## Second meeting of the International Health Regulations (2005) Emergency Committee regarding the upsurge of mpox 2024

27 November 2024

The Director-General of the World Health Organization (WHO) is hereby transmitting the report of the second meeting of the International Health Regulations (2005) (IHR) Emergency Committee (Committee) regarding the upsurge of mpox 2024, held on Friday, 22 November 2024, from 12:00 to 17:00 CET.

Notwithstanding some progress towards controlling the spread of mpox resulting from national and international response efforts, the Committee noted the rising number and continuing geographic spread of mpox cases, especially those due to monkeypox virus clade Ib infection; the operational challenges in the field in need of stronger national commitments; as well as the need to mount and sustain a cohesive response across countries and partners. The Committee advised that the event continues to meet the criteria of a public health emergency of international concern (PHEIC) and provided its views regarding the proposed temporary recommendations.

The WHO Director-General expresses his most sincere gratitude to the Chair, Members, and Advisors of the Committee. The WHO Director-General concurs with the advice of the Committee that the event continues to constitute a PHEIC for the reasons detailed in the proceedings of the meeting below, and issues revised temporary recommendations in relation to this PHEIC, which are presented at the end of this document.

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#### **Proceedings of the meeting**

Sixteen (16) Members of, and two Advisors to, the International Health Regulations (2005) (IHR) Emergency Committee (Committee) were convened by teleconference, via Zoom, on Friday, 22 November 2024, from 12:00 to 17:00 CET. Thirteen (13) of the 16 Committee Members, and one of the two Advisors to the Committee participated in the meeting.

The Director-General of the World Health Organization (WHO) delegated the WHO Deputy Director-General to welcome the Committee Members and Advisors, and invited Government Officials designated to present to the Committee on behalf of the five invited States Parties – Burundi, the Democratic Republic of the Congo (DRC), Kenya, Rwanda and Uganda.

The WHO Deputy Director-General recalled that the determination of the public health emergency of international concern (PHEIC), on 14 August 2024, was a call for national authorities to invest energetically to prevent and control the transmission of monkeypox virus (MPXV) with particular focus on clade Ib, to reduce the risk of international spread of mpox, and for the international community to act cohesively and intensely with all the tools and resources available for the prevention and control of mpox.

Highlighting the evolution of mpox globally (see details under the heading "Session open to representatives of States Parties invited to present their views), the WHO Deputy Director-General stressed that, since the Committee last met in August 2024, the situation has become more complex and continues to require a coordinated international response, including in all countries and especially in those with limited number of mpox cases before wider spread of disease may occur. He outlined the constructive collaborations and efforts of WHO and numerous partners, including the Africa Centres for Disease Control and Prevention (Africa CDC), to scale up the response at regional, national and sub-national levels; and the establishment,

by WHO and partners, of the Access and Allocation Mechanism (AAM) as part of the interim Medical Countermeasures Network endorsed by WHO Member States, to support the equitable allocation and distribution of vaccines, therapeutics and diagnostics. The WHO Deputy Director-General outlined a number of challenges States Parties are facing to interrupt the transmission of mpox, including a number of concurrent health emergencies and competing health priorities, hence requiring political commitment and resources to further scale up targeted and integrated interventions at local levels.

The Representative of the Office of Legal Counsel briefed the Members and Advisors on their roles and responsibilities and identified the mandate of the Committee under the relevant articles of the IHR. The Ethics Officer from the Department of Compliance, Risk Management, and Ethics provided the Members and Advisors with an overview of the WHO Declaration of Interests process. The Members and Advisors were made aware of their individual responsibility to disclose to WHO, in a timely manner, any interests of a personal, professional, financial, intellectual or commercial nature that may give rise to a perceived or actual conflict of interest. They were additionally reminded of their duty to maintain the confidentiality of the meeting discussions and the work of the Committee. Each Member and Advisor was surveyed, with no conflicts of interest identified.

The meeting was handed over to the Chair who introduced the objectives of the meeting, which were to provide views to the WHO Director-General on whether the event continues to constitute a PHEIC, and if so, to provide views on the potential proposed temporary recommendations.

#### Session open to representatives of States Parties invited to present their views

The WHO Secretariat presented an overview of the global epidemiological situation of mpox, all MPXV clades included, highlighting that, since the Committee last met in August 2024, MPXV transmission has been reported in all six WHO Regions. While the WHO African Region represents the largest contributor to the global increase of mpox cases due to clades Ia, Ib and IIa, mpox in the WHO Western Pacific Region has been increasing due to an MPXV clade IIb outbreak among men who have sex with men reported from Australia.

With regards to the spread of MPXV clade Ib in the WHO African Region, since the Committee last met, the WHO Secretariat presented that the foci of transmission are in the DRC, with clade Ib now detected in six provinces, including in the urban area of the capital Kinshasa. MPVX virus clade Ib has also spread in neighboring countries, including in Burundi (2,083 mpox cases, growing in the urban areas of Bujumbura and Gitega) and Uganda (582 mpox cases, growing in the capital Kampala) with established sustained community transmission; and Kenya (17 mpox cases) and Rwanda (37 mpox cases) with clusters of mpox cases (data reported as of 19 November 2024).

Additionally, travel-related cases of MPXV clade Ib infection, mostly epidemiologically linked to the above-mentioned countries, have been detected in eight countries in the following WHO Regions – African Region (Zambia and Zimbabwe); Americas Region (United States of America); European Region (Germany, Sweden, and the United Kingdom. In the United Kingdom, transmission within the household of the case occurred); and South-East Asian Region (India and Thailand).

Available data from sub-national level in the DRC shows that the observed dynamics of transmission of MPXV clade Ib are changing over time and are diverse across affected health zones. Since MPXV clade Ib was first detected in September 2023 in South Kivu province in the health zone of Kamituga, the most affected age group has shifted from adults, where transmission was first observed and appears to have been sustained by contact within commercial sexual networks, to younger age groups, including children, and sustained by household and likely broader community transmission through close physical contact.

The same epidemiological characteristics are being observed in the capital Kinshasa, where the outbreak is largely driven by transmission between adults, but where steadily more children are being reported as a result of close physical contact within households and/or the community. It is worth noting that, regardless of the circulating MPXV clades, adults of 50 year of age are less affected, likely due to the immunity conferred by prior vaccination against smallpox.

The WHO Secretariat indicated that information about mortality in confirmed cases of mpox, regardless of the MPXV clade, is limited. In the DRC, based on routine syndromic surveillance data, deaths attributed to mpox are predominant in rural areas known to be endemic for MPXV clade Ia – with variable case fatality rates observed across those areas, but being consistently higher in children under 5 years of age.

Outside the DRC, deaths associated with MPXV clade Ib infection have been reported in Burundi (1), Uganda (2) and Kenya (1).

The WHO Secretariat presented the assessed risk by MPXV clades and further expressed in terms of overall public health risk where any given clade/s is/are circulating, and risk of national and international spread, as: Clade Ib – high public health risk and high risk of national/international spread; Clade Ia – high public health risk and moderate risk of national/international spread; Clade II – moderate public health risk and moderate risk of national/international spread.

The WHO Secretariat subsequently provided an update on actions WHO has taken, with States Parties and partners, following the issuance of the temporary recommendations on 19 August 2024, the extension of the standing recommendations for mpox, and the WHO appeal: mpox public health emergency 2024, and based on the WHO Mpox global strategic preparedness and response plan, September 2024-February 2025; the Africa CDC-WHO Mpox Continental Preparedness and Response Plan for Africa, September 2024-February 2025; A coordinated research roadmap – Mpox virus - Immediate research next steps to contribute to control the outbreak (2024).

In addition to the overview provided by the WHO Deputy Director-General, the WHO Secretariat provided detailed updates on progress and challenges related to the following areas of the response, including: collaborative surveillance, safe and scalable clinical care, community protection, access to countermeasures, including diagnostics and vaccines (over 1.1 million doses of MVA-BN vaccine allocated to date), operations (deployment of human resources, dispatch of personal protective equipment, diagnostic tests, etc. to the field), funding (of the 87.4 million USD needed as per WHO appeal, 40.6 million USD were received or pledged; 3.5 million USD were release from the WHO's Contingency Funds for Emergencies), and coordination with partners.

Representatives of Burundi, the DRC, Kenya, Rwanda and Uganda updated the Committee on the mpox epidemiological situation in their countries and their current response efforts, needs and challenges. Vaccine against mpox is currently being used in the DRC and Rwanda, and there are plans to use it in Kenya and Uganda, whereas vaccination against mpox is currently not encompassed by the response strategy of Burundi.

Members of, and the Advisor to, the Committee then engaged in questions and answers with the WHO Secretariat and invited Government Officials, on the issues and challenges presented.

The determination that the upsurge of mpox constitutes a PHEIC in August 2024 was regarded by States Parties attending the meeting as having boosted domestic response efforts and the mobilization of international resource to support those efforts.

However, the lack of information at national and local levels, including the suboptimal implementation of response interventions, was regarded as an obstacle to progress in controlling and interrupting MPXV transmission. Examples to that effect related to the proportion of suspect mpox cases tested; the time from diagnosis to subsequent isolation of mpox cases; the trend of mpox test positivity rate; the proportion of contacts that have completed the follow-up period; the proportion of mpox cases with an unknown epidemiological link, and trend thereof; and challenges with mpox vaccination implementation. Challenges with vaccination implementation include: the current vaccination coverage in countries with mpox vaccine; the time elapsed between the last exposure of an unvaccinated contact; and the administration of mpox vaccine.

The observed multifaceted dynamics of the spread of MPXV was discussed at length in terms of (a) the expansion of transmission from within known commercial sexual networks, and subsequently within households, and to the wider community with sustained transmission; (b) opportunities to refine the risk assessment approach, considering lower geographical levels and vulnerable subsets of population; and (c) the potential for predictive mathematical modeling approaches to anticipate MPXV spread both within countries and internationally.

Aspects related to the use of mpox vaccines as part of the response were discussed, including, but not limited to, (a) progress with global and domestic regulatory issues; (b) challenges for use of mpox vaccines in and infants, children, adolescents, and immunocompromised persons (as per <u>WHO vaccine position</u> paper, August 2024); (c) need to implement vaccination as part of an integrated targeted response to interrupt MPVX transmission in hot spots at the local level, as opposed to a broader geographical use of the vaccine; (d) uncertainties related to the effectiveness of post-exposure use of the vaccine; (e) possible inclusion of studies to assess vaccine effectiveness in the vaccine deployment plans; and (f) approaches to overcome vaccine hesitancy.

The coordination between Africa CDC and WHO in supporting States Parties response efforts in implementing the Africa CDC-WHO Mpox Continental Preparedness and Response Plan for Africa, September 2024-February 2025 was reported as collaborative, constructive and progressive. WHO and Africa CDC have a joint continental incident management system team based in Kinshasa, DRC. A significant achievement of this coordination is the alignment of the vaccine allocation process and the AAM with the Technical Review Committee and the vaccination group within the Continental IMST.

#### **Deliberative session**

Following the session open to invited States Parties, the Committee reconvened in a closed session to examine the questions in relation to whether the event constitutes a PHEIC or not, and if so, to consider the temporary recommendations drafted by the WHO Secretariat in accordance with IHR provisions.

The Chair reminded the Committee Members of their mandate and recalled that a PHEIC is defined in the IHR as an "*extraordinary event, which constitutes a public health risk to other States through the international spread of disease, and potentially requires a coordinated international response*".

## The Committee was unanimous in expressing the views that the ongoing upsurge of mpox still meets the criteria of a PHEIC and that the Director-General be advised accordingly.

The overarching consideration underpinning the advice of the Committee is the limited effectiveness and efficiency of the response implemented at local level, particularly in Burundi and the DRC, to interrupt MPXV transmission – specifically in terms of surveillance, laboratory diagnostics, contact tracing, and community education and engagement. If duly and systematically implemented early on, such interventions

could substantially contribute to the interruption of transmission both locally and globally, especially considering that access to mpox vaccine is often challenging, and the strategic use of vaccine has yet to be fully elaborated.

On that basis, and further elaborating upon issues addressed during the question and answers session, the Committee considered that:

The event is "**extraordinary**" because of (a) the increased number of mpox cases and geographical expansion of foci of MPXV clade Ib transmission within States Parties; (b) the evolving dynamics of MPXV clade Ib transmission – from within known commercial sexual networks, to within households, to the wider community – resulting in the infection of broader age-groups, and/or vulnerable population groups, and/or co-infection and co-circulation with other MPXV clades and/or pathogens, and, hence, generating uncertainties and unknowns in terms of morbidity and mortality, and, consequently, leading to new response challenges, including regarding clinical care; (c) the risk of MPVX clade Ib mutations in the context of sustained community transmission, resulting in new dynamics of transmission and/or virulence); (d) the ongoing prevalence of MPXV clade Ia infections in DRC with new foci of sexual network disease transmission in the capital Kinshasa.

The event "constitutes a public health risk to other States through the international spread of disease" because of (a) the documented recent exportation of MPVX clade Ib cases from States Parties where that clade is circulating to others within the WHO African Region and at least three additional WHO Regions; (b) the epidemiological link of exported MPVX clade Ib cases in the areas where exposure occurred is not known; (c) the risk that MPXV, and clade Ib in particular, is introduced in States Parties that may not comply with reporting requirement to WHO under IHR provisions, and/or may not have the capacities to implement response interventions.

The event **"requires a coordinated international response"** through (a) intensified engagement of international partners with national authorities to (i) raise the profile of mpox as public health priority, and (ii) strengthen prevention and response operations at the local level through the deployment of dedicated human resources and supplies; (b) mobilization of financial resources and their effective and efficient use; (c) the facilitation of equitable access to mpox including vaccines and diagnostics, including with the view to build capacity for the local and/or regional production of vaccine in the mid- to longer term.

The Committee indicated the need to start elaborating on the considerations that would inform their future advice to terminate the PHEIC while assessing the three criteria defining a PHEIC.

# The Committee subsequently considered the draft of the temporary recommendations proposed by the WHO Secretariat.

Notwithstanding that temporary recommendations constitute non-binding advice to States Parties, and noting that it was the first time that a set of temporary recommendations included one related to reporting on the implementation thereof, the WHO Secretariat presented the structure and outcome of the survey to that effect administered to, and completed online by the five States Parties to which the temporary recommendations issued on 19 August 2024 were directed to (Burundi, the DRC, Kenya, Rwanda and Uganda). Provided that the Director-General would determine that the event still constitutes a PHEIC, and issue temporary recommendations accordingly, the Committee formulated suggestions to the WHO Secretariat to improve the survey by encompassing the local dimension of the response, and to use the outcome of the survey for shaping the proposed temporary recommendations.

The Committee then considered the revised set of temporary recommendations proposed by the WHO Secretariat, should the Director-Generals determine that the event still constitutes a PHEIC. The Committee had received the proposed set ahead of the meeting and, noting the proposal to extend most of the temporary recommendations issued on 19 August 2024, the Committee formulated suggestions regarding the definition of "hot spot", referred to in some of the recommendations.

The Committee indicated that it would be giving further consideration to the proposed temporary recommendations while finalizing the report of the meeting.

#### Conclusions

The Committee reiterated its concern regarding the continuing spread of MPXV and uncertainties ensuing, and the effectiveness and efficiency of the response at the local level. The Committee underscored the need for the sustained commitment by national authorities in focusing efforts and resources at the local level to interrupt MPVX transmission, as well as the role of coordinated international cooperation in supporting and complementing such efforts in a synergistic manner. Therefore, the Committee considers that the determination by the WHO Director-General that the upsurge of mpox still constitutes a PHEIC would be warranted.

The WHO Deputy Director-General expressed his gratitude to the Committee's Officers, its Members and Advisor and closed the meeting.

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#### **Temporary recommendations**

**These temporary recommendations** are issued to **States Parties** experiencing the transmission of monkeypox virus (MPXV), **including**, but not limited to, those where there is **sustained community transmission**, and where there are clusters of cases or sporadic travel-related cases of MPXV clade Ib.

They are intended to be implemented by those States Parties in addition to the current <u>standing</u> recommendations for mpox, which will be extended until 20 August 2025.

In the context of the global efforts to prevent and control the spread of mpox disease outlined in the <u>WHO</u> <u>Strategic framework for enhancing prevention and control of mpox- 2024-2027</u>, the aforementioned <u>standing recommendations</u> apply to **all States Parties**.

All current WHO interim technical guidance can be accessed on <u>this page</u> of the WHO website. WHO evidence-based guidance has been and will continue to be updated in line with the evolving situation, updated scientific evidence, and WHO risk assessment to support States Parties in the implementation of the WHO Strategic Framework for enhancing mpox prevention and control.

Pursuant to Article 3 Principle of the International Health Regulations (2005) (IHR), the implementation of these temporary recommendations, as well as of the standing recommendations for mpox by States Parties shall be with full respect for the dignity, human rights and fundamental freedoms of persons, in line with the principles set out in Article 3 of the IHR.

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**Note:** The text in backets next to each temporary recommendation indicates the status with respect to the set of temporary recommendations issued on 19 August 2024. The following temporary recommendation issued on that occasion was terminated – "Prepare for the introduction of mpox vaccine for emergency response through convening of national immunization technical advisory groups, briefing of national regulatory authorities, preparing national policy mechanisms to apply for vaccines through available mechanisms".

#### **Emergency coordination**

- Secure political commitment and engagement to intensify prevention and response efforts, including resource allocation, in hot spots defined as the lowest operational level reporting mpox cases in the prior 4 weeks (NEW);
- Establish or enhance national and local emergency prevention and response coordination arrangements (EXTENDED, with re-phrasing);
- Establish or enhance the coordination of all partners and stakeholders engaged in or supporting prevention and response activities through cooperation, including by introducing accountability mechanisms (EXTENDED, with re-phrasing);
- Establish a mechanism to constantly monitor the effectiveness of prevention and response measures implemented in the hot spots, so that such measures can be adjusted as needed (NEW);
- Engage and strengthen partner organizations for collaboration and support, including humanitarian actors in contexts with insecurity or areas with internal or refugee population displacements and hosting communities insecure areas (EXTENDED, with rephrasing);

#### **Collaborative surveillance and laboratory diagnostics**

- Enhance surveillance, by increasing the sensitivity of the approaches adopted and ensuring comprehensive geographical coverage (EXTENDED);
- Expand access to accurate, affordable and available diagnostics to test for mpox, including through strengthening arrangements for the transport of samples, the decentralization of testing and arrangements to differentiate MPXV clades and conduct genomic sequencing (EXTENDED, with rephrasing);
- Identify, monitor and support the contacts of people with mpox to prevent onward transmission (EXTENDED);
- Scale up efforts to thoroughly investigate cases and outbreaks of mpox to understand the modes of transmission, and prevent its onward transmission to contacts and communities (EXTENDED, with rephrasing);
- Report to WHO suspect, probable and confirmed cases of mpox in a timely manner and on a weekly basis (EXTENDED);

#### Safe and scalable clinical care

• Provide clinical, nutritional and psychosocial support for patients with mpox, including, where appropriate and possible, isolation in care centres and materials and guidance for home-based care (EXTENDED, with re-phrasing);

- Develop and implement a plan to expand access to optimised supportive clinical care for all patients with mpox, including children, patients living with HIV, and pregnant women. This includes offering HIV tests to adult patients who do not know their HIV status and to children as appropriate, with linkages to HIV treatment and care services when indicated; and the prompt identification and effective management of endemic co-infections, such as malaria, varicella zoster and measles viruses, and other sexually transmitted infections (STIs) among cases linked to sexual contact (EXTENDED, with rephrasing);
- Strengthen health and care workers' capacity, knowledge and skills in the clinical and infection and prevention and control pathways –screening, diagnosis, isolation, to discharge of patients, including post discharge follow up for suspected and confirmed mpox –, and provide health and care workers with personal protective equipment (MODIFIED);
- Enhance infection prevention and control (IPC) measures and availability of water sanitation, hygiene (WASH) and waste management services and infrastructure in healthcare facilities and treatment centers to ensure quality healthcare service delivery and protection of health and care workers and patients (NEW);

### **International traffic**

• Establish or strengthen cross-border collaboration arrangements for surveillance, management and support of suspect cases and contacts of mpox, the provision of information to travellers and conveyance operators, without resorting to general travel and trade restrictions unnecessarily impacting local, regional or national economies (EXTENDED, with re-phrasing);

#### Vaccination

- Prepare for the integrated targeted use of vaccine for "Phase 1-Stop the outbreaks" (as defined in the WHO <u>"Mpox global strategic preparedness and response plan</u>" (2024)) through identifications of hot spots to interrupt sustained community transmission (NEW);
- Initiate plans for vaccination in the context of an integrated response in hot spots, targeting people at high risk of infection (e.g., contacts of cases of all ages, including sexual contacts, and health and care workers, etc.). This entails a targeted integrated response, including active surveillance and contact tracing, the agile adaptation of immunization strategies and plans to concerned hot spots; the availability of vaccines and supplies; the proactive community engagement, to generate and sustain demand for and trust in vaccination; and the collection of data during vaccination according to implementable research protocols (MODIFIED);

#### **Community protection** (MODIFIED)

- Strengthen, particularly in hot spots, risk communication and community engagement systems with affected communities and local workforces for outbreak prevention, response and vaccination strategies, including through training, mapping high risk and vulnerable populations, social listening and community feedback, while managing misinformation. This entails, inter alia, communicating effectively the uncertainties regarding the natural history of mpox, updated information about mpox including information from ongoing clinical trials, about the efficacy of vaccines against mpox, and the uncertainties regarding duration of protection following vaccination (MODIFIED);
- Address stigma and discrimination of any kind via meaningful community engagement, particularly in health services and during risk communication activities (EXTENDED);

• Promote and implement IPC measures and basic WASH and waste management services in household settings, congregate settings (e.g. prisons, internally displaced persons and refugee camps, etc.), schools, points of entry and cross border transit areas (MODIFIED, and previously under "Safe and Scalable Clinical Care");

## Governance and financing

- Galvanize and scale up national funding and explore external opportunities for targeted funding of prevention, readiness and response activities (EXTENDED);
- Integrate mpox prevention and response measures in existing programmes aimed at prevention, control and treatment of other endemic diseases especially HIV, as well as other STIs, malaria, tuberculosis, and COVID-19, as well as non-communicable diseases –, striving, to the extent possible, not to negatively impact their delivery (EXTENDED);

### Addressing research gaps

- Invest in addressing outstanding knowledge gaps and in generating evidence, during and after outbreaks, as defined in <u>"A coordinated research roadmap Mpox virus Immediate research next steps to contribute to control the outbreak"</u> (2024) (MODIFIED);
- Invest in field studies to better understand animal hosts and zoonotic spillover in the areas where MPXV is circulating (NEW);
- Strengthen and expand use of genomic sequencing to characterize the epidemiology and chains of transmission of MPXV to better inform control measures (NEW);

#### Reporting on the implementation of temporary recommendations

• Report quarterly to WHO on the status of, and challenges related to the implementation of these temporary recommendations, using a standardized tool and channels that will be made available WHO (EXTENDED).

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