RISK MANAGEMENT PLAN – PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for PENTAVAC/ PENTAXIM (DTaP-IPV/Hib)

This is a summary of the risk management plan (RMP) for Diphtheria, Tetanus, acellular Pertussis, inactivated Poliomyeleitis vaccine-Hib (reconstituting Act-HIB) (DTaP-IPV/Hib) vaccine. The RMP details important risks of DTaP-IPV/Hib vaccine how these risks can be minimized and how more information will be obtained about DTaP-IPV/Hib vaccine's risks and uncertainties (missing information).

DTaP-IPV/Hib vaccine summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how DTaP-IPV/Hib vaccine, should be used.

I. THE MEDICINE AND WHAT IT IS USED FOR

DTaP-IPV/Hib vaccine is indicated for active immunization against diphtheria, tetanus, pertussis, poliomyelitis and invasive infections caused by *Haemophilus influenzae* type b (Hib) (such as meningitis, septicemia, cellulitis, arthritis, epiglottitis, pneumopathy and osteomyelitis) (see SmPC for the full indication):

- for primary vaccination in infants, and
- for booster vaccination in children who have previously received a primary vaccination with this vaccine or a diphtheria-tetanus-whole cell pertussis or acellular pertussis-poliomyelitis vaccine, whether mixed or not with freeze-dried conjugate hib vaccine.

DTaP-IPV/Hib vaccine, suspension for injection, is obtained by reconstitution (rehydration) of the powder of conjugate Hib vaccine (vial) with the suspension of combined diphtheria, tetanus, acellular pertussis (DTaP) and IPV, adsorbed (pre-filled syringe). The diphtheria and tetanus toxins, obtained from cultures of *Corynebacterium diphtheria* and *Clostridium tetani*, are formaldehyde detoxified and then purified. The poliomyelitis vaccine is obtained from the propagation of poliovirus types one, two and three on Vero cells. The pertussis toxin (ptx) is inactivated by glutaraldehyde, which is then purified and then treated with formaldehyde. The acellular pertussis (aP) components (pertussis toxoid and Filamentous Hemagglutinin [FHA]) are extracted from *Bordetella pertussis* cultures, and then purified separately. The FHA is native. This vaccine contains the polyribosylribitol phosphate of Hib conjugated to tetanus protein.

II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERIZE THE RISKS

Important risks of DTaP-IPV/Hib vaccine, together with measures to minimize such risks and the proposed studies for learning more about DTaP-IPV/Hib vaccine's risks, are outlined in the next sections.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals (HCPs);
- Important advice on the medicine's packaging;
- The medicine's legal status - the way a medicine is supplied to the patient (eg, with or without prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

Information about adverse reactions is collected continuously and regularly analyzed, including periodic benefit-risk evaluation report (PBRER) assessment, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A List of important risks and missing information

Any identified and potential risks of DTaP-IPV/Hib vaccine require investigation to assure product safety. Important risks of DTaP-IPV/Hib vaccine are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of DTaP-IPV/Hib vaccine. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (eg, on the long-term use of the medicine); thus, the identified and potential risks and missing information are reclassified as follows:

Table 17 - List of important risks and missing information

Important identified risk	None
Important potential risk	None
Missing information	None

II.B Summary of important risks

Not applicable.

II.C Post-authorization development plan

II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of DTaP-IPV/Hib vaccine.

II.C.2 Other studies in post-authorization development plan

There are no studies required for DTaP-IPV/Hib vaccine.