EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 October 2013
EMA/CHMP/389824/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Synflorix

Pneumococcal polysaccharide conjugate vaccine (adsorbed)

On 24 October 2013, 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. 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 indicationas follows:
"Active immunisation against invasive disease, pneumonia 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 follows[2]:

Active immunisation against invasive disease, **pneumonia** 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.

The use of Synflorix should be determined on the basis of official recommendations taking into consideration the impact on **pneumococcal**~~invasive~~ disease**s** in different age groups as well as the variability of ~~serotype~~ **the** 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7<sector fax>
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union