

(English version)

**Question for written answer E-001055/26
to the Commission
Christine Anderson (ESN)
(13 March 2026)**

Subject: Minutes of extraordinary PRAC meetings on COVID-19 vaccines

According to information provided by the German Federal Government in response to a parliamentary question (reference number 2/531, February 2026), special meetings of the European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) were held on 18 December 2020 (on Comirnaty), on 4 January 2021 (on Spikevax) and on 22 January 2021 (on Vaxzevria) including the review of the respective risk-management plans for COVID-19 vaccines.

1. What specific documents — e.g. agendas, minutes, assessment reports, memoranda on decisions or other meeting documents — exist relating to the PRAC extraordinary meetings of 18 December 2020, 4 January 2021 and 22 January 2021?
2. Where are these documents archived, and which institution (EMA, Commission or other) is responsible for their storage and management in each case?
3. Are these documents available in full, or, to the Commission's knowledge, have any individual minutes, reports or other documents relating to the aforementioned meetings gone missing?

Submitted: 13.3.2026

**Answer given by Mr Várhelyi on behalf of the European Commission
(4 May 2026)**

The Commission would like to inform the Honourable Member that both EU citizens and healthcare professionals receive timely updates on all scientific recommendations taken by the European Medicines Agency (EMA).

Following each meeting of the EMA's safety committee (Pharmacovigilance Risk Assessment Committee — PRAC ⁽¹⁾), the key outcomes are communicated through the PRAC highlights ⁽²⁾.

Furthermore, during the pandemic, the EMA implemented additional measures for COVID-19 medicinal products to maximise the transparency of its regulatory activities related to COVID-19 medicines ⁽³⁾.

Furthermore, all three extraordinary PRAC meetings (18 December 2020, 4 January 2021 and 22 January 2021) were convened to enable the PRAC to provide advice on the Risk Management Plans (RMPs) for the respective vaccines prior the Committee for Medicinal Products for Human Use (CHMP) plenary meeting on the vaccines marketing authorisation applications aiming at issuing a scientific opinion.

The outcome (minutes) of these extraordinary PRAC meetings were subsequently incorporated into the minutes for the following PRAC plenaries, which are publicly available ⁽⁴⁾, ⁽⁵⁾.

Additionally, the PRAC recommendations to the CHMP on the RMP are also included in the marketing authorisation assessment reports.

They are therefore reflected in the respective European public assessment reports, in particular in the assessment reports for Vaxzevria ⁽⁶⁾, ⁽⁷⁾ and Spikevax ⁽⁸⁾, ⁽⁹⁾.

The PRAC committee operates under EMA's responsibility.

⁽¹⁾ <https://www.ema.europa.eu/en/committees/pharmacovigilance-risk-assessment-committee-prac>.

⁽²⁾ <https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-9-12-march-2026>.

⁽³⁾ <https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/coronavirus-disease-covid-19/covid-19-medicines/transparency-exceptional-measures-covid-19-medicines>.

⁽⁴⁾ https://www.ema.europa.eu/en/documents/minutes/minutes-prac-meeting-23-26-november-2020_en.pdf.

⁽⁵⁾ https://www.ema.europa.eu/en/documents/minutes/minutes-prac-meeting-11-14-january-2021_en.pdf.

⁽⁶⁾ <https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria>.

⁽⁷⁾ https://www.ema.europa.eu/en/documents/assessment-report/vaxzevria-previously-covid-19-vaccine-astrazeneca-epar-public-assessment-report_en.pdf.

⁽⁸⁾ <https://www.ema.europa.eu/en/medicines/human/EPAR/spikevax>.

⁽⁹⁾ https://www.ema.europa.eu/en/documents/assessment-report/spikevax-previously-covid-19-vaccine-moderna-epar-public-assessment-report_en.pdf.