EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

General Working Group of the Health Security Committee Meeting

Monday 19 August 2024 – 10h00-12h30
Summary Report

Chair: Deputy Head of Unit, European Commission, DG SANTE B2

Participants: AT, BE, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, MT, NL, PL, PT, RO, SE, SI, SK, IS, LI, NO, DG SANTE, SG, DG ECHO, DG HERA, DG RTD, DG INTPA, JRC, EMA, ECDC, WHO, Africa CDC

EU/EEA only

Agenda points

1. Mpox global situation
    a. Epidemiological update in Africa
    b. International Health Regulation (IHR) Emergency Committee
2. Mpox epidemiological update and rapid risk assessment in the EU/EEA
3. Coordinated response at Eu/EEA level
    a. Discussion on a coordinated EU response to avoid any possible dissemination of Mpox (Clade I and II) within the EU/EEA
    b. Mpox vaccine and antiviral authorization
    c. Mpox vaccine and therapeutics procurement
    d. Mpox wastewater surveillance
    e. Summary of survey results on mpox public health measures
    f. Discussion and follow up actions

Key messages

DG SANTE called this meeting given the evolving situation of mpox in Africa and following the World Health Organization's (WHO) declaration on 14 August 2024 of the ongoing mpox outbreak in the African continent being a public health emergency of international concern (PHEIC) under the International Health Regulations.

1. International Health Regulation (IHR) Emergency Committee

The World Health Organization Regional Office for Europe (WHO EURO) gave a summary of the outcomes of the IHR emergency committee meeting that took place on 14 August. Following the meeting, the WHO declared that the upsurge of mpox in the Democratic Republic of the Congo (DRC) and a growing number of African countries constitutes a public health emergency of international concern (PHEIC). The Emergency Committee deliberated on whether to recommend designating mpox a PHEIC based on three criteria: 1. Serious, sudden, unusual, or unexpected event; 2. Event carries implications for public health beyond the affected state's national border; and 3. Event may require

immediate international concern. Given that there has been sustained and increased human-to-human transmission, reported deaths in children, spread of mpox to other African countries, and the response requires international collaboration, the Emergency Committee recommended declaring mpox a PHEIC.

The WHO IHR Emergency Committee has finalized its report from the meeting that took place on 14 August and will reconvene in three months' time to evaluate the situation. In August 2023, the WHO Director-General issued standing recommendations for mpox, which apply until the end of August 2024 and are also valid for the current ongoing mpox clade I outbreak. The standing recommendations include developing national mpox plans, strengthening testing and surveillance; increasing communication and engagement; investing in research; providing travelers with information; delivering optimal clinical care and working towards equitable access to safe, and effective vaccines. Finally, the WHO Director-General is planning to issue temporary recommendations as follow up to the recognition of the PHEIC.

2. Epidemiological update in Africa

The Africa Centres for Disease Control and Prevention (Africa CDC) gave an epidemiological update of mpox in the African continent. Since January 2024, there have been over 18.000 confirmed and suspected cases and 541 deaths reported in Africa, with most of the cases (94%) and deaths (99%) reported in the Democratic Republic of the Congo (DRC). Compared to the same period in 2023, there has been a 160% increase in the number of cases and 19% increase in the deaths. This outbreak presents a high case fatality rate (>3.2%). Children under 15 years of age represent the most affected age group, compromising 60% of the cases affected by MPXV (mpox virus) clade Ia. Africa CDC reported several challenges across the African region including limited testing, funding, contact tracing, case management, and sequencing capacities as well as limited surveillance. Other challenges include limited availability of vaccines and medical countermeasures to respond to the outbreak. Africa CDC explained that the reasons the Public Health Emergency of Continental Security (PHEC) was declared on 13 August include a significant increase in the number of suspected cases; an increase in the affected countries; documented reports of sexual transmission of MPXV clade I; and the limited understanding of the transmission dynamics of mpox.

Some countries asked for further clarification on the age distribution, specifically among children, of cases and deaths. Africa CDC reported that given the current level of data, it is not possible to provide this information yet.

3. Mpox epidemiological update and rapid risk assessment in the EU/EEA

The ECDC gave an update on the epidemiological situation and a summary of the latest Rapid Risk Assessment (RRA) published on 16 August. ECDC presented on some characteristics of MPXV clade I that are not sufficiently understood, such as the efficiency of transmission by different routes, the areas in Africa with ongoing community transmission, the epidemiology of clade Ia and Ib, the severity and clinical course by clade, and the case fatality by age groups and virus clade (and sub-clade).

In its latest RRA, the ECDC assessed the risk for EU/EEA citizens travelling to affected countries and having close contact with affected communities as moderate. It also concluded that the overall risk for the EU/EEA general population is currently assessed as low. However, if sustained transmission of mpox clade I is established in the EU/EEA, people with multiple sexual partners are at a higher likelihood of infection. Within this group, unvaccinated, immunocompromised individuals, and those who do not have a history of previous infection with mpox clade IIb are at higher risk of more severe illness.

The ECDC described the objectives of the current EU/EEA mpox response which includes supporting the response in Africa; preventing the importation of cases; preventing transmission events in the EU/EEA; ensuring the population is informed consistently and correctly; and addressing the knowledge gaps. ECDC also presented targeted recommendations for public health authorities.

The ECDC also presented possible triggers that could escalate the level of risk in the EU/EEA, including: secondary transmission within the EU/EEA; severe cases among EU citizens; if the epidemic situation becomes established in areas outside of Africa with higher chances of international spread; data emerge showing increased transmissibility through respiratory droplets; increases of clade I infections among risk groups through sexual transmission; and the identification of one case in the EU/EEA without a known epidemiological link.

4. Discussion on a coordinated EU response to avoid any possible dissemination of mpox within the EU/EEA

DG SANTE opened the floor for discussion on what the EU response to the current situation should be. Belgium explained they put forward a call for a coordinated EU response, which follows an official request from the Africa CDC and the DRC Ministry of Health. Belgium explained the need for a coordinated approach because there is a need to limit the outbreak in Africa and to reduce the risk of spread in the EU.

DG SANTE asked the HSC if there would be a need to update the 2022 HSC Opinion on Recommendations for a Common EU approach regarding vaccination policies for the mpox outbreak. At the moment, the Health Security Committee (HSC) agreed there is no need to update the Opinion or issue a new opinion. DG SANTE will continue consulting the HSC on the need to issue a HSC Opinion specific to the current mpox outbreak and, if needed, what elements should be included. At this point countries have not expressed need for such an opinion.

DG RTD highlighted the need to consider having a coordinated response for research as there are many knowledge gaps with the currently circulating clade Ib.

5. Mpox vaccines and antivirals authorization

The European Medicines Agency (EMA) gave an overview of the vaccine (Imvanex by Bavarian Nordic) and antiviral medication (Tecovirimat by SIGA Technologies Netherlands B.V.) with current market authorizations in the EU. The safety profile of the Imvanex vaccine in adults has been well characterized in clinical trials. The safety and immunogenicity of the vaccine in children below 18 years has not been established. Bavarian Nordic has recently submitted data to the EMA from a clinical trial in adolescents aged 12 to 17 and is under expediated assessment. Evidence on vaccine efficacy against clade I is expected based on animal studies and cross-reactive antibodies, however, effectiveness data are not available for the time being due to the unavailability of the vaccine in endemic African regions. Tecovirimat is well-tolerated and safe. Recent reports from a clinical trial conducted in DRC indicate that tecovirimat was not superior to placebo in mpox lesion resolution, and the provided clinical benefit comes to those who are treated early and with severe disease. However, the data have not yet been submitted to the EMA and only after proper assessment it will be possible to define any change on the recommended use of tecovirimat.

6. Mpox vaccine and therapeutics procurement

DG HERA gave an update on the procurement of vaccines and therapeutics, focusing on its efforts regarding the EU's preparedness to ensure medical countermeasures availability and support to African countries in light of the ongoing public health emergency. HERA recalled the Commission's purchase of mpox vaccines in 2022. The 334.540 doses were all donated to interested EU4Health

participating countries. It also reminded Member States that at EU level, with the support of DG ECHO, there are stockpiles of vaccines and antivirals in the rescEU stockpile, which can be used as a last resort in case of a need. Additionally, for vaccines there is a Joint Procurement Agreement with Bavarian Nordic for the purchase of up to two million vaccine doses, in which 14 EU/EEA countries are participating. For therapeutics there is a Joint Procurement agreement with Meridian Medical Technologies for the supply of up to 100.000 treatment courses of Tecovirimat SIGA, in which 13 EU/EEA countries are participating. On 14 August, the Commission, Bavarian Nordic, and Africa CDC signed a tripartite donation agreement for the donation of 215.000 vaccine doses to African countries to combat the mpox outbreak. HERA is also working closely with Africa CDC to enhance access to mpox diagnostics and genetic sequencing in the region. A €3.5 million grant is expected to be deployed in early autumn to support these efforts.

DG ECHO elaborated on the Union Civil Protection Mechanism (UCPM) for which there has been no request for assistance so far but highlighted that it is available for Member States to use in case there is a need. Furthermore, DG ECHO provides regular humanitarian funding to Africa and has provided EUR 1 million to contain the spread of mpox in the DRC. DG INTPA is also working on reprogramming funds following a request from Africa CDC.

7. Mpox wastewater surveillance

The Joint Research Centre (JRC) gave an update on the EU Wastewater Observatory for Public Health and explained that wastewater surveillance is used in the surveillance for mpox. Currently four EU/EEA countries have such surveillance in place. Two EU/EEA countries conduct wastewater for selective flights and at airports. None of the EU/EEA conducting wastewater surveillance have reported samples of MPXV clade I. The JRC stressed the importance of wastewater surveillance as a tool for tracking the virus's circulation in the population.

8. Summary of the results on mpox public health measures

A survey was shared with the HSC in preparation for the meeting asking for measures in place regarding the possible spread of MPXV clade I in the EU/EEA. Some countries reported planning communication campaigns to increase awareness as well as reviewing their preparedness plans including contact tracing and vaccination policies. Communication campaigns across the EU are targeting travellers returning from affected regions, clinicians, and groups at risk. The target groups for vaccination campaigns include at risk groups, healthcare professionals, laboratory professionals, and sex workers. Most of the countries report that the laboratory diagnostic methods used are able to detect both MPXV clade I and clade II (and subtypes). Some countries offer tecovirimat to cases affected by severe forms of mpox.

9. Discussion and follow up actions.

- This meeting provided an important opportunity for all parties to provide updates on the latest situation and coordinate next steps.
- The HSC agreed that, at this stage, there is no need to update the HSC opinion (on mpox vaccination issued in 2022) or issue a new opinion.
- Moreover, the HSC did not express a need to convene a meeting of the Advisory Committee on public health emergencies for considering a declaration of a public health emergency at Union level.
- DG SANTE will continue consulting the HSC on the need to issue a HSC Opinion specific to the current mpox outbreak and, if needed, what elements should be included. At this point countries have not expressed need for such an opinion.

- Belgium called for a coordinated approach, especially when it comes to travel guidance to avoid having conflicting recommendations across the EU/EEA. The Commission will further consult the Health Security Committee about the need for a HSC opinion on travel advice.
- The HSC members agreed on the importance of a closely coordinated approach and the need to continue monitoring the situation very closely.
- ECDC reiterated that, considering the current epidemiological situation, the risk for Europe is low. Possible triggers for escalating the level of risk in the EU/EEA – which are thus crucial to carefully monitor - include:
    - secondary transmission within the EU/EEA;
    - severe cases among EU citizens;
    - if the epidemic situation becomes established in areas outside of Africa with higher chances of international spread;
    - data emerge showing increased transmissibility through respiratory droplets;
    - increases of Clade I infections among risk groups through sexual transmission; and
    - the identification of one case in the EU/EEA without a known epidemiological link.
- Following WHO's declaration of a PHEIC (public health emergency of international concern), the WHO International Health Regulations Emergency Committee has finalized its report from the meeting that took place on 14 August. The Committee will reconvene in three months to evaluate the mpox situation.
- Moreover, the WHO Director-General will issue temporary recommendations as a follow-up to the 2024 mpox PHEIC recognition.
- WHO noted that the standing recommendations that were issued to State Parties in August 2023 (and that apply until the end of August 2024), are also valid to the current outbreak caused by mpox virus clade I. These include developing national mpox plans, strengthening testing and surveillance; increasing communication and engagement; investing in research; providing travellers with information; delivering optimal clinical care and working towards equitable access to safe, and effective vaccines.