WHO Target Product Profiles for mpox Vaccines
Version 1, 16 August 2024

Purpose of the document

Selected disease areas are identified as WHO priorities for research and product development. In the case of mpox[1], target product profile development followed evidence of increasing transmission and possible need to make one or more vaccines available under WHO's emergency use listing (EUL) procedure. This target product profile is intended to convey, based on the most recently available data, WHO's current priorities for vaccine development, regardless of regimen (including whether they are intended as primary vaccination or as boosters), and whether they are intended to address currently circulating variants or future variants.

The target audience includes vaccine scientists, product developers, manufacturers, and funding agencies.
All the requirements contained in WHO guidelines for WHO policy recommendation and prequalification will also apply. The criteria below lay out some of the considerations that will be relevant in WHO's case-by-case assessments of mpox vaccines in the future. Therefore, should a vaccine's profile be sufficiently superior to the critical characteristics under one or more categories, this may outweigh failure to meet another specific critical characteristic. Vaccines that fail to meet multiple critical characteristics are unlikely to achieve favorable outcomes from WHO's processes.

Acknowledgement

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[1] monkeypox virus is the cause of mpox disease

I. Background

The Director-General of the World Health Organization (WHO), having concurred with the advice offered by the International Health Regulations (2005) (IHR or Regulations) Emergency Committee regarding the upsurge of mpox 2024 during its first meeting, held on 14 August 2024, has determined, on the same date, that the ongoing upsurge of mpox in the Democratic Republic of the Congo and a growing number of countries in Africa constitutes a public health emergency of international concern (PHEIC) under the provisions of the International Health Regulations.

Globally, the multi-country outbreak of mpox has led to 116 countries and territories in all WHO regions reporting 99 176 confirmed cases and 208 deaths (CFR 0.2%) between May 2022 and June 2024. Two regions, the Western Pacific and the South-east Asian regions, experienced the peak of their mpox outbreaks around mid-2023 and, along with other regions, continue to report sporadic cases and outbreaks. Clade II MPXV is circulating mostly in West Africa. The situation in the Democratic Republic of Congo, linked to Clade I MPXV, has continued to evolve with cases rising steadily since late 2022 and has now become particularly concerning. This increased case reporting is driven by two concomitant outbreaks, including (1) outbreaks in historically endemic parts of the Democratic Republic of the Congo, affecting primarily children, and (2) a rapidly expanding outbreak of a new strain of MPXV clade I – named clade Ib – which appears to be spreading predominantly through sexual networks, expanding geographically in eastern provinces of the Democratic Republic of the Congo, and now also affecting neighbouring countries.

While newer generation poxvirus vaccines are approved or authorized in some countries for mpox prevention, no vaccine is yet globally available, with wide gaps in availability between Northern countries and LMICs.

This document describes the preferred and minimally acceptable profiles for human vaccines for all clades of mpox. All vaccines considered for use must meet appropriate regulatory standards. In general, the minimally acceptable profiles are aligned with expectations for emergency use listing of new vaccines. Licensed or pre-qualified vaccines would likely have more of the attributes of the preferred profile.

This revised Target Product Profile (TPP) was developed through a consultation process that included discussions with key stakeholders, including those in affected regions, in human and animal health, scientific, funding and manufacturing communities. It is intended that it will guide and prioritize the development of vaccines and decisions about need for boosters, based on the available data on mpox. As new scientific evidence is generated, this TPP may again require further review and revision.

Vaccine characteristic	Preferred	Critical or Minimal[2]
Indication for use	Prevention of mpox disease and reduction of severe mpox disease. Prevention of mpox disease transmission	Prevention of mpox disease and/or reduction of severe mpox disease
Contraindication	Minor (e.g., hypersensitivity or linked to specific adverse events)	Limited contraindications may include severely immunocompromised patients
Target population	Adults, adolescents, children, and infants Data to support administration to special populations such as those who are pregnant, lactating, or immunocompromised	Adults
Safety/Reactogenicity	Minimal reactogenicity No serious ADRs	Up to mild-moderate reactogenicity Serious adverse events occurring only in rare circumstances
consiMeasures of Efficacy	Efficacy point estimate in poxvirus naives >90% Direct evidence of efficacy against disease caused by relevant monkeypox clades, preferably generated through randomized clinical trials	Efficacy point estimate in poxvirus naives >60% Animal studies, immune responses[3], and/or observational data supporting efficacy against mpox Additionally evidence of efficacy against smallpox if available would be supportive
Dose regimen	Single dose	Two or fewer doses for primary regimen. Boosters are acceptable
Durability of protection	≥3 years	≥6 months after the primary series

[2] Generally aligned with Emergency Use Authorization Listing of Vaccines

[3] Immune response data against monkeypox virus could be adequate if supported by other relevant evidence

Vaccine characteristic	Preferred	Critical or Minimal[2]
Deployability		
Route of Administration	Not requiring specialized equipment or supplies	Any route of administration is acceptable, including IM, subcutaneous, or ID via bifurcated needle
Product Stability and Storage	Shelf life ≥ 2 years at ambient temperature	Shelf life ≥ 1 year at achievable storage temperature in regions intended for deployment.
Co-administration with other products	No interactions with other vaccines Able to be administered with antivirals	Some interactions may be acceptable but these should not limit or impact use in outbreak response
Presentation	Multidose and single dose vials are both available Barcodes on secondary packaging, including serialization, GTIN, expiry and lot number For parenteral, dose volume of 0.5 mL preferred, with AD syringes that are WHO prequalified	Single or multi-dose vials suitable for outbreak response
Registration and Prequalification	Prequalification In addition, relevant NRA approval	EUL
Availability	Sufficient supplies at affordable price available to developing countries, without conditions that limit use for research.	Adequate timely supply of doses to respond to the public health emergency

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