

(English version)

**Question for written answer E-001388/26
to the Commission
Gerald Hauser (Pfe)
(7 April 2026)**

Subject: COVID-19 vaccines as nanomedicine

The abstract of the study ‘Feeding Next-Generation Nanomedicines to Europe: Regulatory and Quality Challenges’ ⁽¹⁾ states that, over the past fifty years, many innovative nanomedicines have been developed and put on the market.

A globally uniform regulatory definition is still lacking; generally, the term is taken to mean medicinal products developed or manufactured using nanotechnology.

In 2006, the European Medicines Agency (EMA) described nanomedicine as a use of nanotechnology for diagnosing, treating or preventing diseases based on specific physical, chemical and biological properties at the nanometer scale.

Unlike with conventional medicinal products, the behaviour of nanomedicines within the body is determined primarily by the nanosystem-specific factors such as size, shape, and surface area. These properties influence uptake, distribution and possible side effects. Owing to their small size, they can penetrate deep into tissue and interact with cells, which can also pose risks that are difficult to predict.

1. Were COVID-19 vaccines using nanotechnology classified as nanomedicines and, if not, why not?
2. Did these COVID-19 vaccines undergo all the tests required for nanomedicines?
3. Have COVID-19 vaccines that are nanomedicines — and for which not all the tests required for nanomedicines were carried out — been withdrawn from the market?

Submitted: 7.4.2026

**Answer given by Mr Várhelyi on behalf of the European Commission
(22 June 2026)**

The mRNA COVID-19 vaccines Spikevax, Comirnaty and Kostaive are considered nanotechnology-based medicinal products as they contain lipid nanoparticles (LNPs).

These vaccines were developed and tested in accordance with all EU required regulatory standards for quality, safety and efficacy.

As noted in the European Medicines Agency (EMA)’s EU-IN Horizon Scanning Report ‘Nanotechnology-based medicinal products for human use’ from 2025 ⁽²⁾, LNPs have been thoroughly researched and effectively used in clinical settings for the delivery of numerous active substances.

There is no dedicated EU legal framework for nanomedicines; they are regulated under existing medicines legislation, complemented by relevant EMA guidance documents, e.g. on liposomes, block-copolymer micelles, intravenous iron nanoparticles, surface coatings ⁽³⁾.

⁽¹⁾ EMA, Reflection Paper on Nanotechnology-Based Medicinal Products for Human Use, EMEA/CHMP/79769/2006, 2006.

⁽²⁾ https://www.ema.europa.eu/en/documents/report/nanotechnology-based-medicinal-products-human-use-eu-horizon-scanning-report_en.pdf.

⁽³⁾ <https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-guidelines/multidisciplinary-guidelines/multidisciplinary-guidelines-nanomedicines>.