

(English version)

**Question for written answer E-002597/24  
to the Commission  
Gerald Hauser (PFE)  
(20 November 2024)**

*Subject:* Largest autopsy-based study on COVID-19 vaccines

On 17 November 2024, the specialist journal ‘Science, Public Health Policy and the Law’ published on its website the largest autopsy-based study on COVID-19 vaccines to date <sup>(1)</sup>. The study provides robust evidence that COVID-19 vaccines can be linked to death.

The study, entitled ‘A Systematic Review of Autopsy Findings in Deaths After COVID-19 Vaccination’, concludes that the consistency seen among cases in this review with known COVID-19 vaccine mechanisms of injury and death, coupled with autopsy confirmation by physician adjudication, suggests there is a high likelihood of a causal link between COVID-19 vaccines and death. It also states that further research would be needed to clarify these findings.

1. Are deaths occurring shortly after COVID-19 vaccination now being investigated across the EU?
2. What does the Commission intend to do as a result of these scientific findings?
3. Are people who have been vaccinated in the past and those who will be vaccinated in the future actively informed of this risk?

Submitted: 20.11.2024

**Answer given by Mr Várhelyi on behalf of the European Commission  
(10 February 2025)**

1. As the Commission noted in its reply to Question E-003117/2023 <sup>(1)</sup>, ‘the European Medicines Agency (EMA) and national authorities evaluate data on reported events in EudraVigilance <sup>(2)</sup> to determine if there is any signal indicating causality and take action as appropriate’. EMA and national authorities closely monitor emerging data and will take regulatory action if new evidence indicates any causal relationship.
2. The Commission relies on EMA to continuously monitor the COVID-19 vaccine safety assessing all available data, including EudraVigilance reports, scientific literature, and studies <sup>(3)</sup>. EMA has reviewed the study mentioned in the Honourable Member's letter and concluded that, given the methodological limitations of the study- which was withdrawn from a scientific journal because of serious concerns about its quality- considers no action necessary at this stage.
3. The Commission considers safety a core requirement for all vaccines. COVID-19 vaccines used in the EU have undergone EMA's rigorous scientific assessment. Information on risks, including rare side effects, are publicly available in resources such as product information <sup>(4)</sup>, the European Public Assessment Reports <sup>(5)</sup>, and periodic safety update reports (PSURs) <sup>(6)</sup>, which are regularly updated to keep healthcare professionals and patients informed. When necessary to ensure vaccine safety regulatory actions are taken in accordance with the applicable legislation.

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<sup>1</sup> <https://publichealthpolicyjournal.com/a-systematic-review-of-autopsy-findings-in-deaths-after-covid-19-vaccination/>

<sup>(1)</sup> [https://www.europarl.europa.eu/doceo/document/E-9-2023-003117-ASW\\_EN.html](https://www.europarl.europa.eu/doceo/document/E-9-2023-003117-ASW_EN.html)

<sup>(2)</sup> <https://www.ema.europa.eu/en/human-regulatory-overview/research-development/pharmacovigilance-research-development/eudravigilance>

<sup>(3)</sup> <https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/pharmacovigilance-marketing-authorisation/risk-management/risk-management-plans>

<sup>(4)</sup> [https://ec.europa.eu/health/documents/community-register/html/index\\_en.htm](https://ec.europa.eu/health/documents/community-register/html/index_en.htm)

<sup>(5)</sup> <https://www.ema.europa.eu/en/medicines/what-we-publish-medicines-when/european-public-assessment-reports-background-context>

<sup>(6)</sup> <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/periodic-safety-update-reports-psurs>