22 August 2014
EMA/521678/2014
Committee for Medicinal Products for Human Use (CHMP)

Imvanex

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: modified vaccinia ankara virus

Procedure No. EMEA/H/C/002596/PSUV/0007

Period covered by the PSUR: 31.07.2013 to 30.11.2013

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7455
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for IMVANEX, the scientific conclusions of PRAC are as follows:

The PRAC considered that whilst currently, there appears to be one case of serious hypersensitivity reaction vaccination in clinical trials, there is a plausible temporal relationship between vaccination and the onset of events. Therefore the PRAC requested that this risk should be reflected in section 4.8 of the SmPC by including the term 'angioedema'. The Patient Leaflet is updated accordingly.

Therefore, in view of available data regarding Imvanex, the PRAC considered that changes to the product information were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for IMVANEX, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance modified vaccinia ankara virus is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.