Communication of the President of the Office of 22 July 2022 on the recommendation to extend the indication for Imvanex smallpox vaccine to include protection of adults against monkeypox by the CHMP and the EMA.

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PREZES
Urzędu Rejestracji Produktów Leczniczych,
Wyrobów Medycznych i Produktów Biobójczych

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The medicine has been approved in the EU since 2013 for the prevention of smallpox. It contains an attenuated (weakened) form of the vaccinia virus called 'modified vaccinia virus Ankara', which is related to the smallpox virus. It was also considered a potential vaccine for monkeypox because of the similarity between the monkeypox virus and the smallpox virus. The marketing authorisation holder is Bavarian Nordic A/S.

The CHMP based their recommendation on data from several animal studies which showed protection against the monkeypox virus in non-human primates vaccinated with Imvanex. The CHMP considered that the effectiveness of Imvanex in the prevention of monkeypox disease in humans could be inferred from these studies.

To confirm the effectiveness of the vaccine against monkeypox, the company will collect data from an observational study that will be carried out during the ongoing monkeypox outbreak in Europe.

The safety profile of the medicine is favourable, with mild to moderate side effects, and the CHMP concluded that the medicine's benefits are greater than the risks.

In addition to the use for the prevention of monkeypox, the CHMP recommended authorising Imvanex to protect people against disease caused by vaccinia virus, which leads to symptoms similar to, but milder than those of smallpox.

The product information for Imvanex will be updated shortly with information for healthcare professionals and members of the public.

An assessment report with details of EMA's evaluation of Imvanex will be published on the EMA website.

More information will be available in an overview of the vaccine in lay language, including a description of the vaccine's benefits and risks and why EMA recommended its authorisation in the EU.

More information available on the website: https://www.ema.europa.eu/en/news/ema-recommends-approval-imvanex-prevention-monkeypox-disease [1]

on behalf of President

Vice-President for Medicinal Products
Office for Registration of Medicinal Products,
Medical Devices and Biocidal Products
/-/ Marcin Kołakowski

Źródłowy URL: https://archiwum.urpl.gov.pl/pl/node/7146

Odnośniki
[1] https://www.ema.europa.eu/en/news/ema-recommends-approval-imvanex-prevention-monkeypox-disease