21 February 2013
EMA/CHMP/113895/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Hexacima

Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and *Haemophilus influenzae* type B conjugate vaccine (adsorbed)

On 21 February 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Hexacima, 0.5 ml, suspension for injection intended for primary and booster vaccination of infants and toddlers from six weeks to 24 months of age against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by *Haemophilus influenzae* type b.

The applicant for this medicinal product is Sanofi Pasteur S.A. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Hexacima are diphtheria toxoid (D), tetanus toxoid (T), two-component acellular pertussis (pertussis toxoid (PTxd) and filamentous haemagglutinin (FHA)), inactivated poliomyelitis virus types 1,2 and 3 (IPV), *Haemophilus influenzae* type b polysaccharide (polyribosylribitol phosphate) conjugated to tetanus protein (PRP-T) and hepatitis B surface antigen (HBsAg).

The benefits with Hexacima are its ability to protect infants and toddlers from six weeks to 24 months of age against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by *Haemophilus influenzae* type b. The vaccine can be used as primary or a booster vaccination. It is given as three doses at least four weeks apart in accordance with official recommendations.

The most common side effects are pain, swelling, induration and erythema at the injection site, vomiting, irritability, somnolence, anorexia, pyrexia, abnormal (prolonged) crying, and diarrhoea.

A pharmacovigilance plan for Hexacima will be implemented as part of the marketing authorisation.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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The approved indication is:

“Hexacima (DTaP-IPV-HB-Hib) is indicated for primary and booster vaccination of infants and toddlers from six weeks to 24 months of age against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by *Haemophilus influenzae* type b (Hib).

The use of this vaccine should be in accordance with official recommendations.”

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made 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 there to be a favourable benefit-to-risk balance for Hexacima and therefore recommends the granting of the marketing authorisation.