



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

General Working Group of the Health Security Committee Meeting

Friday 06 September 2024 – 10h00-12h30

Summary Report

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

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

EU/EEA only

Agenda points

1. Mpox
 - a. Update on vaccines (including the mode of administration) and antivirals
 - b. Mpox global and Africa epidemiological situation
 - c. Mpox epidemiological update and recommendations
 - d. HSC survey results
 - e. MS measures in response to the mpox outbreak
 - f. Update on vaccines availability in the EU and donations to African countries
 - g. Update on Team Europe support actions to African countries
 - h. Research gaps and actions

Key messages

The meeting commenced with a warm welcome by DG SANTE, who outlined the agenda for the session and announced the upcoming General Working Group of the Health Security Committee meeting, now set to take place on 11 September in the afternoon (instead of the morning, to accommodate speakers from the US, who will provide an update on the avian influenza outbreaks)

The new Director of Public Health, Cancer, and Health Security at DG SANTE, Mr Antonio Parenti, extended a heartfelt welcome to the participants. He acknowledged the pivotal role of the Health Security Committee as a platform that facilitates the effective tackling of health threats at the EU level. Furthermore, Mr. Parenti reminded participants about the forthcoming in-person senior-level meeting of the Health Security Committee, scheduled to take place in Luxembourg on 13-14 November.

a. Update on vaccines (including the mode of administration) and antivirals

The European Medicines Agency (EMA) provided an update on its support to the African network of regulatory authorities, aiming to facilitate a joint review for the regulatory approval of mpox vaccines. Currently, these vaccines are only approved for use in two African countries.

The EMA announced that it is likely to recommend extending the approval of the mpox vaccine for use in adolescents aged 12-15 years, based on data submitted by Bavarian Nordic. This decision is expected

to be made before the end of September. However, the approval for use in children aged 2 and above will require a review of the trial data currently being collected in the Democratic Republic of Congo (DRC). As a result, the timeline for this approval is uncertain and may be longer.

EMA highlighted the need to mobilize manufacturing capacity. EMA also emphasized the importance of gathering more data on the intradermal administration of the vaccine, as well as use of the booster dose. Current data shows low antibody levels after two years, which may not necessarily indicate a loss of immune response. Further studies are needed to inform the use of booster doses.

EMA called for a coordinated study approach, utilizing the vaccine monitoring platform to identify study protocols that can help address knowledge gaps. This will enable a better understanding of the vaccine's effectiveness and inform its optimal use. Currently, the available evidence does not support a recommendation for booster doses. EMA will continue monitoring the situation and provide updates as more data becomes available.

b. Mpox global and Africa epidemiological situation

The World Health Organization (WHO), regional Office for Africa, provided an overview of the current mpox epidemiological situation in Africa, emphasizing that Mpox is affecting all continents, thus justifying the classification as Public Health Emergency of International Concern (PHEIC). As of the report date, the Democratic Republic of Congo (DRC) remains the most critical hotspot, with 444 reported deaths. However, other countries on the continent are now reporting new cases, including Guinea and Gabon, which have reported cases in the past week. In total, 17 countries in Africa have reported mpox cases.

The WHO confirmed that cases in Africa are attributed to both clade I and II, with subclade Ib being the most common in DRC, Uganda, and Burundi. The causes of rapid spread of subclade Ib are still unclear, and further research is needed to understand its transmission dynamics.

The WHO highlighted that the number of children affected by mpox suggests that transmission is not solely through sexual contact, but also through close contact within households. This indicates a need for targeted interventions to prevent transmission in these settings.

The WHO has classified African countries into four groups based on their epidemiological situation and defined corresponding prioritized activities for each group. Readiness assessments conducted by the WHO in countries neighbouring DRC have identified consistent gaps, highlighting areas for improvement.

The WHO outlined plans for vaccination deployment in DRC, which will involve adapted models tailored to specific areas and hotspots, including Goma in DRC. The goal is to ensure effective vaccination strategies that take into account local epidemiological conditions.

The WHO presented a comprehensive continental plan developed with Africa CDC. The plan addresses all aspects of the response, aiming to complement national plans. The plan requires adaptation and integration with each country's context to ensure effective implementation.

The WHO clarified that post-exposure vaccination is typically recommended within four days from exposure. However, in DRC, where community transmission is high, the vaccine will be offered regardless of the time since exposure to ensure protection against future contacts.

The WHO reported that most severe cases of mpox occur among people living with HIV, although exact data on deaths related to HIV coinfection is not available. Additionally, there is insufficient data at this

stage to define the exact transmission pathways for the new subclade. Further research is needed to better understand the epidemiology of mpox in Africa.

c. Mpox epidemiological update and recommendations

The European Centre for Disease Prevention and Control (ECDC) presented their activities on mpox, both within the EU and in Africa.

The ECDC emphasized their ongoing support for Africa while continuing to monitor cases in Europe. They proposed a country classification system, independent of the clade, based on the presence of imported cases, clusters of cases, or community transmission. The ECDC will discuss this classification system with EU/EEA countries.

The ECDC provided an overview of their ongoing activities, including:

- Expert deployment to the Democratic Republic of Congo (DRC)
- Organization of public webinars
- Organization of an ad hoc meeting of the National Immunization Technical Advisory Group (NITAG)
- Support provided to laboratories through the European Emerging and Vector-borne Diseases Network (EVD-Net)
- Surveying national laboratory capacities regarding clade testing and genomic surveillance

Furthermore, the ECDC announced the forthcoming publication on their website of guidance for:

- Traveling to affected areas.
- Management of patients, including self-isolation until resolution of lesions and contact tracing (self-monitoring for 3 weeks).
- Vaccination recommendations targeting high-risk groups for exposure and/or severe outcomes.

The World Health Organization Regional Office for Europe (WHO EURO) commented that they are also working on recommendations for travellers and discussing a possible country classification.

d. HSC survey results

DG SANTE presented an overview of the results from the HSC survey on Mpox preparedness and response.

Key findings of the HSC survey are:

- Over half of the countries surveyed plan to launch communication campaigns and update their vaccination strategies in response to Mpox.
- While few countries specified the targets of their communication campaigns, the majority aim to reach clinicians and high-risk groups.
- Eleven countries reported providing vaccines, with six countries providing additional details on their vaccination campaigns.
- Most countries offer vaccines in specialized clinics catering to patients with Sexually Transmitted Diseases.
- Laboratory capacity varies across countries, with 20 countries able to test for clades, although 11 countries only test a fraction of detected cases. Not all countries sequence viral material from all detected cases, and sequence sharing through the Global Initiative on Sharing All Influenza Data (GISAID) is not universal.

DG SANTE requested that the HSC provide additional information on:

- The current scope of Mpox vaccination activities
- Details on preparedness plans for Mpox

DG SANTE reminded the HSC of the EWRS functionality, which enables the sharing of information on public health measures. The chair encouraged HSC members to utilize this functionality to facilitate information exchange and coordination.

e. MS measures in response to the mpox outbreak

The Swedish representative provided an update on the imported case of Mpox subclade Ib, confirming that no secondary cases have been identified to date. Furthermore, Sweden has revised its guidance on Mpox to ensure that all isolates are sequenced, as opposed to the previous practice of only sequencing severe or imported cases.

The representative also reported that the issue has received significant media attention in Sweden, resulting in effective public awareness. In addition, Sweden has issued travel advice to inform travellers of the risks associated with travel to some African countries, as well as updated its vaccine recommendations to include travellers with higher risk of exposure.

f. Update on vaccines availability in the EU and donations to African countries

DG HERA provided a summary of the vaccine donation timelines, highlighting that the first 100,000 vaccine doses were delivered to the DRC on 05 September. In addition, DG HERA is coordinating EU country donations, which currently totals 560,000 doses. Efforts are being made to maximize the use of these vaccines. Some countries are intending to donate vaccines to African countries under the umbrella of the framework contract or through bilateral purchases of new vaccines, and some are intending to donate from national stocks, which is more complex due to logistical challenges and different conditions.

DG HERA also reported on an initiative focused on Mpox diagnostics in Africa, which has a budget of over €9 million. In addition, the DURABLE laboratory network has made significant contributions to the identification of clade Ib and the development of a PCR assay to detect the new clade.

Regarding the Joint Procurement of 2022, DG HERA noted that the existing contracts have upper ceilings of EUR 2 million doses for Imvanex vaccines and EUR 10 million for treatment courses of the antiviral Tecovirimat. According to the latest vaccine deployment data collected in July 2023, 385,000 doses have been administered. DG HERA does not have any information indicating that EU countries will require high volumes of vaccines, but seeks input from Member States on this matter.

DG HERA noted that some countries may be using the vaccine intradermally. ECDC highlighted that data collected in 2022/2023 showed that less than 20% of doses were administered intradermally.

g. Update on Team Europe support actions to African countries

DG INTPA provided an overview of the planned support to Africa under existing funding streams and projects. The support goes beyond vaccine provisions and aims to address all aspects of the response to Mpox, including strengthening health systems. This comprehensive approach is aligned with the continental plan, which seeks to build resilience and capacity in African countries to respond to the outbreak. DG INTPA highlighted that support will be provided through various funding channels and projects, focusing on strengthening health systems, improving surveillance and monitoring, and enhancing preparedness and response capacities. This multi-faceted approach aims to ensure a sustainable and effective response to the Mpox outbreak in Africa.

DG ECHO provided an update on the European Union's humanitarian support to Africa in response to the Mpox outbreak.

DG ECHO announced that funding has been allocated for the deployment of ECDC staff as part of the EU Health Task Force (EUHTF). The EUHTF will provide technical assistance and support to local health authorities in responding to the outbreak.

Additionally, DG ECHO reported that EU 1 million has been released to support response efforts in the DRC, EU 200,000 were released to replenish the Disaster Relief Emergency Fund (DREFT) from the International Federation of Red Cross and Red Crescent Societies (IFRC) for the response in Burundi and there is regular funding for surveillance of communicable diseases in Uganda and Kenya. Until now, the Union Civil Protection Mechanism (UCPM) has not been activated as no country has requested it.

EEAS reported about a discussion on Mpox organized by the American Ministry of Foreign Affairs and its work with EU Delegations specifically also to combat mis- and disinformation about the disease and the response that EEAS has been observing.

h. Research gaps and actions

DG RTD provided an update on the research initiatives and funding opportunities related to the Mpox response. DG RTD informed about the research studies that were funded during the 2022 outbreak, which aimed to address various aspects of the Mpox response.

DG RTD mentioned that additional funding was made available through the ECTDP3 (The European & Developing Countries Clinical Trials Partnership) network, which supports the development of clinical trials for infectious diseases, including Mpox. DG RTD noted that DG HERA and DG RTD are coordinating clinical trial mechanisms to facilitate the development and implementation of clinical trials for Mpox treatments and vaccines.

DG RTD also outlined potential priority areas for research, including:

- Understanding the new clade's transmissibility and how it differs from previous strains.
- Studies for vaccine efficacy of existing vaccines against the new clade and to inform vaccine development strategies.
- Studies to determine the optimal timing and efficacy of booster doses for Mpox vaccines.
- Studies to evaluate the efficacy of vaccines and treatments in specific populations, such as children, pregnant women, and immunocompromised individuals.

These research priority areas will help inform the development of effective countermeasures and response strategies for the Mpox outbreak.