EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

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

International non-proprietary name: prepandemic influenza vaccine (h5n1) (surface antigen, inactivated, adjuvanted)

Procedure No. EMEA/H/C/PSUSA/00010008/201410

Period covered by the PSUR: 20 October 2013 – 19 October 2014

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) / prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted), the scientific conclusions of CHMP are as follows:

In line with other vaccines, the Core Safety Information includes a warning on anxiety-related reactions (including syncope, hyperventilation or stress-related reactions), as a psychogenic response to the needle injection. This warning is already reflected in the SmPC of Foclivia. The PRAC requested that a similar warning is added to Section 4.4 of the SmPC for Aflunov and Prepandemic Influenza vaccine with this PSUR assessment procedure. The PRAC also requested that the package leaflets for these products should be updated accordingly.

Therefore, in view of available data regarding pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) / prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted), the PRAC considered that changes to the product information of prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) 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 prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing prepandemic influenza vaccine (H5N1) (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.