EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Media and Public Relations

News announcement

EMA response to the monkeypox public health emergency

The European Medicines Agency (EMA) has initiated a series of actions to respond to the ongoing monkeypox outbreak, which has been escalated by the World Health Organization (WHO) to a Public Health Emergency of International Concern (PHEIC) on Saturday 23 July. This is the first new PHEIC to be declared since the regulation reinforcing EMA's role in crisis preparedness and management of medicinal products and medical devices has become applicable.

Since the start of the recent monkeypox outbreak, EMA has been monitoring the situation closely and already taken multiple actions to prepare for and support the EU response. This includes the Agency's recommendation on 22 July to approve an extension of indication for the vaccine Imvanex to protect adults from monkeypox disease. The new powers given to the Agency under its extended mandate trigger additional activities now that monkeypox has been declared a public health emergency.

Monitoring of supply, demand and shortages of medicinal products

The EMA Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), established by the new Regulation, will produce and maintain a formal **list of critical medicines** for the monkeypox public health emergency. The list will be drawn up in a collaborative process involving Member States, healthcare professionals, patients and consumers.

Marketing authorisation holders of medicines included in the list will be required to regularly update EMA with relevant information on potential or actual shortages and available stocks, forecasts of supply and demand. In addition, Member States will provide regular reports on estimated demand for these medicines at national level.

This will enable the MSSG to recommend and coordinate appropriate EU-level actions to the European Commission and EU Member States in order to prevent or mitigate potential or actual shortages of critical medicines to safeguard public health.

There are currently **two medicinal products** authorised specifically for monkeypox in the EU:

- The medicine Tecovirimat SIGA is authorised for use to treat smallpox, monkeypox and cowpox.
- The vaccine Imvanex is authorised to protect adults against smallpox and monkeypox. Imvanex is marketed as Jynneos in the US and considering the limited availability of Imvanex, the ETF has

recommended that Jynneos can be used to provide protection against monkeypox disease in the EU.

Emergency Task Force (ETF)

The remit of EMA's Emergency Task Force (ETF) will be formally extended to deal with both COVID-19 and monkeypox. The ETF was initially set up during the COVID-19 pandemic to bring together the best expertise available in the EU medicines regulatory network. Recognising its central role in guiding and accelerating the development and authorisation of medicines during an emergency, it has been formalised through the new Regulation.

In relation to the monkeypox outbreak, the ETF was already activated to discuss the treatments and vaccines available, and the possible medical countermeasures. Following the declaration of a PHEIC, the ETF's composition will be reviewed and formally approved by EMA's Management Board, taking into account specific expertise relevant to the therapeutic response to the monkeypox outbreak.

The tasks of the ETF will then be formally expanded to cover monkeypox, including providing **scientific advice and reviewing the available scientific data** on medicinal products that have the potential to address the public health emergency, coordinating **independent monitoring studies** on the use, effectiveness and safety of medicinal products intended to be used against monkeypox, as well as giving **recommendations to the Member States on the use of an unauthorised medicinal product**, upon request from the European Commission or a Member State.

Of particular importance is the need to give advice on **clinical trial protocols** and **provide advice to developers on clinical trials** for medicinal products intended to treat, prevent or diagnose the disease causing the public health emergency. The ETF can also provide **scientific support to facilitate clinical trials**. The aim of these support activities for developers, including academics, is to enable rapid approval and conduct of large, well-designed trials, including platform trials, that can provide the robust data needed to enable decision making and to avoid duplication of investigations.

In the context of the monkeypox outbreak, the ETF has already been facilitating the conduct of large multinational trials in the EU on the use of the antiviral tecovirimat and the vaccine Imvanex by reviewing the trial protocols and liaising with the Clinical Trial Coordination Group (CTCG) and national regulatory bodies to coordinate and facilitate the approval of clinical trial applications by national competent authorities.

EMA closely cooperates with national competent authorities, European Union bodies and agencies, including the European Centre for Disease Prevention and Control (ECDC) and the European Commission's DG SANTE and Health Emergency preparedness and Response Authority (HERA), the WHO, third countries, and international scientific organisations, on scientific and technical issues that relate to the public health emergency and to medicinal products which have the potential to protect public health.

Notes

1. EMA has created a new functional mailbox (PHEearlyinteractions@ema.europa.eu) to help developers contact its Health Threats and Vaccines Strategy Office, which supports the activities of the ETF.

2. Clinical trial sponsors can use a dedicated mailbox (PHEsupportCT@ema.europa.eu) to submit their proposal together with the study protocol and the list of countries where they wish to conduct the trial, if available.

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