EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 October 2013
EMA/355025/2014
Committee for Medicinal Products for Human Use (CHMP)

Assessment report under Article 46

Infanrix hexa

International non-proprietary name: diphtheria (d), tetanus (t), pertussis (acellular, component) (pa), hepatitis b (rdna) (hbv), poliomyelitis (inactivated) (ipv) and haemophilus influenzae type b (hib) conjugate vaccine (adsorbed)

Procedure No. EMEA/H/C/000296/P46/110

Note

Assessment report as adopted by the CHMP with all information of a commercially confidential nature deleted.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

ADMINISTRATIVE INFORMATION

Currently approved indication(s):	Infanrix hexa is indicated for primary and booster vaccination of infants against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and disease caused by *Haemophilus influenzae* type b.

1. RECOMMENDATION

Based on the review of the data from study 10PN-PD-DIT-028 (Synflorix, COMPAS study) the Rapporteur considers that the benefit-risk balance for Infanrix hexa remains unchanged. Please refer to the ongoing Synflorix variation application EMEA/H/C/973/II-52 for detailed information.

2. BACKGROUND

The study reports of 10PN-PD-DIT- 028, i.e. Interim Report Main, Report Main and Annex Report Main, are being submitted to comply with the requirements of Article 46 of the Paediatric Regulation (EC) No 190112006.

Study 10PN-PD-DIT-028 (=COMPAS study) was a phase III, randomized, controlled multicentre study conducted in healthy children in Argentina (42 centres), Panama (16 centres) and Colombia (3 centres) to evaluate Synflorix' efficacy against community acquired pneumonia (CAP) and acute otitis media (AOM).

Synflorix (10Pn-PD-DiT vaccine) is a 10-valent pneumococcal polysaccharide conjugate vaccine composed of Streptococcus pneumoniae polysaccharide serotypes 1,4, 5, 6B, 7F, 9V, 14, 23F conjugated to protein D, serotype 18C conjugated to tetanus toxoid and serotype 19F conjugated to diphtheria toxoid.

Infanrix-hexa was not specifically studied in this study. All subjects in the control group of the COMPAS study were administered Infanrix hexa at 2, 4 and 6 months of age in addition to a booster shot at 15-18 months of age.

According to Product Information, Infanrix hexa can be administered at the same time as Prevenar (pneumococcal saccharide conjugated vaccine, adsorbed).

3. SCIENTIFIC DISCUSSION

No immunogenicity results were generated for Infanrix-hexa in the COMPAS study. Since Infanrix-hexa was co-administered with other vaccines in the study, the safety analysis performed in the study does not relate to the administration of this vaccine alone. The overall safety conclusion from the study was

that Synflorix was generally well tolerated when administered according to a 3+ I dose schedule in subjects aged between 6 and 16 weeks at the time of the first vaccination.

Assessor's note: *for the study design as well as the aim of the different study reports, please refer to the ongoing Synflorix variation application EMEA/H/C/973/II-52 for detailed information.*

4. MAH'S OVERALL CONCLUSION

GlaxoSmithKline has reviewed the results of this study and has concluded that no changes to the Product Information are needed since no data specifically on Infanrix hexa were obtained in this study.

5. RAPPORTEUR's CONCLUSION

The MAH's overall conclusion is endorsed.

6. REQUEST FOR SUPPLEMENTARY INFORMATION AND MODIFICATION OF THE SPC

None