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

Summary of risk management plan for TETRAVAC/TETRAXIM/TETRAVAC ACELLULAIRE (DTaP-IPV)

This is a summary of the RMP for TETRAVAC/TETRAXIM/TETRAVAC ACELLULAIRE. The RMP details important risks of TETRAVAC/TETRAXIM/TETRAVAC ACELLULAIRE how these risks can be minimized, and how more information will be obtained about TETRAVAC/TETRAXIM/TETRAVAC ACELLULAIRE's risks and uncertainties (missing information).

TETRAVAC/TETRAXIM/TETRAVAC ACELLULAIRE's SmPC and its PL give essential information to HCPs and patients on how TETRAVAC/TETRAXIM/TETRAVAC ACELLULAIRE should be used.

Important new concerns or changes to the current ones will be included in updates of TETRAVAC/TETRAXIM/TETRAVAC ACELLULAIRE's RMP.

VI.1 THE MEDICINE AND WHAT IT IS USED FOR

TETRAVAC/TETRAXIM/TETRAVAC ACELLULAIRE is authorized TETRAXIM is indicated for primary vaccination of infants and children from 6 weeks or 2 months of age against diphtheria, tetanus, pertussis and poliomyelitis, and for first and further booster vaccination according to official recommendations. It contains Diphtheria, Tetanus, Pertussis (acellular, component), Poliomyelitis (Inactivated) vaccine (adsorbed) as the active substance and it is given by IM route of administration.

VI.2 RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERIZE THE RISKS

Important risks of TETRAVAC/TETRAXIM/TETRAVAC ACELLULAIRE, together with measures to minimize such risks and the proposed studies for learning more about TETRAVAC/TETRAXIM/TETRAVAC ACELLULAIRE'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;
- Important advice on the medicine's packaging;
- The authorized pack size - the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;

- 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.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including Periodic Safety Update Report assessment, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of TETRAVAC/TETRAXIM/TETRAVAC ACELLULAIRE vaccine is not yet available, it is listed under 'missing information' outlined in the next section.

VI.2.1 List of important risks and missing information

Important risks of TETRAVAC/TETRAXIM/TETRAVAC ACELLULAIRE 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. Any identified and potential risks of TETRAVAC/TETRAXIM/TETRAVAC ACELLULAIRE vaccine require investigation to assure product safety. Identified risks are concerns for which sufficient evidence of a link to the use of TETRAVAC/TETRAXIM/TETRAVAC ACELLULAIRE vaccine exists. Potential risks are concerns for which significant causal evidence has not been established. Missing information refers to topics for which there is no or limited data with which to determine causality.

Table 24 - List of important risks and missing information

Important identified risk	None
Important potential risk	None
Missing information	• Subjects with history of severe prematurity • Immuno-compromised individuals • Duration of protection with acellular pertussis vaccines

VI.2.2 Summary of important risks

Table 25 - Missing information with corresponding risk minimization activities and additional pharmacovigilance activities if any: Subjects with history of severe prematurity

Subjects with history of severe prematurity.	
Risk minimization measures	**Routine risk minimization measures:** SmPC: Labelled in section 4.4; PL: Labelled in section 4 **Additional risk minimization measures:** None

PL: Package Leaflet; SmPC: Summary of Product Characteristics.

Table 26 - Missing information with corresponding risk minimization activities and additional pharmacovigilance activities if any: Immuno-compromised individuals

Immuno-compromised individuals	
Risk minimization measures	**Routine risk minimization measures:** SmPC: Labelled in section 4.4; PL: Labelled in section 2 **Additional risk minimization measures:** None

PL: Package Leaflet; SmPC: Summary of Product Characteristics

Table 27 - Missing information with corresponding risk minimization activities and additional pharmacovigilance activities if any: Duration of protection with acellular pertussis vaccines

Duration of protection with acellular pertussis vaccines	
Risk minimization measures	**Routine risk minimization measures:** To date, vaccine failure is an event under monitoring through routine Pharmacovigilance activities. **Additional risk minimization measures:** None

VI.2.3 Post-authorization development plan

VI.2.3.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of TETRAVAC/TETRAXIM/TETRAVAC ACELLULAIRE vaccine.

VI.2.3.2 Other studies in post-authorization development plan

There are no studies required for TETRAVAC/TETRAXIM/TETRAVAC ACELLULAIRE vaccine.