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WHO prequalifies first vaccine against mpox

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Single-dose of MVA-BN vaccine given before exposure has an estimated 76% effectiveness in protecting people against mpox

The World Health Organization (WHO) has announced MVA-BN vaccine as the first vaccine against mpox to be added to its prequalification list.

The prequalification approval is expected to facilitate timely and increased access to this vital product in communities with urgent need, to reduce transmission and help contain the outbreak. WHO's assessment for prequalification is based on information submitted by the manufacturer, Bavarian Nordic A/S, and review by the European Medicines Agency, the regulatory agency of record for this vaccine.

The MVA-BN vaccine can be administered in people over 18-years of age as a 2-dose injection given 4 weeks apart. After prior cold storage, the vaccine can be kept at 2–8°C for up to 8 weeks.

While MVA-BN is currently not licensed for persons under 18 years of age, this vaccine may be used "off-label" in infants, children and adolescents, and in pregnant and immunocompromised people. This means vaccine use is recommended in outbreak settings where the benefits of vaccination outweigh the potential risks.

WHO also recommends single-dose use in supply-constrained outbreak situations. WHO emphasizes the need to collect further data on vaccine safety and effectiveness in these circumstances.

Available data shows that a single-dose MVA-BN vaccine given before exposure has an estimated 76% effectiveness in protecting people against mpox, with the 2-dose schedule achieving an estimated 82% effectiveness. Vaccination after exposure is less effective than pre-exposure vaccination.