

(English version)

**Question for written answer E-003631/25
to the Commission
Christine Anderson (ESN)
(18 September 2025)**

Subject: Whether EU authorities possessed but did not publish evidence of myocarditis risk before July 2021, when product information was updated

A US Senate report published on 21 May 2025 alleges that federal health agencies had knowledge from as early as February 2021 of increased myocarditis risk following mRNA COVID-19 injections, especially in young males, but did not communicate this risk until late June 2021, when the US Food and Drug Association updated prescribing information and vaccine fact sheets to include myocarditis and pericarditis warnings ⁽¹⁾.

In July 2021, the European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee concluded that there was a 'possible link' between the mRNA vaccines Comirnaty and Spikevax and very rare cases of myocarditis and pericarditis, leading to updates in product information and communications to healthcare professionals. Prior to this, independent studies, including a large Nordic cohort analysis, had also flagged an elevated risk in young men.

Can the Commission clarify the following:

1. Did the EMA, national competent authorities or the Commission itself have in their possession evidence or internal analyses indicating an increased risk of myocarditis or pericarditis prior to July 2021?
2. Were any draft safety communications, alerts or professional advisories on myocarditis or pericarditis considered or prepared before July 2021, either by the EMA or national authorities?
3. Did the Commission, through its representatives on the relevant committees or internal briefings, have knowledge that such risks or drafts existed prior to their first public communication in July 2021?

Submitted: 18.9.2025

**Answer given by Mr Várhelyi on behalf of the European Commission
(11 November 2025)**

In March 2021, the European Medicines Agency (EMA) was made aware, through report of the Comirnaty marketing authorisation holder, of cases of myocarditis reported in Israel, where the vaccination campaign was more advanced than in the EU. The first cases of myocarditis and pericarditis occurring in the EU/European Economy Area were reported to the EMA in the March and April 2021 through monthly safety reports for Spikevax and Comirnaty, respectively.

Based on these first reportings, the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) requested the marketing authorisation holders to provide a cumulative review on cases of myocarditis and pericarditis to be assessed.

The EMA communicated about this emerging safety issue at the different phases of its assessment. When first measures were taken in early May 2021 through both the EMA's PRAC highlights ⁽¹⁾, and in the monthly safety updates for the public of the same month ⁽²⁾.

The EMA issued further communications in June 2021 ⁽³⁾, and then in July 2021 when the evaluation ended and the PRAC recommended listing myocarditis and pericarditis as new side effects in the product information for these vaccines, together with a warning to raise awareness among healthcare professionals and people taking these vaccines ⁽⁴⁾.

¹ ¹US Senate Permanent Subcommittee on Investigations 'Failure to Warn: How Federal Health Agencies Downplayed the Risk of Myocarditis and Other Adverse Events Following COVID-19 Vaccination', 21 May 2021, <https://www.hsgac.senate.gov/wp-content/uploads/2025.05.21-PSI-Majority-Staff-Interim-Report-Failure-to-Warn.pdf>.

⁽¹⁾ <https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-3-6-may-2021>.

⁽²⁾ https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccine-safety-update-comirnaty-11-may-2021_en.pdf.

https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccine-safety-update-spikevax-previously-covid-19-vaccine-moderna-11-may-2021_en.pdf.

⁽³⁾ <https://www.ema.europa.eu/en/news/covid-19-vaccines-update-ongoing-evaluation-myocarditis-pericarditis>.

⁽⁴⁾ <https://www.ema.europa.eu/en/news/comirnaty-spikevax-possible-link-very-rare-cases-myocarditis-pericarditis>.