17 December 2015
EMA/CHMP/777080/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vaxelis

diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus type B conjugate vaccine (adsorbed)

On 17 December 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Vaxelis, intended for prophylaxis against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by *Haemophilus influenzae* type b (Hib), in infants and toddlers from the age of 6 weeks. The applicant for this medicinal product is Sanofi Pasteur MSD SNC.

Vaxelis will be available as a suspension for injection in pre-filled syringes. The active substances of Vaxelis are derived from diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus type B bacteria. Vaxelis is a combined bacterial and viral vaccine (ATC code: J07CA09) that works by inducing the immune system to mount a specific immune response against the antigens included in its formulation.

The benefits with Vaxelis are its ability to elicit immune responses to each antigen, which are above predefined thresholds of protection and non-inferior to immune responses of a comparator vaccine after the booster dose. The most common side effects are decreased appetite, somnolence, vomiting, crying/irritability, fever and injection site reactions (erythema, pain and swelling).

The full indication is: “primary and booster vaccination in infants and toddlers from the age of 6 weeks against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by *Haemophilus influenzae* type b (Hib). The use of Vaxelis 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.

[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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