EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Adjupanrix

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

International non-proprietary name: pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted)

Procedure No.: EMEA/H/C/001206/PSUV/0032

Period covered by the PSUR: 20 May 2012 – 19 May 2013

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Scientific conclusions

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

In relation to the identified risk of fever in children (<6 years), the PRAC does not agree with the MAH that the EU SmPC contains appropriate information on this safety concern. As an identified risk, an appropriate warning should be included in section 4.4. Moreover section 4.8 should be revised to reflect reactogenicity data from the three paediatric studies D-Pan H5N1-009, -013 and 032.

Therefore, in view of the available data regarding fever in children, 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 Adjupanrix, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance split influenza virus, inactivated, containing antigen A/VietNam/1194/2004 (H5N1) like strain used (NIBRG-14) (produced in eggs) is favourable subject to the proposed changes to the product information.

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