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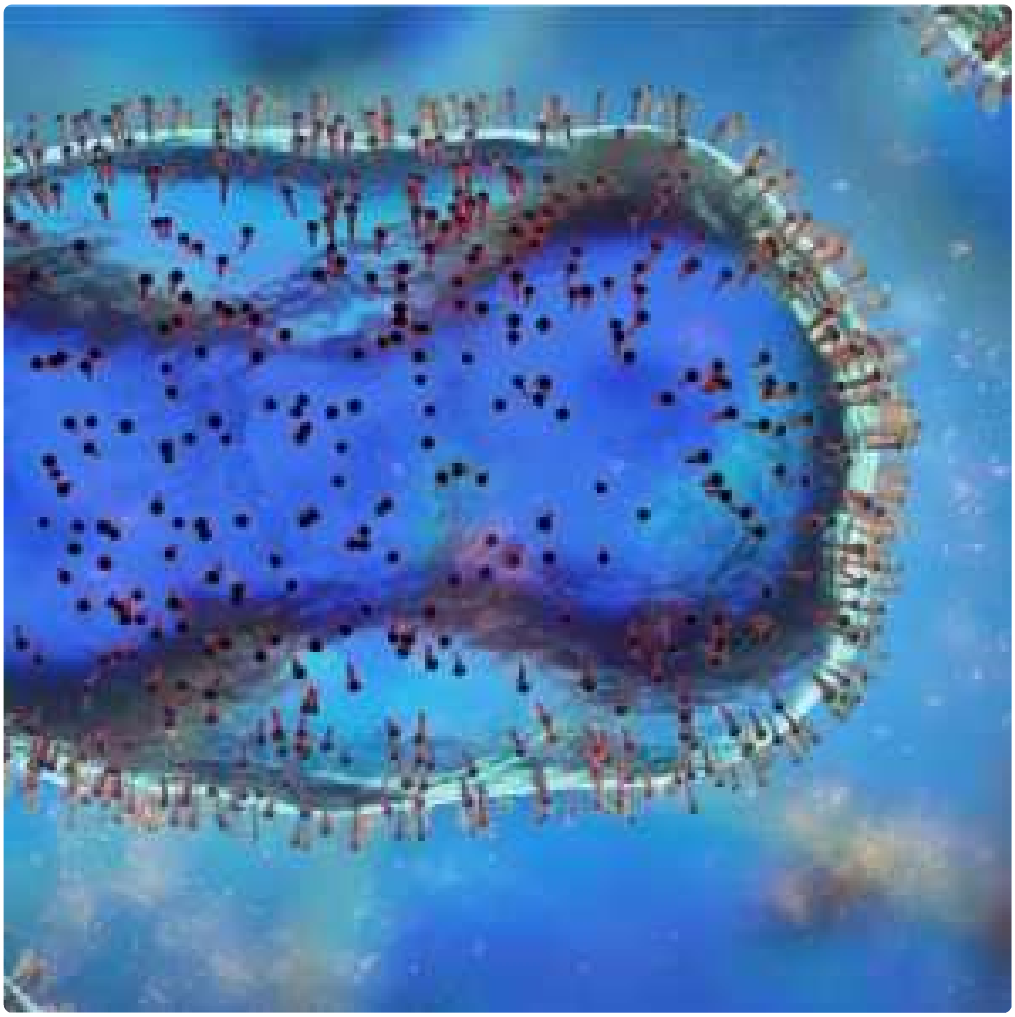

EMA recommends extending indication of mpox vaccine to adolescents

19 September 2024

Vaccine assessment can support African regulators in fight against ongoing outbreak

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> *The European Commission issued its decision on the Imvanex extension of indication in adolescents on 19 September 2024.*

EMA has recommended extending the indication of the smallpox and mpox vaccine Imvanex to adolescents from 12 to 17 years of age.

Imvanex is already authorised in the European Union (EU) to protect against smallpox, mpox and the disease caused by the vaccinia virus in adults. It contains a live, highly weakened form of a virus called "modified vaccinia virus Ankara" (MVA-BN), which is related to the smallpox virus. EMA's human medicines committee (CHMP) based the recommendation to extend the use of Imvanex to adolescents on the interim results of a study that compared the vaccine's ability to generate an immune response (produce virus-specific antibodies) in 315 adolescents and in 211 adults.

The immune response in adolescents was similar to adults. Therefore, it is inferred that the vaccine will provide similar protection in adolescents to that expected in adults. According to the submitted data, the safety profile of Imvanex in adolescents was comparable to that seen in adults and no additional risk has been identified. As part of its recommendation, EMA has requested the marketing authorisation holder to submit the final results of the study by 30 May 2025 to further characterise the information about safety in adolescents.

The Agency's assessment has important implications for the global response to the mpox outbreak in the Democratic Republic of the Congo (DRC) and other countries, which was declared a public health emergency of international concern (PHEIC) by the World Health Organization (WHO) on 14 August 2024.

EMA is the regulatory agency of record for prequalification of this vaccine by WHO on 13 September 2024. This means that CHMP's assessment constitutes the basis for WHO prequalification approval to facilitate timely and increased access to this vaccine in communities with urgent need. Previously, EMA's assessment was also taken into account by the national regulatory authority of the DRC in the fast-track approval of the vaccine. In addition, WHO has cooperated in EMA's assessment of the extension of indication in adolescents, a population that is particularly vulnerable to mpox.

Mpox is a disease that is transmitted to people by animals, mainly rodents, but can also spread between people with direct contact. It is endemic in certain parts of Central and West Africa. The current surge in cases in the DRC and several neighbouring countries is driven by the mpox clade I strain that is known to cause a more severe form of mpox in humans than the mpox clade II strain that spread during the 2022/2023 PHEIC. Mpox can be fatal for people with weak immune systems.

Data indicate that Imvanex protects against both the clade I and clade II mpox strains.

In the EU, decisions on how vaccinations should be given are the prerogative of the expert bodies guiding vaccination campaigns in each Member State. The European Centre for Disease Prevention and Control (ECDC) published advice for public health authorities for mpox on their website.

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OUTSIDE WORKING HOURS

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Tel: +31 (0)88 781 6000