27 June 2022
EMA/606208/2022

Monkeypox: EMA starts review for Imvanex

Emergency Task Force (ETF) gives advice on importation of US vaccine

EMA's human medicines committee (CHMP) has started a review of data to extend the use of the smallpox vaccine Imvanex to include protecting people from monkeypox disease.

Imvanex is currently authorised in the EU for the prevention of smallpox in adults. It contains a live modified form of the vaccinia virus called 'vaccinia Ankara', which is related to the smallpox virus. It is also considered a potential vaccine for monkeypox because of the similarity between the monkeypox virus and the smallpox virus.

The decision to start this review is based on results from laboratory studies (non-clinical data) suggesting that the vaccine triggers the production of antibodies that target the monkeypox virus and may help protect against the disease.

Supplies of Imvanex are currently very limited in the EU. Imvanex is marketed as Jynneos in the US where it is authorised for the prevention of both monkeypox and smallpox.

Advice on use of Jynneos

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 task force has given this advice to support national authorities who may decide, as a temporary measure, to import Jynneos from the US in view of the rising rates of infection across the EU.

The ETF noted the US FDA's conclusion that the efficacy of Jynneos in the prevention of monkeypox disease can be inferred from the antibody responses against the vaccinia virus in clinical studies.

In addition, studies in animals, including primates, showed that the vaccine protected animals who were exposed to the monkeypox virus and boosted pre-existing immunity induced by earlier generations of smallpox vaccines.

The most commonly reported side effects with Jynneos are pain, redness, swelling, itching and hardening at the injection site, muscle pain, headache and fatigue. Further information about the ETF's advice is available here [LINK].

The ETF has given its advice to address the outbreak of monkeypox in multiple EU countries in the context of its public emergency preparedness activities which include giving advice to support regulatory activities and product-related assessments.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

More about the vaccine

Jynneos/Imvanex is expected to prepare the body to defend itself against infection with smallpox and monkeypox. It contains a modified form of the vaccinia virus called vaccinia Ankara, a virus that is closely related to the variola (smallpox) virus and monkeypox virus but does not cause disease in humans and cannot replicate (reproduce) in human cells. Because of the similarity between the smallpox virus and the monkeypox virus, antibodies produced against it are also expected to protect against monkeypox.

When a person is given the vaccine, the immune system recognises the virus in the vaccine as 'foreign' and makes antibodies against it. When the person comes into contact again with this or similar viruses, these antibodies together with other components of the immune system will be able to kill the viruses and help protect against disease.

More about monkeypox

Monkeypox is a rare disease caused by infection with the monkeypox virus, which causes symptoms similar to those of smallpox. Monkeypox begins with fever, headache, muscle aches and exhaustion and can be fatal, even though it is typically milder than smallpox. It is transmitted to people from various wild animals, such as rodents and primates, but can also be transmitted between people following close contact. Current outbreaks reported since May 2022 are the first reported outside of Africa with no links to endemic areas.

More about the procedures

The review on the use of Imvanex against monkeypox was started on the basis of ETF's advice. EMA will now assess the available data while awaiting a formal application to extend the use of Imvanex from the company that markets the vaccine.

This type of review process is one of the ways authorities in the EU are working to ensure that EU Member States have timely access to a vaccine against monkeypox.

The ETF has given advice on the use of Jynneos during the review of Imvanex in the context of EMA's preparedness activities. The task force continues to monitor the monkeypox outbreak in Europe and is in close contact with public bodies, including the European Centre for Disease Prevention and Control (ECDC) and the European Health Emergency preparedness and Response Authority (HERA), and with developers to help make medicines available for preventing and treating monkeypox.