



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

16 February 2012  
EMA/CHMP/70728/2012  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Nimenrix

#### Meningococcal group A, C, W135 and Y conjugate vaccine

On 16 February 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Nimenrix, powder and solvent for solution for injection intended for active immunisation of individuals from the age of 12 months and above against invasive meningococcal diseases caused by *Neisseria meningitidis* group A, C, W-135 and Y. The applicant for this medicinal product is GlaxoSmithKline Biologicals. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Nimenrix is a Meningococcal group A, C, W138 and Y conjugate vaccine, Meningococcal vaccines (J07AH08) where the anti-capsular meningococcal antibodies protect against meningococcal diseases via complement mediated bactericidal activity.

The benefits with Nimenrix are its ability to prevent invasive disease caused by *Neisseria meningitidis* groups A, C, W-135 and Y in individuals from 12 months and above. The most common side effects are redness, pain and swelling. A pharmacovigilance plan for Nimenrix will be implemented as part of the marketing authorisation.

The approved indication is: "Indication for active immunisation of individuals from the age of 12 months and above against invasive meningococcal diseases caused by *Neisseria meningitidis* group A, C, W-135 and Y". The use of this vaccine should be in accordance with official recommendations. It is proposed that Nimenrix is prescribed by physicians experienced in the treatment of invasive disease caused by *Neisseria meningitidis* groups A, C, W-135 and Y.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.



The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Nimenrix and therefore recommends the granting of the marketing authorisation.