20 November 2014
EMA/CHMP/26383/2015
Committee for Medicinal Products for Human Use (CHMP)

Optaflu

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

Common name: influenza vaccine (surface antigen, inactivated, prepared in cell cultures)

Procedure No. EMEA/H/C/000758/PSUV/0070

Period covered by the PSUR: 1 September 2013 – 30 April 2014

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

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

During the current PSUR period (19 May 2014), the MAH updated their reference safety information regarding the AE term Extensive Limb Swelling (ELS) and announced an adaptation of the EU SmPC/PL accordingly. It was noted that ELS is a rare but known reaction that may occur with any vaccine. Based on the review of ten cases presented in this PSUR, ELS has been reported in 4 cases cumulatively and cannot be excluded in 4 cases.

Therefore, in view of available data regarding extensive limb swelling, 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 Optaflu, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance 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.