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

London, 24 September 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
PREVENAR 13

Common Name:
Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed)

On 24 September 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending the granting of a marketing authorisation for the medicinal product Prevenar 13, 13-valent pneumococcal conjugate vaccine adsorbed intended for "Active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* in infants and children form 6 weeks to 5 years of age".

The applicant for this medicinal product is Wyeth Lederle Vaccines SA.

The active substance of Prevenar 13 is Pneumococcal polysaccharide conjugate vaccine 13-valent, adsorbed, included the *Streptococcus pneumoniae* polysaccharide serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F each conjugated to a carrier protein (Pneumococcal vaccine, J07AL02), which act by developing an immune response protecting against the above-mentioned diseases.

The benefits with *Prevenar 13* are its ability to prevent invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* in infants and children. The most common side effects are injection-site reactions, fever, irritability, decreased appetite, and increased and/or decreased sleep.

A pharmacovigilance plan for Prevenar 13, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: "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. See sections 4.4 and 5.1 for information on protection against specific pneumococcal serotypes". The immunisation schedules for Prevenar 13 should be based on official recommendations.

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 Prevenar 13 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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