

(English version)

Question for written answer E-001495/25
to the Commission
Gerald Hauser (P/E)
(10 April 2025)

Subject: Liability exemptions in EU vaccine contracts

On 11 November 2020, the Commission concluded contracts with Pfizer/Biontech and other manufacturers for the supply of COVID-19 vaccines, even before their authorisation. Already during the contract negotiations, it came to light that the manufacturers were demanding an extensive liability exemption in the event of unexpected side effects. However, key passages on liability were redacted in the contracts published by the Commission. Unredacted versions have now become public. Point I.12 of the contract with Pfizer/Biontech states that the vaccines would be administered under epidemic conditions and under the sole responsibility of the participating Member States. The latter undertook to accept full liability and to indemnify manufacturers against any damages or legal costs arising from the consequences of vaccination.

1. Why were such far-reaching commitments to assume liability made on behalf of the manufacturers without full transparency vis-à-vis the European Parliament and the public?
2. What is the Commission's risk-benefit assessment of mRNA vaccines?
3. Why were extensive liability exemptions in favour of vaccine manufacturers agreed at all?

Submitted: 10.4.2025

Answer given by Ms Lahbib on behalf of the European Commission
(23 June 2025)

The (Advanced) Purchase Agreements for the supply of COVID-19 vaccines to the Member States were concluded in full transparency with the Member States. Negotiations were carried out by a Joint Negotiation Team that consisted of representatives of the Commission and of several Member States.

This team reported regularly to a Vaccines Steering Board co-chaired by the Commission and a Participating Member State, which provided guidance throughout the process.

The Commission has provided information to the Parliament on a continuous basis, in line with its Treaty obligations and the framework Agreement on relations between the two institutions ⁽¹⁾.

All mRNA vaccines that receive a marketing authorisation are based on a thorough review by the European Medicine Agency (EMA), of clinical evidence confirming a favourable benefit-risk profile.

Adapted versions are also approved based on data showing their ability to induce an immune response that can predict clinical efficacy and safety.

The safety profile of all medicinal products authorised in the EU, including mRNA vaccines, is subject to continuous monitoring. There is a robust pharmacovigilance system established in the EU to detect, assess, and address potential side effects ⁽²⁾.

The Commission and Member States considered early introduction of the vaccine to be in the interest of public health. Member States were therefore willing to reduce manufacturers' risks linked to liability for adverse effects ⁽³⁾.

A citizen who has suffered adverse effects from one of the COVID-19 vaccines purchased under the contracts can claim damages against the manufacturer of the vaccine ⁽⁴⁾.

⁽¹⁾ The Commission has pro-actively published redacted versions of the contracts concluded with the vaccine producers on its website.

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

⁽³⁾ This was intended as a risk sharing principle in the vaccine strategy.

⁽⁴⁾ If the claim is successful, the Member State that administered the vaccine can, under certain conditions, be responsible for compensating the injured party and paying the vaccine manufacturer's legal costs (indemnification).