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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): meningococcal group a, c, w135, y conjugate vaccines (conjugated to tetanus toxoid carrier protein)

Procedure No. EMEA/H/C/PSUSA/00010044/202004

Period covered by the PSUR: 20 April 2019 to 19 April 2020

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## Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for meningococcal group a, c, w135, y conjugate vaccines (conjugated to tetanus toxoid carrier protein), the scientific conclusions of CHMP are as follows:

In view of available data, the PRAC considers that a causal relationship between Nimenrix and lymphadenopathy cannot be ruled out. The PRAC concluded that the product information of products containing Nimenrix should be amended accordingly.

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 meningococcal group a, c, w135, y conjugate vaccines (conjugated to tetanus toxoid carrier protein) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing meningococcal group a, c, w135, y conjugate vaccines (conjugated to tetanus toxoid carrier protein) is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.