



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 January 2015
EMA/CHMP/39942/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Prevenar 13

pneumococcal polysaccharide conjugate vaccine

On 22 January 2015, 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 Pfizer Limited. 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 change to an indication as follows²:

Active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* in infants, children and adolescents from 6 weeks to 17 years of age.

Active immunisation for the prevention of invasive disease **and pneumonia** caused by *Streptococcus pneumoniae* in adults ≥ 18 years of age and the elderly.

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 risk of invasive disease **and pneumonia** in different age groups, underlying comorbidities as well as the variability of serotype epidemiology in different geographical areas.

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.

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.

