

# **SPECIAL SESSION OF THE DIRECTING COUNCIL**

## **SPECIAL SESSION OF THE REGIONAL COMMITTEE OF WHO FOR THE AMERICAS**

*Virtual Session, 5 August 2022*

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*Provisional Agenda Item 3.1*

CDSS2/2  
29 July 2022  
Original: English

### **UPDATE ON MONKEYPOX IN THE REGION OF THE AMERICAS AND ACCESS TO VACCINES**

#### **Background**

1. Monkeypox disease has been reported regularly in nine countries of Central and West Africa since its causal virus was first recognized in 1958 in the Democratic Republic of Congo (1). This occurrence has been linked to repeated zoonotic spillover events. However, since mid-May 2022, an unexpected and increasing number of monkeypox cases have been reported first in multiple countries in Europe and later in other regions, including the Americas. As of 20 July 2022, 14,533 probable and laboratory-confirmed cases were reported to the World Health Organization (WHO) from 72 countries across all six WHO regions (2). Of these, 3,388 cases (23%) were reported in 18 countries of the Americas.
  2. Since mid-May 2022, the Pan American Sanitary Bureau (PASB) has provided technical cooperation and support to the Member States of the Pan American Health Organization (PAHO) for the implementation of a series of comprehensive measures aimed at preventing and stopping the transmission of monkeypox virus. These measures include, among others, communication with and engagement of affected communities; activities to raise knowledge and awareness among health workers; early detection and surveillance of cases, including laboratory confirmation; and isolation of cases and tracing of contacts (3).
  3. Recognizing the complexities and uncertainties associated with this public health event and having considered the views of a committee of experts and advisors convened under the statutes of the International Health Regulations (2005) (IHR), the WHO Director-General declared on 23 July 2022 that the multi-country monkeypox outbreak constitutes a Public Health Emergency of International Concern (PHEIC). The temporary recommendations released jointly with this declaration include a recommendation that WHO Member States consider post- and pre-exposure vaccination against monkeypox of select at-risk groups, as a complement to several other measures (2).
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4. In response to PAHO Member State requests, PASB is working to secure access to safe and efficacious vaccines with indication for prevention of smallpox and monkeypox disease.

### **Situation Analysis**

5. There is currently only one smallpox and monkeypox vaccine, which is a live, non-replicating vaccine. Although it has not been approved in the WHO prequalification program, the vaccine has been licensed by the United States Food and Drug Administration (4), Health Canada (5), and the European Medicines Agency (6), with indication for prevention of smallpox and monkeypox disease in adults 18 years and older. As such, it meets the eligibility criteria to be procured through the PAHO Revolving Fund for Access to Vaccines (the Revolving Fund).

6. In anticipation of a potential regional need and in response to inquiries from several PAHO Member States regarding vaccine access, PASB initiated an early negotiation with the vaccine manufacturer for its eventual supply through the Revolving Fund. These discussions are ongoing, and PASB continues to analyze technical, regulatory, programmatic, legal, and ethical aspects of this matter, as well as logistics, price, and availability. PASB notes that global availability currently depends on a single manufacturer and supply is extremely limited, even though vaccine demand continues to increase.

7. PASB has conducted two meetings of the PAHO Technical Advisory Group (TAG) on Vaccine-Preventable Diseases. The TAG strongly endorses the WHO recommendation that only close contacts of a confirmed monkeypox case should be offered vaccination. Post-exposure vaccination (ideally within four days of exposure) may be considered by some countries for high-risk close contacts (7).

8. PASB recommends that each Member State convene its National Immunization Technical Advisory Group (NITAG) for any decision about the use of vaccine. The decision should be informed by a risk-benefit analysis and should take into account the WHO temporary recommendations issued by the Director-General on 23 July 2022. These recommendations call on States Parties of the IHR to make all efforts to use existing or new vaccines against monkeypox within a framework of collaborative clinical efficacy studies, using standardized design methods and data collection tools for clinical and outcome data, to rapidly increase evidence generation on efficacy and safety, collect data on effectiveness of vaccines (e.g., comparison of one- and two-dose vaccine regimens), and conduct vaccine effectiveness studies (2).

9. PASB notes that some of the supporting documents that the Revolving Fund usually obtains from manufacturers to facilitate importation processes may not be available because reference authorities have approved the vaccine only for emergency use. Each Member State will need to confirm its acceptance of product characteristics, assume certain liabilities, and possibly consent to provide exemptions for importation before PASB can issue a purchase order for that Member State. PASB will continue to provide technical

cooperation to national regulatory authorities to ensure that they have all relevant information needed for decision making, importation, and oversight of the product at country level.

10. On 15 July 2022, PASB convened a meeting with ministers of health of PAHO Member States to present various considerations and challenges regarding access to the monkeypox vaccine. At this meeting, the Director of PASB requested that Member States inform PASB of their interest in acquiring the vaccine through the Revolving Fund so that PASB could advance in discussions with the manufacturer.

11. As of 28 July 2022, 10 PAHO Member States have confirmed their interest in accessing this vaccine, and several other countries are in the process of discussing technical recommendations with their NITAGs.

12. Considering the recent WHO declaration of PHEIC and the extremely limited availability of smallpox and monkeypox vaccine at least for the foreseeable future, PASB considers that extraordinary negotiations are needed to ensure that the Region of the Americas has equitable access to this vaccine through the Revolving Fund. An equitable allocation entails prioritizing health needs, which will maximize the impact of the vaccines.

13. Given this situation, it is important to recall that in 2013, the Member States of PAHO, through Resolution CD52.R5 (8), ratified the principles, terms and conditions, and procedures of the Revolving Fund and instructed PASB to administer this Fund so that these principles are respected and fulfilled without exception. In view of the provisions of Resolution CD52.R5, PASB requests the authorization of Member States to continue working to secure a supply of monkeypox vaccine for the Region, even if the price and conditions offered are not fully aligned with the principles of the Revolving Fund.

#### **Action by the Directing Council**

14. In view of the limited worldwide availability of monkeypox vaccine, and to guarantee a supply of this vaccine to be used as per the VIII Ad Hoc Meeting of the PAHO Technical Advisory Group on Vaccine-Preventable Diseases (8), the Directing Council is invited to take note of this document and consider adopting the proposed resolution presented in the Annex.

Annex

**References**

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CDSS2/2  
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### ***PROPOSED RESOLUTION***

#### **UPDATE ON MONKEYPOX IN THE REGION OF THE AMERICAS AND ACCESS TO VACCINES**

##### ***THE SPECIAL SESSION OF THE DIRECTING COUNCIL,***

(PP1) Having reviewed the Update on Monkeypox in the Region of the Americas and Access to Vaccines (Document CDSS2/2);

(PP2) Recognizing the ongoing valuable efforts by the Pan American Health Organization (PAHO) Revolving Fund for Access to Vaccines (Revolving Fund) to secure access to monkeypox vaccines for the Member States of PAHO;

(PP3) Reaffirming the principles, terms and conditions, and procedures of the Revolving Fund and its benefit for public health in the Region of the Americas, as ratified by the Member States of PAHO in Resolution CD52.R5 (2013);

(PP4) Recognizing that the goal of the global response to the monkeypox outbreak is to stop transmission and to effectively use any public health measures to prevent onward spread of the disease, including the use of safe and efficacious vaccines;

(PP5) Recognizing that the Pan American Sanitary Bureau (PASB) requires the approval of the Member States of PAHO in order to conduct any extraordinary negotiation with manufacturers that may be needed in the current global context,

#### ***RESOLVES:***

(OP)1. To urge Member States to:

- a) implement temporary recommendations issued by the WHO Director-General in relation to the multi-country outbreak of monkeypox, as appropriate;
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- b) continue to recognize PASB and the Revolving Fund as the strategic regional technical cooperation mechanism most suitable for providing equitable access to monkeypox vaccine;
- c) promote solidarity and pan-Americanism through participation in the Revolving Fund;
- d) promote collaborative studies to fill evidence gaps and scale up pharmacovigilance efforts.

(OP)2. To request the Director to:

- a) continue to support the Member States of PAHO in implementing a coordinated response to address the multi-country outbreak of monkeypox, including supporting equitable access to monkeypox vaccine;
- b) provide technical cooperation and strategic support to national authorities to facilitate their access to relevant information needed for decision making, importation, deployment, and oversight of monkeypox vaccines at country level;
- c) maintain dialogue with partners and global producers of monkeypox vaccine in an effort to obtain doses of the vaccine for the Region of the Americas;
- d) conduct extraordinary negotiations with manufacturers for the best possible price for procurement of monkeypox vaccine for the Region of the Americas, and if necessary, as an exceptional measure, adjust the terms and conditions of the Revolving Fund in order to address the special circumstances that currently exist in order to secure a supply of monkeypox vaccines.

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