

(English version)

**Question for written answer E-000075/25
to the Commission
Gerald Hauser (P/E)
(10 January 2025)**

Subject: Derogation in Directive 2009/120/EC

In 2009, under Commission Directive 2009/120/EC, all medicinal products containing nucleic acid were defined as gene therapy medicinal products. That means, of course, that all vaccines containing mRNA or DNA are also biological gene therapy medicinal products. In complete contrast to that, however, vaccines against infectious diseases were statutorily exempted from that directive, in just one sentence, which was (and is) medically nonsensical.

This is at variance with what are increasingly clear-cut and dire safety concerns and incalculable risks associated with mRNA vaccines: the European Medicines Agency database now holds details of millions of vaccine side effects and tens of thousands of deaths following COVID-19 vaccination with gene therapy medicinal products; and only recently was a trial of an mRNA vaccine against RSV in children in the US halted because of safety concerns.

1. Why were DNA and mRNA gene therapy vaccines exempted from the directive in spite of the fact that the derogation makes no medical sense and has been heavily criticised by doctors and scientists since 2009?
2. Why did the Commission give in to the intense approaches made by the vaccine/pharma lobby, disregarding the safety concerns that were already being voiced at the time, and adopt this derogation, which goes against all medical sense and care considerations?
3. Does the Commission intend to scrap, at long last, this senseless and dangerous statutory derogation?

Submitted: 10.1.2025

**Answer given by Mr Várhelyi on behalf of the European Commission
(24 March 2025)**

Directive 2009/120/EC ⁽¹⁾, amending Directive 2001/83/EC ⁽²⁾, excludes vaccines against infectious diseases from the definition of gene therapy medicinal products.

mRNA vaccines authorised in the EU against COVID-19 are not genetically modified organisms and do not contain genes as their active substance. They are not used with the aim to restore, correct, or modify human genes.

mRNA vaccines are biological medicines regulated under the EU pharmaceutical legislation to ensure their quality, safety, and efficacy.

Under the legislation, the Committee for Medicinal Products for Human Use (CHMP) may also recommend additional measures, such as long-term monitoring, based on specific risks following a case-by-case assessment ⁽³⁾.

The safety and efficacy of mRNA vaccines authorised in the EU against COVID-19 have been rigorously assessed through clinical trials and post-authorisation monitoring.

The European Medicines Agency (EMA) and Member States continuously monitor the safety of COVID-19 vaccines to ensure any possible risks are detected and managed as early as possible ⁽⁴⁾. All data confirm that COVID-19 vaccines have a favourable safety profile.

Regarding safety concerns in respiratory syncytial virus (RSV) vaccine trials in infants, these are not linked to the mRNA technology ⁽⁵⁾ but rather to challenges previously observed with other RSV vaccines in this age group.

Currently, RSV vaccines are only authorised for use in adults ⁽⁶⁾, with trials ongoing to assess their safety and efficacy in infants and toddlers.

⁽¹⁾ <https://eur-lex.europa.eu/eli/dir/2009/120/oj/eng>

⁽²⁾ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67, ELI: <http://data.europa.eu/eli/dir/2001/83/oj>)

⁽³⁾ <https://www.ema.europa.eu/en/committees/committee-medicinal-products-human-use-chmp>

⁽⁴⁾ <https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/coronavirus-disease-covid-19/covid-19-medicines/safety-covid-19-vaccines>

⁽⁵⁾ <https://www.fda.gov/media/184301/download>

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

<https://www.ema.europa.eu/en/medicines/human/EPAR/arexvy>;

The Commission remains committed to ensuring that all medicines, including vaccines, authorised in the EU meet the highest standards of safety, efficacy, and quality, in full compliance with the EU pharmaceutical legislation.
