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EMA/482801/2014
Committee for Medicinal Products for Human Use (CHMP)

# Nimenrix

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

International non-proprietary name: meningococcola group a, c, w135 and y conjugate vaccine

Procedure No. EMEA/H/C/002226/PSUV/0020

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

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## Scientific conclusions

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

No new signals were evaluated during the reporting period; however the MAH conducted an evaluation of extensive limb swelling (ELS)/severe injection site reactions cases received during the reporting period. These events are currently classified as an important potential risk in the Risk Management Plan (RMP). In light of the results of the evaluation, and based on the existent biological plausibility, the MAH has agreed to upgrade these events to an identified risk in the next RMP version. The MAH will include the term 'extensive limb swelling' in the reference safety information (RSI). As identified risks should be reflected in the product information (PI) and the MAH has agreed to include the term ELS at the injection site with a frequency of rare in the Nimenrix summary of product characteristics (SmPC) and package leaflet (PL).

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 Nimenrix, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance MENINGOCOCCAL GROUP A, C, W135 AND Y CONJUGATE VACCINE is favourable subject to the proposed changes to the product information.

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

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