21 June 2012
EMA/CHMP/409930/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1]

Hexaxim

diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA),poliomyelitis (inactivated) and *Haemophilus influenzae* type b conjugate vaccine (adsorbed) combined bacterial and viral vaccine

On 21 June 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a scientific opinion in accordance with Article 58 of Regulation (EC) No 726/2004, for the medicinal product Hexaxim, 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 scientific opinion holder for this medicinal product is Sanofi Pasteur. It may request a re-examination of this CHMP opinion, provided it notifies the European Medicines Agency in writing of its intention within 15 days of receipt of the opinion.

Hexaxim is a hexavalent paediatric combination vaccine, ATC code J07CA09.

The active substances in Hexaxim 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 of Hexaxim 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 Hexaxim will be implemented as part of the post-opinion commitments.

[1] Scientific opinion in accordance with Article 58 of (EC) No Regulation 726/2004 in the context of cooperation with the World Health Organisation (WHO)

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The approved indication is:

“Hexaxim 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.”

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).

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Hexaxim 0.5 ml suspension for injection.

This medicinal product Hexaxim 0.5 ml suspension for injection is exclusively intended for markets outside the European Union.