reflect the actual epidemiological situation, clinical burden of disease, and principles of proportionality. Broader public health conclusions of the conference are stated insofar as they support evidence-based decision-making, proportionality, and legal accountability.

At EMA level, public trust depends on transparent regulatory reasoning, lawful access to documents, and open scientific scrutiny. EMA should therefore ensure that the special meeting allows substantive discussion with relevant committees and product responsible persons, and that scientific disagreements on unresolved questions of quality and safety are addressed through evidence and disclosure, rather than procedural exclusion or excessive redaction.

Procedure under Article 20 and special meeting with EMA

Unresolved questions of quality, safety, and pharmacovigilance set out in this submission require immediate regulatory reassessment. EMA is therefore requested to initiate without delay a procedure under Article 20 of Regulation (EC) No. 726/2004 and ensure measures under Article 116 of Directive 2001/83/EC as necessary regulatory steps, including suspension or withdrawal if legal conditions are met.

The special EMA meeting proposed within the Transparency4Safety initiative must be convened without delay with participation of relevant EMA authorities, responsible product experts, and scientific committees, and its proceedings must be livestreamed or otherwise made accessible to applicants and the interested public.

The undersigned request to be invited as experts in their respective fields. They are prepared to present their analyses, additional evidence, and thematic expert opinions, and to discuss these issues with relevant EMA committees, product responsible persons, and competent scientific authorities.

Accordingly, EMA is respectfully requested to:

1. Make available priority CTD documents (all versions) for Comirnaty, Spikevax, and related mRNA-LNP products in unredacted form under Regulation (EC) No. 1049/2001 and on the basis of the public-interest override for independent scientific verification;
2. Enable independent re-analysis of batch quality, composition, and stability, including residual DNA, undeclared micro- and nanoparticles, adverse event data by batch, and pharmacovigilance signals;
3. Require or support access to anonymised vaccination, batch, morbidity, mortality, and adverse event data necessary for independent scientific analysis;
4. Initiate a procedure under Article 20 of Regulation (EC) No. 726/2004 and ensure measures under Article 116 of Directive 2001/83/EC, including suspension or withdrawal where legal conditions are met;
5. Clarify the regulatory implications for Comirnaty, Spikevax, and other centrally authorised mRNA-LNP products against infectious diseases;
6. Accept that the undersigned scientists may be nominated by the Transparency4Safety initiative as lead representatives for a meeting with EMA and may submit further thematic

expert opinions, evidence, and scientific submissions concerning mRNA vaccine technology.

We would appreciate your timely response.

Yours sincerely,

Prof. MUDr. Viliam Fischer, CSc., FICS, Bratislava
Prof. MUDr. Štefan Hrušovský, CSc., Bratislava
Prof. RNDr. Jaroslav Turánek, CSc., DSc., Brno
MUDr. Peter Lipták, Bratislava
RNDr. Tomáš Fürst, PhD., Olomouc
MUDr. Martin Jančuška, Vienna
Prof. MUDr. Jan Žaloudík, CSc., Brno
MUDr. Margaréta Černáková, Bratislava
MUDr. Soňa Peková, PhD., Hradec Králové