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

London, 22 January 2009
Doc.Ref. EMEA/CHMP/13120/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
SYNFLORIX
Common Name: ***pneumococcal polysaccharide conjugate vaccine (adsorbed)***

On 22 January 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Synflorix, suspension for injection, intended for the "active immunisation against invasive disease and acute otitis media caused by Streptococcus pneumoniae in infants and children from 6 weeks up to 2 years of age".
The applicant for this medicinal product is GlaxoSmithKline Biologicals S.A.

The active substances in the 10-valent vaccine Synflorix included the *Streptococcus pneumoniae* polysaccharide serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F each conjugated to a carrier protein (Pneumococcal vaccine, J07AL52), which act by developing an immune response protecting against the above-mentioned diseases.
The benefits with Synflorix are its capability to prevent invasive disease and acute otitis media caused by Streptococcus pneumoniae in infants and children. The most common side effects after primary vaccination are redness at the injection side and irritability.

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

The approved indication is: "Active immunisation against invasive disease and acute otitis media caused by *Streptococcus pneumoniae* in infants and children from 6 weeks up to 2 years of age. See sections 4.4 and 5.1 for information on protection against specific pneumococcal serotypes. The use of Synflorix 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."

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 Synflorix and therefore recommends the granting of the marketing authorisation.

* 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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