(English version)

Question for written answer E-002695/24
to the Commission
Leire Pajín (S&D)
(27 November 2024)

Subject: Competition among protein-based COVID-19 vaccines

Member States are promoting seasonal vaccination campaigns against COVID-19 in an effort to prevent the spread of the virus. Those campaigns are geared mainly towards the most vulnerable, such as healthcare workers, the elderly and people with immunodeficiency.

The EMA has authorised a broad range of messenger RNA vaccines. However, for protein-based vaccines, in the context of the update for the 2024 campaign, only one model has obtained approval.

Bearing in mind that the availability of and access to a larger supply of vaccines has a direct impact on the optimisation of public resources and provides greater coverage among the general population:

1. What view does the Commission take of the paucity of competition in protein-based vaccines for the 2024 campaign?

2. Is the Commission considering backing the availability of more protein-based vaccines for forthcoming COVID-19 vaccination campaigns?

Submitted: 27.11.2024

Answer given by Mr Várhelyi on behalf of the European Commission
(10 February 2025)

The availability of COVID-19 protein-based vaccines is primarily determined by clinical development priorities of vaccine developers. Neither the Commission nor the European Medicines Agency (EMA) have control over this aspect.

EU regulators, including EMA, assess the scientific evidence submitted by developers in the context of a marketing authorisation application.

While they can provide guidance on vaccines development, the actual production of such products ultimately depends on the companies developing them.

As regards COVID-19 vaccines, Comirnaty and Spikevax (mRNA-based) and Nuvaxovid and Bimervax (protein-based) are authorised in the EU.

For the autumn 2024 COVID-19 vaccination campaigns, EMA issued a statement ([1]) and the Commission authorised adapted mRNA vaccines (Comirnaty JN.1, Comirnaty KP.2 and Spikevax JN.1) and an adapted protein-based vaccine (Nuvaxovid JN.1).

EMA is currently assessing an adapted Bimervax vaccine (JN.1). Overall, these vaccines are expected to also cover the emerging XEC variant.

In principle, the Commission supports the availability of any type of COVID-19 vaccine following EMA's recommendation on approval ([2]). Vaccination policy is a national competence, and the Commission supports EU countries in coordinating their policies and programmes.

In July 2024, the Commission and 15 countries launched a call for tender for the supply of protein-based COVID-19 vaccines under the Joint Procurement Agreement ([3]), offering an alternative option to citizens who cannot or do not want to receive a mRNA COVID-19 vaccine.

This call for tender targets producers of protein-based COVID-19 vaccines authorised for use in the EU. More information will be available after the closure of the procedure.

([1]) https://www.ema.europa.eu/en/documents/other/ema-confirms-its-recommendation-update-antigenic-composition-authorised-covid-19-vaccines-2024-2025_en.pdf
([2]) https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/coronavirus-disease-covid-19/covid-19-medicines
([3]) https://health.ec.europa.eu/health-security-and-infectious-diseases/preparedness-and-response-planning_en#joint-procurement-of-medical-countermeasures-ensuring-proper-preparedness