EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 October 2014
EMA/CHMP/26367/2015
Committee for Medicinal Products for Human Use (CHMP)

Focetria

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

Common name: influenza vaccine h1n1v (surface antigen, inactivated, adjuvanted)

Procedure No. EMEA/H/C/000710/PSUV/0033

Period covered by the PSUR: 23 March 2013 – 22 March 2014

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Scientific conclusions

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

Based on the findings of an observational study conducted in >2000 pregnant women, reflecting the use of Focetria in pregnant women, influenza A (H1N1) vaccination with Focetria does not seem to be associated with an increased risk of adverse pregnancy outcomes, especially in the second or third trimesters of pregnancy. Therefore, the relevant SmPC wording currently stating the limited availability of clinical data in pregnant women, is recommended to be changed to reflect the newly available information.

Therefore, in view of available data regarding the use of Focetria during pregnancy, 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 Focetria, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance influenza vaccine h1n1v (surface antigen, inactivated, adjuvanted) is favourable subject to the proposed changes to the product information.

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