9 November 2017
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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): japanese encephalitis virus (inactivated)

Procedure No. EMEA/H/C/PSUSA/00001801/201703

Period covered by the PSUR: 1 April 2016 – 31 March 2017

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for japanese encephalitis virus (inactivated), the scientific conclusions of CHMP are as follows:

After review of available periodic and cumulative information on syncope including convulsive syncope, the PRAC noted that most of the reports of vaccination induced seizures, in particular where syncope was explicitly reported or where onset was temporally close to vaccination, seemed to belong to the category of 'convulsive syncope' with causation being mostly related to vasovagal mechanisms suggesting that they may have been administration related. Therefore, the PRAC is recommending an update to the SmPC section 4.8 to add the term 'syncope' with the frequency rare. The Package leaflet is being updated accordingly.

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

Grounds for the variation to the terms of the marketing authorisation

On the basis of the scientific conclusions for japanese encephalitis virus (inactivated) the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing japanese encephalitis virus (inactivated) is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation should be varied.