19 November 2015
EMA/146531/2016
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): influenza vaccine (surface antigen, inactivated, prepared in cell cultures)

Procedure No. EMEA/H/C/PSUSA/00001745/201504

Period covered by the PSUR: 1 September 2014 to 30 April 2015

Medicinal product no longer authorised

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for influenza vaccine (surface antigen, inactivated, prepared in cell cultures), the scientific conclusions of CHMP are as follows:

In the context of signal evaluation activities, the MAH has conducted a search in its safety database of all cases of paraesthesia reported cumulatively until 30 April 2015. The search retrieved 25 cases of paraesthesia for Optaflu. Of those cases 20 reported paraesthesia within one to three days of vaccination, including 17 cases where paraesthesia was the primary symptom. The outcome was reported as recovered in eight cases, improved in two cases, unchanged at time of reporting in five and unknown in 10 cases. While limited information is available a causal role of influenza vaccine (surface antigen, inactivated, prepared in cell cultures) could not be completely excluded.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing influenza vaccine (surface antigen, inactivated, prepared in cell cultures) were warranted.

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

Grounds for the variation to the terms of the Marketing Authorisation(s)

On the basis of the scientific conclusions for influenza vaccine (surface antigen, inactivated, prepared in cell cultures) the CHMP is of the opinion that the benefit risk balance of the medicinal product(s) containing influenza vaccine (surface antigen, inactivated, prepared in cell cultures) is favourable subject to the proposed changes to the product information

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

Medicinal product no longer authorised