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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: diphtheria, tetanus, pertussis (acellular, component), hepatitis b (rdna), poliomyelitis (inact.) and haemophilus type b conjugate vaccine (adsorbed)

Procedure No. EMEA/H/C/PSUSA/00001122/201410

Period covered by the PSUR: 23 October 2011 – 22 October 2014

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

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for diphtheria, tetanus, pertussis (acellular, component), hepatitis b (rdna), poliomyelitis (inact.) and haemophilus type b conjugate vaccine (adsorbed), the scientific conclusions of CHMP are as follows:

Due to the misalignment of several adverse events between the MAH's reference safety information and the SmPC, the PRAC recommends update of the SmPC of Infanrix Hexa to include upper respiratory tract infection (uncommon) and bronchitis (rare) from clinical data, and thrombocytopenia (rare) from post-marketing data. The package leaflet is updated accordingly. Furthermore, the risk of apnoea and the need for respiratory monitoring when administering the primary immunisation series to very premature infants (born ≤28 weeks of gestation) should be more spread among parents in order to determinate the appropriate timing and modalities of the immunisation. Therefore, the PRAC considers that changes to the PL were also warranted; specifically, section 2 should advise parent on what they need to know before their child receives Infanrix Hexa and that they should talk to the doctor or pharmacist before the child is given Infanrix Hexa if the baby was born very prematurely (at or before 28 weeks of gestation). In these babies, longer gaps than normal between breaths may occur for 2-3 days after vaccination and they may require respiratory monitoring for 48-72h following the administration of the first two or three doses of Infanrix Hexa.

The SmPC of Infanrix Hexa is also recommended to be updated with detailed information on the experience with hepatitis B vaccine, which is already reflected in the MAH's reference safety information for this medicinal product. The following events are to be added: Allergic reactions mimicking serum sickness, neuritis, hypotension, vasculitis, lichen planus, erythema multiforme, arthritis and muscular weakness.

Therefore, in view of available data regarding respiratory disorders and the experience with hepatitis B vaccine, the PRAC considered that changes to the product information were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for diphtheria, tetanus, pertussis (acellular, component), hepatitis b (rdna), poliomyelitis (inact.) and haemophilus type b conjugate vaccine (adsorbed) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing diphtheria, tetanus, pertussis (acellular, component), hepatitis b (rdna), poliomyelitis (inact.) and haemophilus type b conjugate vaccine (adsorbed) is favourable subject to the proposed changes to the product information

The CHMP recommends that the terms of the Marketing Authorisation should be varied.