EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency

List of critical medicines for Monkeypox public health emergency (PHE) under Regulation (EU) 2022/123

Regulation (EU) 2022/123 provides the European Medicines Agency with a framework to monitor and mitigate potential and actual shortages of centrally and nationally authorised medicinal products for human use considered as critical to address a given 'public health emergency'[1] or 'major event'[2].

As further defined in the Regulation, following the recognition of a public health emergency, the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) is responsible for adopting a list of medicinal products considered to be critical during the public health emergency (the 'public health emergency critical medicines list').

[1] 'public health emergency' means a public health emergency recognised by the European Commission in accordance with Decision No 1082/2013/EU
[2] 'major event' means an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State. Such an event concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin or incident that can affect the supply, demand or quality, safety, and efficacy of medicinal products. Such an event may lead to shortages of medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection according to Article 2(b) of Regulation (EU) 2022/123.

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On 19 August the MSSG adopted a list of authorised medicines considered critical for the treatment and protection against Monkeypox and for which supply and demand will be closely monitored in EU/EEA countries.

The list of critical medicines includes all authorised Monkeypox vaccine and therapeutic **(Table 1)** and will be subject to update when necessary, to take into account any changes in Monkeypox epidemiology in EU/EEA which may give rise to an increased risk of shortages of a particular medicine or following the authorisation of new medicines in the EU.

The list will remain in place until the end of the public health emergency.

The MSSG adopted the list after consultation with the Medicines Shortages SPOC Working Party (SPOC WP), and other relevant groups, including the Emergency Task Force (ETF), EMA's Patients' and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Party (HCPWP) and EU Industry (Trade) Associations.

Supply and demand of the medicines included in the list will be closely monitored so that potential shortages can be avoided or managed early. Marketing authorisation holders for medicines on the list will regularly provide EMA with information on potential and existing shortages, including available stocks and forecasts of supply and demand. In addition, national competent authorities, through the SPOC Working Party, will provide regular reports on estimated demand for these medicines at national level. Medicines for which demand is likely to exceed supply will be discussed by the MSSG who will decide on the need for further actions.

The list does not pre-empt or reflect national procurement decisions, nor should it be read as recommendations on national stockpiles.

The list should not be read as providing guidance on the use of Monkeypox products in individual Member States and also does not reflect recommendations for use to treat or prevent Monkeypox. Decisions on vaccination campaigns, the choice of vaccine or treatment and how they are allocated are made at national level.

Table 1. List of critical medicines for Monkeypox public health emergency - authorised Monkeypox therapeutics and vaccines

Product name	International non-proprietary name (INN) or common name	Active substance	Pharmaceutical form(s)	Route of administration	Strengths
Tecovirimat SIGA	Tecovirimat monohydrate	Tecovirimat	Hard capsule	Oral use	All
Imvanex	Smallpox and monkeypox vaccine (Live Modified Vaccinia Virus Ankara)	Modified Vaccinia Ankara – Bavarian Nordic Live virus	Suspension for injection	Subcutaneous use	All