

(English version)

**Question for written answer E-002077/25
to the Commission
Gerald Hauser (Pfe)
(22 May 2025)**

Subject: Transparency of genotoxicological data on the Kostaive vaccine (ARCT-154)

The Kostaive vaccine (ARCT-154) was approved on 14 February 2025. It is based on a new form of mRNA technology in which the mRNA replicates itself in the body's cells after vaccination. In contrast to conventional mRNA vaccines, Kostaive contains additional genetic information.

This so-called self-amplifying mRNA technology is not without controversy, particularly due to potential long-term risks such as possible damage to the genome (genotoxicity).

According to the safety plan of the European Medicines Agency (EMA), Kostaive has not undergone any studies of its own that have specifically investigated possible damage to the genome. Instead, data from similar products were used, for example from the active substance ARCT-810, from a fat-based transport envelope (lipid nanoparticles, LNP for short) and from a computer evaluation of another active substance (ATX-126). According to the EMA's assessment, these results do not indicate any risk of genotoxicity.

1. Why are mRNA vaccines — especially self-amplifying ones — excluded from direct genotoxicity studies, and how robust is the data reported pertaining to ARCT-810?
2. Does the EMA plan to publish the full study reports on ARCT-810, LNP and the in silico analysis of ATX-126 for independent review?
3. What measures is the Commission taking to ensure transparent information on the absence of genotoxic risk of this class of vaccine?

Submitted: 22.5.2025

**Answer given by Mr Várhelyi on behalf of the European Commission
(22 July 2025)**

1. The genotoxicity potential of Kostaive was assessed and is part of the assessment report which is published on the European Medicines Agency (EMA) website ⁽¹⁾.

A lipid nanoparticle (LNP), similar to that used in Kostaive (contained in ARCT-810), was tested for its genotoxicity potential. The studies were completed by in silico modelling which are robust methods to predict the mutagenic potential (ability to induce genetic alterations) of molecules. These tests concluded no genotoxic potential. In addition, based on the data accumulated during the vaccination campaigns, there is no evidence supporting genotoxicity of any mRNA vaccines.

2. The clinical study reports that supported the authorisation of Kostaive have been published on EMA's clinical data website ⁽²⁾.
3. The Commission's authorisation decisions are based on the EMA scientific assessments, whose transparency is ensured through the publication on the EMA website as referred above.

⁽¹⁾ https://www.ema.europa.eu/en/documents/assessment-report/kostaive-epar-public-assessment-report_en.pdf.

⁽²⁾ <https://clinicaldata.ema.europa.eu/web/cdp/home>.