

EN
P-000048/2025
Answer given by Mr Várhelyi
on behalf of the European Commission
(20.2.2025)

The Commission shall adopt its decision on Kostaive based on the scientific evaluation of the quality, safety, and efficacy of the vaccine by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). On 12 December 2024 the CHMP concluded that the benefits of the vaccine outweigh any potential risks and recommended granting marketing authorisation for the prevention of COVID-19 in adults¹.

The EMA was aware of concerns expressed by some academics in Japan during its assessment. Research into self-amplifying mRNA vaccines has been ongoing for over two decades. Notably, the self-amplifying mRNA technology, like other mRNA vaccines, does not interfere with a person's genetic code.

The CHMP identified no major safety concerns, and data indicate that Kostaive's safety profile is comparable to that of existing mRNA vaccines. The most common side effects observed in clinical trials were mild, including pain and tenderness at the injection site, tiredness, headache, muscle and joint pain, chills, dizziness, and fever. Patients involved in the studies with Kostaive have been followed for at least one year.

Kostaive's safety will be closely monitored by EMA and national authorities in the EU to ensure any possible risks are detected and mitigated as early as possible². The assessment report as well as the risk management plan for the vaccine, will be published on EMA's website.

In the framework of marketing authorisation of medicines, the Commission relies on the scientific advice provided by the EMA's scientific committees. Concerns and developments from other jurisdictions in relation to medicines are noted but do not alter the EU's commitment to upholding its rigorous safety, efficacy, and quality standards.

¹ <https://www.ema.europa.eu/en/medicines/human/EPAR/kostaive>

² <https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/coronavirus-disease-covid-19/covid-19-medicines/safety-covid-19-vaccines>