European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 17 December 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
MENVEO

Common Name: ***Meningococcal Group A, C, W-135 and Y Coniugate Vaccine***

On 17 December 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Menveo, MenA-CRM_{197}, MenC- CRM_{197}, MenW_{135}- CRM_{197} and MenY- CRM_{197} (Meningococcal groups A, C, W and Y oligosaccharides Conjugated to Corynebacterium diphtheriae CRM_{197} Protein) powder and solution for injection intended for the active immunization of adolescents (from 11 years of age) and adults at risk of exposure to Neisseria meningitidis groups A, C, W135 and Y, to prevent invasive disease. The use of this vaccine should be in accordance with official recommendations. The applicant for this medicinal product is Novartis Vaccines and Diagnostics S.r.l.

The active substance of Menveo is a Meningococcal Group A, C, W-135 and Y Coniugate Vaccine, belongs to the therapeutic group of Meningococcal vaccines (ATC code: J07AH). The efficacy of Menveo has been inferred by measuring the production of serogroup-specific anti-capsular antibodies with bactericidal activity. Serum bactericidal activity (SBA) was measured using human serum as the source of exogenous complement (hSBA). The hSBA was the original correlate of protection against meningococcal disease.

The benefits with Menveo are its ability to prevent invasive disease caused by Neisseria meningitidis groups A, C, W_{135} and Y in adolescents (from the age of 11 years old) and adults. The most common side effects are pain, erythema and induration, headache, myalgia, chills, and malaise.

A pharmacovigilance plan for Menveo, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: active immunization of adolescents (from 11 years of age) and adults at risk of exposure to Neisseria meningitidis groups A, C, W135 and Y, to prevent invasive disease. The use of this vaccine should be in accordance with official recommendations. It is proposed that Menveo is prescribed by physicians experienced in the treatment of invasive disease caused by Neisseria meningitidis groups A, C, W135 and Y.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

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

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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