



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 June 2011
EMA/CHMP/497733/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion¹ (post authorisation)

Synflorix

pneumococcal polysaccharide conjugate vaccine (adsorbed)

On 23 June 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 Synflorix. The marketing authorisation holder for this medicinal product is GlaxoSmithKline Biologicals S.A.

The CHMP adopted a change to an indication as follows:

“Active immunisation against invasive disease and acute otitis media caused by *Streptococcus pneumoniae* in infants and children from 6 weeks up to 5 years of age.”

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 Synflorix will be as follows²:

Active immunisation against invasive disease and acute otitis media caused by *Streptococcus pneumoniae* in infants and children from 6 weeks up to **5** 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.

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.

