EN
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Answer given by Mr Várhelyi
on behalf of the European Commission
(14.2.2025)

1. The European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) is responsible for monitoring the safety of all authorised medicinal products in the EU, including COVID-19 vaccines. The EU's pharmacovigilance system was further strengthened during the COVID-19 pandemic with enhanced real-world safety monitoring. The PRAC may establish contacts on an advisory basis, with representatives of patient organisations and relevant health-care professionals' associations[1]. Given this framework, a new task force is unnecessary.

2. The Commission acknowledges the importance of addressing concerns about COVID-19 vaccines and fostering trust through ongoing safety monitoring and transparent communication[2]. EMA and national authorities rigorously monitor vaccine safety, and rare side effects are published with updates to product information[3] where necessary to mitigate risks. Healthcare access, including diagnosis and treatment, remains the responsibility of Member States. The Commission supports them by ensuring healthcare professionals and patients have access to up-to-date safety information via public reports.

3. The COVID-19 vaccines contracts have not changed the EU liability rules and patients' rights are fully preserved in line with the EU Product Liability Directive[4]. The contracts for the purchase of COVID-19-vaccines contain clauses that outline in detail the obligations and responsibilities of the parties involved regarding potential losses, damages, liabilities, or legal claims arising from the COVID-19 vaccines. However, the application of such clauses falls under the remit of the Member States as they have purchased the vaccines.

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[1] https://www.ema.europa.eu/en/documents/other/prac-rules-procedure_en.pdf
[2] European public assessment reports: https://www.ema.europa.eu/en/medicines/what-we-publish-medicines-when/european-public-assessment-reports-background-context
Periodic safety update reports (PSURs): https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/periodic-safety-update-reports-psurs
[3] https://ec.europa.eu/health/documents/community-register/html/index_en.htm
[4] Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC OJ L, 2024/2853, 18.11.2024, ELI: http://data.europa.eu/eli/dir/2024/2853/oj