

EN
E-000398/2026
Answer given by Mr Várhelyi
on behalf of the European Commission
(9.4.2026)

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. Therefore, they are not considered a gene therapy. mRNA vaccines are biotechnology medicinal products regulated under the EU pharmaceutical legislation to ensure their quality, safety, and efficacy.

The definitions and detailed requirements for gene therapy and somatic cell therapy medicinal products were updated in 2009¹ to take into account scientific and technical progress in the field of advanced therapies, as reflected in Regulation (EC) No 1394/2007².

Hundreds of millions of people worldwide have received the mRNA COVID-19 vaccines. All EU-authorised medicines, including mRNA vaccines, are continuously and rigorously monitored. According to the European Medicines Agency, enhanced monitoring has found no safety issues related to the distribution of vaccine components³.

¹ ELI: <http://data.europa.eu/eli/dir/2009/120/oj>.

² ELI: <http://data.europa.eu/eli/reg/2007/1394/oj>.

³ COVID-19 vaccines: key facts: <https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/coronavirus-disease-covid-19/covid-19-medicines/covid-19-vaccines-key-facts#mrna-covid-19-vaccines-7221>.