



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 May 2013
EMA/CHMP/256704/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Imvanex

Modified Vaccinia Ankara virus

On 30 May 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the vaccine against smallpox called Imvanex by Bavarian Nordic A/S. This recommendation will now be forwarded to the European Commission, which will issue a legally binding decision.

Imvanex is recommended to be used for "active immunisation against smallpox in adults". The CHMP recommended that Imvanex be used for primary vaccination (individuals previously not vaccinated against smallpox) or booster vaccination (for individuals previously vaccinated against smallpox) and can also be used in immunocompromised people.

The active substance of Imvanex is Modified Vaccinia Ankara virus – Bavarian Nordic (MVA-BN) live virus. It is a live attenuated virus which works by inducing the immune system to produce antibodies against the smallpox virus. It will be available as a suspension for subcutaneous injection. As opposed to traditional smallpox vaccines, it is non-replicating which means that it does not proliferate in the body.

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Imvanex's benefits are greater than its risks following the assessment of five main studies involving healthy and immunocompromised people. The studies showed that Imvanex was effective at stimulating an immune response against MVA-BN when used as primary or as booster vaccination. However, due to the rarity of the condition and the fact that clinical trials cannot be carried out, comprehensive data on the efficacy and safety was not available at the time of the assessment and the CHMP therefore recommended that Imvanex be approved for use in the EU under exceptional circumstances.²

Regarding its safety, Imvanex is generally well tolerated. The most common side effects are headache, myalgia, nausea, fatigue and erythema, induration, pruritus or swelling at the injection site.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

² In exceptional circumstances, an authorisation may be granted subject to certain specific obligations, to be reviewed annually. This happens when the applicant can show that they are unable to provide comprehensive data on the efficacy and safety of the medicinal product, due to the rarity of the condition it is intended for, limited scientific knowledge in the area concerned, or ethical considerations involved in the collection of such data.



Detailed recommendations on the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.