

(English version)

**Question for written answer E-002698/24
to the Commission
Anders Vistisen (P/E)
(29 November 2024)**

Subject: Failure to acknowledge vaccine-related harm is creating stigmatisation — urgent need for EU action to ensure research and support for those affected

1. Will the Commission set up a task force — possibly in cooperation with the Covid Vaccine Injury Alliance ⁽¹⁾ — in order to identify the challenges facing the group of patients concerned and find solutions?
2. Will the Commission ensure that all EU citizens who have suffered Covid-vaccine-related harm have access to systematic diagnosis and effective treatment, and will it publicly acknowledge citizens who have been harmed as a result of Covid vaccination in order to put a stop to stigmatisation?
3. Will the Commission undertake to establish fair and comprehensive financial compensation for EU citizens who have been harmed as a result of Covid vaccination?

Submitted: 29.11.2024

**Question for written answer E-000019/25
to the Commission
Virginie Joron (P/E)
(7 January 2025)**

Subject: Stigma created by Commission's refusal to recognise harm caused by COVID-19 vaccines

1. Will the Commission set up a working group, potentially in collaboration with the Covid Vaccine Injury Alliance ⁽¹⁾, to identify the challenges facing the patient group concerned and find solutions?
2. Will it ensure that all EU citizens who have been harmed by the COVID-19 vaccines have access to systematic diagnosis and effective treatment, and will it publicly recognise the harm suffered by citizens as a result of COVID-19 vaccination to put an end to the stigma around it?
3. Will it commit to introducing fair and full financial compensation for EU citizens harmed by COVID-19 vaccines?

Submitted: 7.1.2025

**Joint answer given by Mr Várhelyi on behalf of the European Commission
(14 February 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 healthcare 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.

¹ <https://www.covidvaccineinjuryalliance.org/>

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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

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.

⁽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>