Executive Summary of WHO Informal Consultation on the Standardization of Biological Products for Mpox and other Emerging Pathogens

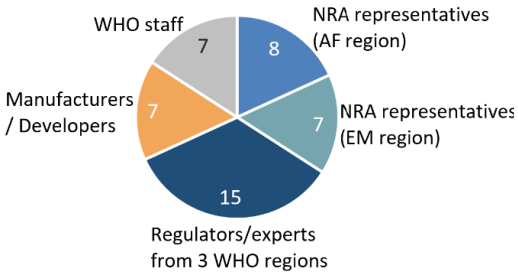
24-25 November 2025
Tunis, Tunisia

Background

Recent resurgence and cross-regional transmission of Mpox (formerly known as monkeypox), particularly in Africa, have underscored the importance of strengthening global and regional preparedness for emerging pathogens. While vaccines and therapeutics originally developed for smallpox are currently being used for Mpox, Mpox-specific biological products remain limited, and reference standards, widely validated assays, and broader regulatory experience are not yet fully established to support consistent evaluation and use. To address these gaps and to facilitate the availability of safe, effective, and quality-assured biological products, a WHO informal consultation on the standardization of biological products for Mpox and other emerging pathogens was held in Tunis, Tunisia, from 24 to 25 November 2025. The detailed agenda is attached to this summary.

A total of 44 participants joined the consultation both in person and virtually. These included 8 regulators from national regulatory authorities (NRAs) in 7 countries of the African region and 7 regulators from 6 countries of the Eastern Mediterranean region. In addition, 13 experts from 4 NRAs and 1 Health Authority from 4 countries (Canada, Germany, Uganda, and the United Kingdom) also participated. Furthermore, 2 representatives from Foundation for Innovative New Diagnostics (FIND) and Coalition for Epidemic Preparedness Innovations (CEPI), 7 experts from manufacturers and developers, and 7 WHO staff from Headquarters and the WHO Regional Office for Africa took part in the consultation.

(a) Countries of participating regulators/experts



(b) Participants composition

(c)

Objectives

The consultation aimed to advance the development, evaluation, and availability of safe, effective, and quality-assured biological products for Mpox and other emerging pathogens, while strengthening regional and global collaboration. The meeting pursued three specific objectives:

- To provide an overview of the current global Mpox situation and WHO's ongoing activities, including updates on vaccine and monoclonal antibody (mAb) development.
- To share progress on the development of WHO international reference standards and assays for Mpox, including diagnostics and serological testing.
- To address regulatory considerations and challenges for Mpox vaccines and mAbs, and to identify opportunities to enhance regional collaboration and regulatory convergence.

Key discussion points are briefly described below.

Global Mpox situation and WHO initiatives

Participants reviewed the current epidemiological situation, noting an overall downward trend in reported cases globally, which contributed to WHO's decision to lift the Public Health Emergency of International Concern in September 2025. Several African countries, however, continue to experience new or recurrent transmission, and Mpox remains classified by Africa CDC as a public health emergency of continental security.

The consultation highlighted the role of the WHO Global Strategic Preparedness and Response Plan 2024 in strengthening surveillance systems, increasing testing capacity, and improving data management. Despite this progress, challenges persist, including limited funding for vaccine procurement, operational constraints affecting deployment, and the need to integrate Mpox response activities into primary healthcare to ensure long-term sustainability.

Development of Mpox biological products

Discussions reviewed the development of Mpox vaccines and monoclonal antibodies. Currently licensed vaccines are based on vaccinia virus platforms originally developed for smallpox. New Mpox-specific vaccines, including mRNA-based platforms, are under development. Participants identified correlates of protection (CoP) as a central scientific challenge. Differences in vaccine platforms, immune response profiles, population heterogeneity, and the influence of assay methodology were noted as key factors complicating the definition and measurement of relevant immunomarkers. Issues related to assay variability were recognized as barriers to data comparability.

For monoclonal antibodies, participants noted ongoing early-stage development efforts. Challenges include target selection, potency assessment, production scalability, and the practicality of intravenous administration. Lessons from antibody cocktail approaches used in other diseases, such as Ebola, were noted as potentially informative.

WHO international reference standards for Mpox

WHO presented ongoing work on the development of international standards for anti-Mpox and anti-vaccinia antibodies, as well as reference reagents for Mpox DNA for nucleic acid testing. These standards are expected to play a critical role in supporting assay calibration, enabling comparability of data across laboratories, and strengthening evaluation of vaccines and other biological products.
Participants emphasized the importance of calibrating in-house assays to WHO International Standards when available and highlighted the need for additional training and guidance to ensure proper adoption and implementation.

Assays for Mpox diagnosis and serology

The consultation highlighted biosafety considerations, including containment requirements, personal protective equipment (PPE), standard operating procedures (SOPs), and trained staff as essential components for diagnostic work. Participants noted that assay validation requires access to well-characterized samples, which determine analytical range and robustness.
Assay complexity arising from clade diversity, differences in antigen targets, and varied intended uses (e.g., surveillance versus vaccine evaluation) was discussed. Harmonization of diagnostic, serological, and neutralization assays, supported by WHO International Standards, was identified as essential for ensuring consistent and reliable data to guide public health and regulatory decisions.

Regulatory considerations for Mpox vaccines and mAbs

Participants discussed the absence of Mpox-specific vaccine guidelines and considered how WHO, EMA, and EDQM guidance may serve as references. Large-scale phase III efficacy trials may not be feasible, prompting discussion on alternative approaches that may be considered to support the approval of new products such as non-inferiority studies using licensed vaccines and detailed immune-response characterization. The use of appropriate animal models was highlighted as important for supporting CoP assessment for novel platforms. For monoclonal antibodies, regulatory pathways are expected to align with those applied to other infectious disease mAbs, though no licensed Mpox or smallpox mAbs currently exist.

Panel discussion summary

A dedicated panel discussion, involving invited speakers, two expert panellists and inputs from participants, summarized key messages from the sessions. Panellists emphasized the need for improved data sharing and transparency in reporting cases, supported by continued advocacy from WHO and regional partners. Assay standardization was deemed both feasible and essential, particularly for vaccine evaluation and post-marketing monitoring.

The lack of ongoing CoP studies was noted, although plans from CEPI and other partners were referenced as important future directions. Strengthening regional collaboration, including through reliance mechanisms among regulatory authorities within Africa and at the continental level, was highlighted as a key strategy for enhancing regulatory efficiency and capacity.

Participants also underscored the importance of stronger linkages between laboratories, regulators, and public health institutions within countries, particularly with respect to information sharing on adverse events and product performance.

Key outcomes of the consultation

- Enhanced understanding of the development, evaluation, and regulatory aspects of Mpox biological products.
- Clear identification of regional collaboration opportunities to strengthen access to safe, effective, and quality-assured biological products.
- Reinforced recognition of the importance of assay standardization and the development and use of WHO International Standards.
- Strengthened networks among regulators, laboratories, public health institutions, manufacturers, and WHO.
- Agreement to raise awareness of this important area of work by preparing and disseminating information about the consultation to a broad audience.

WHO Informal Consultation on the Standardization of Biological Products for Mpox and other Emerging Pathogens

24-25 November 2025

Tunis, Tunisia

AGENDA

Chair: Heidi Meyer
Co-Rapporteurs: Giada Mattiuzzo, Chad Irwin

Day 1: Monday, 24 November 2025

Session 1	**Opening of the meeting**	
09:00 – 9:40	Welcome and opening remarks	Ivana Knezevic (WHO HQ)
	Self-introduction	All participants
	Statement on DoI assessment	Ivana Knezevic (WHO HQ)
	Objectives and expected outcomes of the meeting	Eunkyung Kim (WHO HQ)
Session 2	**Mpox global situation and WHO initiatives**	
09:40 – 10:10	Global status of Mpox and WHO response strategies	Sheillah Nsasiirwe (WHO AFRO)
10:10 – 10:30	Questions & Answers	
10:30 – 11:00	***Coffee break***	
Session 3	**Development status of biological products for Mpox**	
11:00 – 11:45	Mpox vaccine development: Developers perspectives	
	- Perspective from Bavarian Nordic	Melvin Sanicas
	- Perspective from BioNTech	Leela Davies
	- Perspective from Moderna	Tiffany Frey, Hiwot Hiruy

11:45 – 12:05	Monoclonal antibodies (mAbs) for Mpox	Paul Kellam (Imperial College London)
12:05 – 12:30	Discussion	
12:30 – 13:30	***Lunch break***	
Session 4	**WHO International Reference Standards for Mpox**	
13:30 – 13:50	The first WHO international standards for anti-Mpox virus antibodies	Giada Mattiuzzo, (MHRA[i])
13:50 – 14:10	The first WHO international standard for anti-vaccinia virus antibodies	Giada Mattiuzzo, (MHRA)
14:10 – 14:30	Reference reagents for Mpox DNA for NAT testing	Graham Prescott (MHRA)
14:30 – 15:00	Discussion	
15:00 – 15:30	***Coffee break***	
Session 5	**Regulatory perspectives on Mpox vaccines and mAbs**	
15:30 – 15:50	Regulatory considerations - Experience gained by PEI/EMA	Heidi Meyer (PEI[ii])
15:50 – 16:10	Regulatory considerations - Experience gained by Health Canada	Chad Irwin (Health Canada)
16:10 – 16:50	Discussion	
16:50 – 17:00	**Wrap-up of day 1**	Chair & Rapporteurs

Day 2: Tuesday, 25 November 2025

Session 6	**Assays for Mpox diagnosis and serology**	
09:00 – 09:20	Molecular assays for Mpox diagnostics	Deogratius Ssemwanga, (UVRI[iii])
09:20 – 09:40	Serological assays for Mpox and vaccine response evaluation	Bassam Hallis (UKHSA[iv])
09:40 – 10:00	Neutralization assays for Mpox antibodies	Giulia Piccini (VisMederi)
10:00 – 10:30	Discussion	

10:30 – 11:00	***Coffee break***	
Session 7	**Strategic reflections on Mpox biological products**	
11:00 – 12:00	Panel discussion: Needs, gaps, and opportunities - *Panellists: session speakers and experts from CEPI[v] and FIND[vi]*	Chair
Session 8	**Conclusions and recommendations**	
12:00 – 12:15	Summary of points raised during the meeting	Chair & Rapporteurs
12:15 – 12:25	Conclusions and next steps	Chair & Rapporteurs
12:25 – 12:30	Closing remarks	Ivana Knezevic (WHO HQ)
12:30	**Close of meeting**	

[i] MHRA: Medicines and Healthcare Products Regulatory Agency
[ii] PEI: Paul-Ehrlich Institute
[iii] UVRI: Uganda Virus Research Institute
[iv] UKHSA: UK Health Security Agency
[v] CEPI: Coalition for Epidemic Preparedness Innovations
[vi] FIND: Foundation for Innovative New Diagnostics