22 September 2011
EMA/CHMP/763049/2011
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Prevenar 13

pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed)

On 22 September 2011, 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 Prevenar 13. The marketing authorisation holder for this medicinal product is Wyeth Lederle Vaccines S.A.. 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 as follows:
" Active immunisation for the prevention of invasive disease caused by *Streptococcus pneumoniae* in adults aged 50 years and older ".
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(s) for Prevenar 13 will be as follows[2]:

Active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* in infants and children from 6 weeks to 5 years of age.

Active immunisation for the prevention of invasive disease caused by *Streptococcus pneumoniae* in adults aged 50 years and older.

See sections 4.4 and 5.1 for information on protection against specific pneumococcal serotypes.

The use of Prevenar 13 should be determined on the basis of official recommendations taking into consideration the impact of invasive disease in different age groups as well as the variability of serotype epidemiology in different geographical areas.

[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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