Addendum to Fact Sheet 15 on National Implementation Measures for the International Health Regulations 2005 (IHR)

hMPXV (the human version of the monkeypox virus) as a Public Health Emergency of International Concern (PHEIC) under the IHR

The World Health Organization's (WHO) International Health Regulations 2005 (IHR) aim to prevent, protect against, control and provide a public health response to the international spread of disease, such as that caused by hMPXV. To avoid discrimination and stigmatisation, this publication refers to "hMPXV" to name the virus driving the 2022 international disease outbreak in humans. On <u>14 June 2022</u> the Director-General announced that "WHO is also working with partners and experts from around the world on changing the name of monkeypox virus, its clades and the disease it causes".



On 23 July 2022, Dr Rosamund Lewis, Technical lead for monkeypox, WHO Health Emergencies Programme, speaks during a press conference to update on the report of the 2nd meeting of the IHR Emergency Committee regarding the multi-country outbreak of monkeypox. During the press conference, WHO Director-General Dr Tedros stated that the global monkeypox outbreak represents a public health emergency of international concern (PHEIC). Photo credit: WHO / Lindsay Mackenzie

NOTIFICATION OF hMPXV AS AN "EVENT"

One way the IHR seeks to control the international spread of disease is by requiring states to report any "event" to the WHO that may constitute a "public health emergency of international concern", also known as a PHEIC (Article 6(1)).

An "event" is defined as a manifestation of disease or an occurrence that creates a potential for disease (Article 1). In May 2022, a number of outbreaks of hMPXV were reported to the WHO.

On 20 May 2022, WHO released a <u>statement</u> noting outbreaks of hMPXV in 11 countries and remarking that they were considered atypical. In light of the majority of cases being found in gay, bisexual and other men who have sex with men, it further emphasised that the stigmatisation of groups because of a disease is never acceptable and can be a barrier to ending an outbreak as it can prevent people from seeking care.

By <u>22 July 2022</u>, over 16000 laboratory confirmed cases of hMPXV and five deaths had been reported to the WHO from all six WHO Regions.

DETERMINATION OF hMPXV AS A "PHEIC"

Having received these reports, the WHO Director-General has the authority to determine whether these constitute a PHEIC (Article 12(1)). A PHEIC is an extraordinary event that poses a risk to the public health of more than one state because of the international spread of the disease, thereby potentially requiring a coordinated international response (Article 1(1)). To come to this determination, the WHO Director-General has to establish an Emergency Committee of experts that provides advice on the matter (Article 48(1)).

The WHO Director-General first convened this Emergency Committee for hMPXV on <u>23 June 2022</u>. At that time the committee decided by consensus that the outbreak did not represent a PHEIC and the Director-General concurred. It was recognised, however, that the situation was urgent and that the event should be closely monitored and reviewed after a few weeks.

The IHR Emergency Committee met again on <u>21 July 2022</u>. This time, the Committee Members were unable to reach a consensus regarding advice on determination of a PHEIC. However, the WHO Director-General, having considered the views of Committee Members and Advisors <u>as well</u> <u>as other factors in line with the IHR</u>, determined that the outbreak of the hMPXV constituted a PHEIC. He then issued a number of temporary recommendations under the IHR.



WHO'S TEMPORARY RECOMMENDATIONS FOR hMPXV

Under Article 15 of the IHR, a "temporary recommendation" refers to nonbinding advice issued by the WHO in response to a PHEIC on the basis of a risk assessment and for a limited amount of time. Their aim is to prevent species in countries may be suspected including in newly affected countries) the or reduce the international spread of disease and minimise interference with temporary recommendations were to: international traffic.

Photo credit• Heidi Soeters/PHII/CL

A number of temporary recommendations for hMPXV were issued on 23 July 2022. The recommendations apply to different groups of IHR States Parties on the basis of their epidemiological situation, patterns of transmission and capacities.

For Group 1 (States Parties, with no history of hMPXV in the human population or not having detected a case of hMPXV for over 21 days) the temporary recommendations included:

- Activate health and multi-sectoral coordination mechanisms to increase countermeasures) the temporary measures were: readiness to respond to hMPXV;
- Prepare interventions to avoid stigmatisation and discrimination against individuals and population groups;
- Establish and intensify disease surveillance in relation to hMPXV;
- Raise awareness about transmission, prevention and protective measures among communities that are currently most affected (e.g. importantly, but not exclusively, gay, bisexual and other men who have sex with men or individuals with multiple sexual partners) as well as among other STATES' population groups that may be at risk (e.g. sex workers, transgender people);
- Immediately report to WHO, through channels established under the provision of the IHR, probable and confirmed cases of hMPXV.

Group 2 (States Parties, with recently imported cases of hMPXV in the human population and/or otherwise experiencing human-to-human transmission of hMPXV, including in key population groups and communities at high risk of exposure) the temporary recommendations included:

- Implement response actions with the goal of stopping human-to-human transmission of hMPXV, with a priority focus on communities at high risk of exposure;
- Implement response actions with the goal of protecting vulnerable groups;
- Report probably and confirmed cases to the WHO under channels established by the IHR;
- Isolation and contact tracing for confirmed cases;
- Use of existing or new vaccines and therapeutics to tackle hMPXV;
- Individuals considered a suspect, probable or confirmed case of hMPXV to reconsider their measures. to avoid travel;
- Refrain from introducing any additional general or targeted international travel-related measures other than those specified in the recommendations.

For Group 3 (States Parties, with known or suspected zoonotic transmission of hMPXV, including those where zoonotic transmission of hMPXV is known to occur or has been reported in the past, those where presence of hMPXV has been documented in any animal species, and those where infection of animal

- Establish or activate collaborative One Health coordination or other mechanisms, between public health, veterinary, and wildlife authorities to understand, monitor and manage the risk of animal-to-human and human-to-animal transmission;
- Undertake detailed case investigations and studies to characterise transmission patterns, including suspected or documented spillovers from, and spillback, to animals.

For Group 4 (States Parties with manufacturing capacity for medical

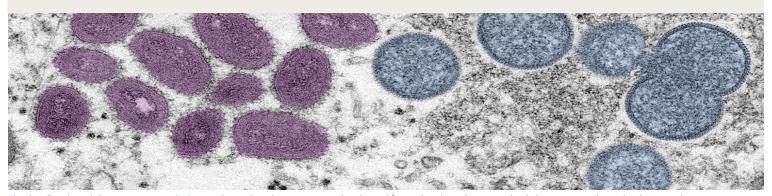
- States Parties with manufacturing capacity for smallpox and hMPXV diagnostics, vaccines or therapeutics to increase production and availability of medical countermeasures;
- To work with WHO to ensure medical countermeasures, and other necessary supplies are made available where they are most needed to support efforts to stop the onward spread of hMPXV.

IMPLEMENTATION OF THE TEMPORARY **RECOMMENDATIONS FOR hMPXV AND THEIR ADDITIONAL MEASURES**

By definition, the temporary recommendations issued by the WHO are recommended courses of action for states and not requirements. However, they constitute authoritative advice from international experts.

Under Article 43 of the IHR, states are allowed to take their own measures, so-called **additional measures**. However, these have to achieve the same or greater level of health protection than the WHO recommendations. States may even take measures that are otherwise prohibited by the IHR (such as requiring invasive medical examinations of travellers as a condition of entry into the state) provided they can show how these are otherwise consistent with the IHR.

Some of these additional measures may also significantly interfere with international traffic (i.e. refusals or delays of entry or departure of international travellers, baggage, cargo, containers, conveyances and goods for more than 24 hours). In that case, states are obliged to give the public health rationale and justification for these measures to the WHO within 48 hours of these measures' implementation. The WHO will review the justification and may request states



This digitally-colorized electron microscopic (EM) image depicted monkeypox virus particles, obtained from a clinical sample associated with the 2003 prairie dog outbreak. It was a thin section image from of a human skin sample. On the left were mature, oval-shaped virus particles, and on the right were the crescents, and spherical particles of immature virions. Photo credit: Cynthia S. Goldsmith, Russel Regnery, / Public Health Image library (PHIL), Centers of Disease Control and Prevention (CDC)

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