Communication of the President of the Office of 28 June 2022 on the review of the European Medicines Agency's data on the extended coverage of Imvanex smallpox vaccine to protect humans against monkeypox

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PREZES
Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych

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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.

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 Food and Drug Administration’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.

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.

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 information available on the EMA website: https://www.ema.europa.eu/en/news/monkeypox-ema-starts-review-imvanex [1]

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President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Odnośniki
[1] https://www.ema.europa.eu/en/news/monkeypox-ema-starts-review-imvanex