

(English version)

**Priority question for written answer P-001831/24
to the Commission
Friedrich Pürner (NI)
(26 September 2024)**

Subject: Authorisation of Mpox vaccines and transparency

On 18 September 2024, during an exchange of views with the Commissioner responsible for health on the EU response to the Mpox virus outbreak, Members of the European Parliament warned that the EU had failed to learn the lessons of the COVID-19 pandemic.

The commitment to ‘protect the ill from harm’ enshrined in the Hippocratic Oath, is a fundamental value that I as a physician feel bound by. Vaccinations can protect, but they can also cause harm. In particular, when a vaccine is not authorised for a specific group of people, or when side effects or harmful effects of vaccines are ignored, as happened in the case of the COVID vaccines.

The EU is donating vaccines to countries affected by the Mpox outbreak. The vaccine is authorised for people aged 12 and over, but there is a lack of data for children, adolescents, pregnant women and immunocompromised people.

In addition, the Court found that the Commission acted in a non-transparent manner in connection with COVID vaccine contracts. This has seriously damaged the EU’s reputation.

1. How is it ensured that the vaccine is not administered indiscriminately to the above-mentioned categories of people?
2. How can the Commission extend the authorisation of the Mpox vaccine to adolescents if clinical trials are not yet completed?
3. What is the Commission doing to ensure greater transparency with regard to the Mpox contracts in light of the debacle associated with the COVID vaccine contracts?

Submitted: 26.9.2024

**Answer given by Ms Kyriakides on behalf of the European Commission
(29 October 2024)**

The Commission authorises medicines based on a recommendation by the European Medicines Agency (EMA).

The vaccine Imvanex ⁽¹⁾ is authorised in the EU to protect against smallpox, mpox and diseases caused by vaccinia virus in individuals aged 12 and older.

The product information ⁽²⁾ includes advice on the use of Imvanex in vulnerable populations, such as immunocompromised, pregnant women or children.

The recommendation to extend the use of Imvanex to adolescents is based on the interim results of a study ⁽³⁾ showing its ability to generate an immune response in adolescents similar to that in adults.

No additional risk was identified for the use of Imvanex in adolescents compared to adults. EMA requested the marketing authorisation holder to submit the study final results by 30 May 2025 to further characterise the safety information for adolescents ⁽⁴⁾.

As for all medicines, data on the use of Imvanex are continuously monitored. Side effects reported with Imvanex are evaluated, and any necessary action taken to protect patients.

On 13 September 2024, Imvanex was prequalified by the World Health Organisation (WHO) ⁽⁵⁾, with EMA as regulatory agency of record, i.e. EMA’s assessment was the basis for WHO prequalification to facilitate timely and increased access to this vaccine in communities with urgent need.

WHO also cooperated in EMA’s assessment of the extension of indication to adolescents, a population particularly vulnerable to mpox.

⁽¹⁾ Union Register of medicinal products <https://ec.europa.eu/health/documents/community-register/html/h855.htm>

⁽²⁾ IMVANEX II-108 https://ec.europa.eu/health/documents/community-register/2024/20240919164097/anx_164097_en.pdf

⁽³⁾ A Phase 2 Randomized Multisite Trial to Inform Public Health Strategies Involving the Use of MVA-BN Vaccine for Mpox <https://www.clinicaltrials.gov/study/NCT05740982>

⁽⁴⁾ EMA recommends extending indication of mpox vaccine to adolescents <https://www.ema.europa.eu/en/news/ema-recommends-extending-indication-mpox-vaccine-adolescents>

⁽⁵⁾ <https://www.who.int/news/item/13-09-2024-who-prequalifies-the-first-vaccine-against-mpox>

The Commission will continue to strive for the greatest transparency possible by complying with Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents ⁽⁶⁾ when applicable.

⁽⁶⁾ <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32001R1049>