

(English version)

**Question for written answer E-002145/24
to the Commission
Gerald Hauser (Pfe)
(17 October 2024)**

Subject: EU citizens want a stocktake of the COVID-19 pandemic

Weekly magazine *Die Weltwoche* has disclosed the alarming results of a German survey on the COVID-19 vaccine: 19% of the vaccinated experienced side-effects; 40% of respondents are calling for a committee of inquiry and 29% are in favour of judicial investigations ⁽¹⁾. To comply with the people's calls for a stocktake and legal consequences, a committee of inquiry would need to be set up at EU level to look into the vaccines and their side-effects. The findings of this committee would then need to be put to judicial review.

1. Does the Commission intend to give the people what they want and set up such a committee at EU level?
2. Will it comply with EU citizens' calls for a judicial review of the COVID-19 crisis, the procurement of COVID-19 medicines, vaccines and other related material, and the information given on side-effects?

Submitted: 17.10.2024

**Answer given by Mr Várhelyi on behalf of the European Commission
(20 January 2025)**

The European Medicines Agency (EMA) already has a dedicated committee, the Pharmacovigilance Risk Assessment Committee (PRAC) ⁽¹⁾, responsible for monitoring the safety of all authorised medicinal products in the EU, including COVID-19 vaccines.

PRAC conducts robust scientific assessments and monitors potential risks to ensure the safety of medicines, updating product information as soon as new evidence becomes available.

The EU pharmacovigilance system is one of the most advanced in the world and was further strengthened during the COVID-19 pandemic, particularly through enhanced real-world monitoring of vaccine safety. Given the existing framework, the establishment of an additional committee would not provide added value.

The Commission listens attentively to the concerns and calls of EU citizens. However, it is important to note that the authorisation and oversight of COVID-19 vaccines authorised at Union level are based on rigorous scientific assessments by the EMA.

Safety monitoring is continuous, with the EMA and Member States working together to detect and address potential risks as early as possible.

The primary responsibility for the safety of an authorised product lies with the marketing authorisation holder. This includes monitoring adverse reaction reports and ensuring that the benefit-risk balance remains positive.

¹ <https://weltwoche.ch/daily/umfrage-zur-corona-impfung-untermauert-verdacht-impfnebenwirkungen-bei-19-prozent-der-geimpften-40-prozent-wollen-untersuchungsausschuss-29-prozent-sind-fuer-juristische-ermittlungen/>

⁽¹⁾ <https://www.ema.europa.eu/en/committees/pharmacovigilance-risk-assessment-committee-prac#:~:text=The%20Pharmacovigilance%20Risk%20Assessment%20Committee%20%28PRAC%29%20is%20the,agendas%2C%20minutes%20and%20highlights%20of%20its%20plenary%20meetings>