



Recommendations for a common EU approach regarding vaccination policies for monkeypox outbreak response

Agreed by the Health Security Committee (HSC) on 30/09/2022

Introduction: the monkeypox outbreak in the EU/EEA

Since the start of the monkeypox (MPX) outbreak early May, the disease- endemic in West and Central Africa- is spreading for the first time in Europe and the total number of reported cases continues to grow, even if recent data suggest that the epidemic might have peaked in the European Union (EU). The reasons behind the reducing trend are unclear as several public health measures have been put in place, apart from vaccinations.

MPX is a viral zoonosis¹ and symptoms in the current outbreak seem less severe with two deaths reported in July and one in August out of a total number of cases detected as of 20 September 2022 in the EU/EEA: 19 827 cases.

In response to this multi-country outbreak, the European Centre for Disease Prevention and Control (ECDC) published a risk assessment on 23 May 2022², which was updated on 8 July 2022³ along with several technical documents including on risk communication and community engagement⁴.

The World Health Organization (WHO) declared the escalating global MPX outbreak a **Public Health Emergency of International Concern (PHEIC)** on 23 July 2022. Before and after the WHO declaration, extensive discussions have taken place in the Health Security Committee (HSC) on the MPX outbreak, including on possible strategies to be used as response. In addition to early diagnosis, isolation and effective contact tracing, strong risk communication, including on the need for behavioural change and community engagement efforts, awareness and educational activities for health professionals, vaccination strategies are key for the effective control of this ongoing outbreak. Currently only one vaccine, Imvanex (Bavarian Nordic A/S), is authorised in the EU for prevention of MPX disease in adults, to be used as a standalone 2-dose regimen.⁵ Imvanex is marketed as Jynneos in the US and considering the limited availability of Imvanex, EMA's Emergency Task Force (ETF) has recommended that Jynneos can be used to provide protection against monkeypox disease in the EU.

The overview provided by a survey conducted at the end of August among Health Security Committee Members shows that 18 out of 29 countries that have already national policies for

¹ A virus transmitted from animals to humans.

² [Risk assessment: Monkeypox multi-country outbreak \(europa.eu\)](https://ecdc.europa.eu/en/news-events/ecdc-releases-first-update-its-rapid-risk-assessment-monkeypox-outbreak)

³ <https://www.ecdc.europa.eu/en/news-events/ecdc-releases-first-update-its-rapid-risk-assessment-monkeypox-outbreak>

⁴ [Risk communication and community engagement approaches during the monkeypox outbreak in Europe; Monkeypox outbreak: Resource toolkit for event organisers Monkeypox infection prevention and control guidance for primary and acute care settings; ECDC publishes contact tracing guidance for the current monkeypox outbreak](https://ecdc.europa.eu/en/news-events/ecdc-releases-first-update-its-rapid-risk-assessment-monkeypox-outbreak)

⁵ <https://www.ema.europa.eu/en/news/ema-recommends-approval-imvanex-prevention-monkeypox-disease>.



the use of Jynneos/Imvanex vaccine with 11 currently working on their preparation. Sixteen countries have already started their vaccination activities.

Purpose of this document

Specific questions remain on which vaccination strategy to follow, particularly taking into consideration the current limited vaccine supply in most countries. This document therefore sets out the key elements to be taken into consideration by Member States for their national MPX vaccination strategies, in line with guidance issued so far by the ECDC/WHO and also bearing in mind their national epidemiological and public health contexts, including their supply of vaccines. By adopting this document, the Health Security Committee calls for a coordinated approach to respond effectively to the MPX outbreak, while taking into account the limited number of vaccines currently available and individual countries' settings. The aim is to have a discussed common approach to avoid "vaccine tourism" while strengthening the European Health Union via shared knowledge and responsibilities.

Options for monkeypox vaccination strategies

The Health Security Committee agrees that the following elements are recommended to be followed at national level for ensuring a coordinated approach to MPX vaccination:

- At this point in time (September 2022), mass vaccination for MPX is neither required nor recommended.
- **Vaccination strategies for MPX should be developed as part of the overall set of control measures**, including strengthening laboratory diagnostics and sequencing, increasing awareness among health professionals, also leveraging STI/HIV services, detecting and managing cases, isolation and contact tracing, risk communication and community engagement, etc.⁶.
- **Continued engagement of most affected communities** is needed to support and complement the MPX vaccination strategies, particularly as scientific evidence on MPX vaccine effectiveness in preventing MPX disease is currently limited. Communication should target risk groups without stigmatizing.
- **MPX vaccines can be used as Post-Exposure Vaccination (PEPV) or as Primary Preventive Vaccination (PPV).**
- Taking into account the current constrained vaccine supply, Member States can consider the feasibility of using Imvanex as intradermal injection as published by EMA on 19 August ⁷, considering it would allow an increase of vaccine coverage. However this mode of administration was linked to higher risk of local reactions in a randomized clinical trial. The lower dose administered intradermally could be used, preferably for PPV providing two doses within a 28 days interval.
- Modelling results conducted by ECDC & HERA showed that **pre-exposure prophylaxis seems to be the most effective strategy for the use of vaccines to**

⁶ See guidance documents published by the ECDC: [Risk communication and community engagement approaches during the monkeypox outbreak in Europe](#); [Monkeypox outbreak: Resource toolkit for event organisers](#); [Monkeypox infection prevention and control guidance for primary and acute care settings](#); [ECDC publishes contact tracing guidance for the current monkeypox outbreak](#).

⁷ [EMA's Emergency Task Force advises on intradermal use of Imvanex / Jynneos against monkeypox | European Medicines Agency \(europa.eu\)](#)



control the outbreak therefore, plans should be made to use monkeypox vaccine for populations at high risk of exposure – based on vaccine availability in each country.

Specific considerations for PPV and PEPV and for the use of both strategies would be the following:

PPV – Primary Preventive Vaccination

- Prioritisation of individuals at substantially higher risk of exposure can be considered according to a risk assessment based on certain criteria or behaviour among men & transgender persons having sex with men;
- The success of PPV efforts depend on, amongst other factors, acceptance of the vaccination by target groups and at risk groups and, of course, upon sufficient supply of vaccines;
- PPV for occupational risk exposure can be considered for staff members who work in “sex on premises” venues, if they are regularly exposed to items or surfaces likely to be contaminated with body fluids or skin cells;
- Based on risk assessment, professionals in healthcare or laboratory settings and outbreak response team members may be targeted for PPV;
- Some other high risk populations such as (female) sex workers might also be considered.

PEPV – Post-Exposure Vaccination

The feasibility of implementing PEPV would depend on an effective contact tracing, referral and screening process and lastly upon vaccine uptake levels.

- The PEPV priority target groups are close contacts of cases⁸. Among these, contacts with a high risk of developing severe disease such as children, and pregnant women should be considered on a case by case basis, since the vaccine has not been yet approved for use in these groups. A written consent form might be used to target these special populations and studies are encouraged;
- The time of vaccination should be as close as possible to the potential date of exposure, ideally within four days of first exposure (and up to 14 days in the absence of symptoms);
- Community engagement efforts for the identification of contacts around cases should be put in place in order to achieve a significant impact on lowering disease burden and transmission.

Combined PPV & PEPV

- In the context of limited vaccine supply a suitable option would be to offer PEPV prioritizing close contacts of cases and/or contact at high risk of severe disease.

⁸ I.e., sexual partners, household contacts, HCWs and individuals with other prolonged physical or high-risk contact as defined in the recent ECDC publication on contact tracing.



- PPV would be offered to laboratory staff and other high risk occupational exposure among health care providers **along with** targeted PPV of individuals at substantially higher risk of exposure. In the context of the current outbreak, for instance, priority may be given to gay, bisexual, transgender and other men who have sex with men (MSM) that meet at least one of the following criteria:
 1. MSM using or eligible for Pre-Exposure Prophylaxis (PrEP) for HIV infection;
 2. MSM with history of at least one sexually-transmitted disease (STD) in the last six months;
 3. Persons living with HIV (PLHIV) with at least one STD in the last six months;
 4. MSM reporting engaging in group sex and/or in chem-sex practices in the last year;
 5. Participation in sexual encounters in clubs/saunas or other establishments;
 6. MSM having multiple sexual partners in the last six months;
 7. MSM & transgender persons who have sex with men who are sex workers;
 8. MSM who have more than one partner who are HIV+;
 9. MSM who plan to engage in sex with several partners.

Less restrictive criteria maybe considered for priority groups as increased amount of vaccine would be available, starting from considering all MSM living with HIV.

Effectiveness and safety of the vaccine – European collaboration is essential

Systematic data collection on the effectiveness and safety of the vaccine, independently of the adopted vaccination strategy would be pivotal. Currently, the evidence of vaccine efficacy for monkeypox is very limited therefore generation of data by countries via systematic data collection is recommended. In addition, they are invited to join multi-country studies of those currently ongoing or to develop new protocols focusing on vaccine use. Here participating countries can take advantage of additional resources made available by the European Commission via the HORIZON EUROPE programme⁹, using the VACCELERATE network¹⁰ and the support provided by the European Medicines Agency (EMA).

There is a need for countries to commit to collecting data on vaccine administration as these are part of their agreement, if receiving vaccine donations from the European Commission.

Pharmacovigilance reporting according to the EMA guidance for the management of cases of adverse reactions associated to Jynneos or Imvanex use in EU Member States in prevention of monkeypox disease will also need to be implemented.

The generation of evidence on vaccine use collected systematically either under studies or as part of the national public health protocols is vital to allow prepare for the next outbreak, should this one be contained, or to better respond to the current one making a better use of the vaccine once supply would increase.

⁹ https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe_en

¹⁰ <https://vaccelerate.eu/>