13 December 2012
EMA/CHMP/800917/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Ixiaro

Japanese encephalitis vaccine (inactivated, adsorbed)

On 13 December 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Ixiaro. The marketing authorisation holder for this medicinal product is Intercell AG. They may request a re examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a change to the indication as follows:

"Ixiaro is indicated for active immunization against Japanese encephalitis in adults, adolescents, children and infants aged 2 months and older."

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

For information, the full indication for Ixiaro will be as follows[2]:

Ixiaro is indicated for active immunization against Japanese encephalitis in adults, **adolescents, children and infants aged 2 months and older**.

Ixiaro should be considered for use in individuals at risk of exposure through travel or in the course of their occupation.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.
[2] The text in bold represents the new or the amended indication.

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