15 March 2012
EMA/CHMP/187861/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Menveo

meningococcal group A, C, W135 and Y conjugate vaccine

On 15 March 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Menveo. The marketing authorisation holder for this medicinal product is Novartis Vaccines and Diagnostics S.r.l. They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new indication for the powder (in vial) with solution (in vial) presentations only (EU/1/10/614/002, EU/1/10/614/003) as follows:

Menveo is indicated for active immunisation of children (from 2 years of age), adolescents 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.

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

For information, the full indication for the Menveo powder (in vial) with solution (in vial) presentations will be as follows[2]:

"Menveo is indicated for active immunization of ~~adolescents~~ **children** (from ~~11~~ **2** years of age), **adolescents** 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."

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.
[2] The text in bold represents the new or the amended indication.

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