

(English version)

**Question for written answer E-001675/25
to the Commission
Gerald Hauser (Pfe)
(25 April 2025)**

Subject: Liver damage as a side effect of COVID-19 vaccination

Scientific publications document cases of liver damage following vaccination against COVID-19, including immune-mediated hepatitis, acute liver cell injury and liver impairment in transplant patients. Here are a few examples:

- Liver injury following SARS-CoV-2 vaccination: A multicenter case series ⁽¹⁾
- Liver injury after SARS-CoV-2 vaccination: Features of immune-mediated hepatitis, role of corticosteroid therapy and outcome ⁽²⁾
- Histological and serological features of acute liver injury after SARS-CoV-2 vaccination ⁽³⁾
- Risk of acute liver injury following the mRNA (BNT162b2) and inactivated (CoronaVac) COVID-19 vaccines ⁽⁴⁾
- Severe de novo liver injury after Moderna vaccination — not always autoimmune hepatitis ⁽⁵⁾

Not only can liver damage be caused by mRNA vaccination, but the vaccines also have a wide range of other side effects.

1. In hindsight, what does the Commission make of the scientific diligence shown in authorising the mRNA vaccines in view of the wide range of side effects they have?
2. Are any investigations currently being carried out by the Commission or subordinate EU authorities into the safety of mRNA vaccines?
3. Were potential hepatotoxicity, genotoxicity, cardiotoxic effects, immunotoxicity, neurotoxic effects and possible long-term effects on liver function and genetic integrity investigated when the mRNA vaccines were authorised?

Submitted: 25.4.2025

**Answer given by Mr Várhelyi on behalf of the European Commission
(8 July 2025)**

The authorisation of COVID-19 vaccines is based on a thorough scientific assessment by the European Medicines Agency (EMA) about the vaccine quality, safety, and efficacy ⁽¹⁾.

Initially, COVID-19 vaccines were granted a conditional marketing authorisation (CMA) ⁽²⁾, a pathway used to expedite access to medicines addressing unmet needs, particularly during public health emergencies. A CMA requires the marketing authorisation holder to provide further data post-authorisation to confirm the benefit-risk balance.

Following authorisation, all medicinal products authorised in the EU, are subject to continuous and rigorous safety monitoring, which was further enhanced for COVID-19 vaccines.

The EU pharmacovigilance system detects, assesses, and addresses potential side effects ⁽³⁾, with the EMA's safety Committee (PRAC) ⁽⁴⁾ analysing new risks that may emerge from various sources, including clinical practice, clinical studies, and medical literature.

Current scientific data from over 13 billion COVID-19 vaccine doses administered worldwide shows a very good safety profile. Most adverse drug reactions are mild and short-lived.

¹ <https://pubmed.ncbi.nlm.nih.gov/34339763/>

² <https://pubmed.ncbi.nlm.nih.gov/35567545/>

³ <https://pubmed.ncbi.nlm.nih.gov/36440259/>

⁴ <https://pubmed.ncbi.nlm.nih.gov/35817224/>

⁵ <https://pubmed.ncbi.nlm.nih.gov/35439566/>

⁽¹⁾ Approval of vaccines in the EU: <https://vaccination-info.europa.eu/en/about-vaccines/approval-vaccines-eu>; COVID-19 vaccines: development, evaluation, approval and monitoring: <https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/coronavirus-disease-covid-19/covid-19-public-health-emergency-international-concern-2020-23/covid-19-vaccines-development-evaluation-approval-monitoring>.

⁽²⁾ Conditional marketing authorisation: <https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/conditional-marketing-authorisation>.

⁽³⁾ Pharmacovigilance: Overview: <https://www.ema.europa.eu/en/human-regulatory-overview/pharmacovigilance-overview>.

⁽⁴⁾ Pharmacovigilance Risk Assessment Committee (PRAC): <https://www.ema.europa.eu/en/committees/pharmacovigilance-risk-assessment-committee-prac>.

Serious effects are very rare ⁽⁵⁾ and thoroughly assessed. In 2022, PRAC concluded that there was no evidence supporting a causal link between mRNA COVID-19 vaccines and AIH ⁽⁶⁾.

Each vaccine has published product information and an assessment report detailing all examined aspects ⁽⁷⁾. If a reasonable possibility exists that a side effect is linked to the vaccine, it is included in the product information to ensure transparency for healthcare professionals and patients.

⁽⁵⁾ Safety of COVID-19 vaccines: <https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/coronavirus-disease-covid-19/covid-19-medicines/safety-covid-19-vaccines#suspected-side-effects-13834>.

⁽⁶⁾ Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 4-7 April 2022: <https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-4-7-april-2022>.

⁽⁷⁾ COVID-19 medicines: <https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/coronavirus-disease-covid-19/covid-19-medicines>.