SUMMARY OF RISK MANAGEMENT PLAN FOR REPEVAX (TDAP5-IPV)

This is a summary of the RMP for REPEVAX (Tdap5-IPV). The RMP details important risks of REPEVAX (Tdap5-IPV), how these risks can be minimized, and how more information will be obtained about REPEVAX (Tdap5-IPV), risks and uncertainties (missing information).

REPEVAX (Tdap5-IPV), summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how REPEVAX (Tdap5-IPV), should be used.

Important new concerns or changes to the current concerns will be included in updates of REPEVAX's RMP.

VI.1. THE MEDICINE AND WHAT IT IS USED FOR

REPEVAX is authorized for active immunization against diphtheria, tetanus, pertussis and poliomyelitis in persons from 3 years of age as a booster following primary immunization. (see SmPC for the full indication). It contains diphtheria and tetanus toxoids, and pertussis and inactivated poliomyelitis antigens as the active substances and it is given by intramuscular route.

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

Information about adverse reactions is collected continuously and regularly analysed, including PBRER assessment, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

The following measures constitute routine risk minimization measures to minimize the risks identified for medicinal products:

- 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 authorised 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 (e.g., with or without prescription) can help to minimize its risks.

There are no important risks of REPEVAX that require additional measures to minimize such risks or additional studies for learning more about these risks. Therefore they are not included in the RMP.

If important information that may affect the safe use of REPEVAX 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

Missing information refers to topics or certain populations for which there is no or limited data regarding potential adverse effect of the product, and there is an expectation that future feasible additional pharmacovigilance activities may better characterize the safety.

Table 1 - List of important risks and missing information

Important identified risks	NONE
Important potential risks	Chorioamnionitis with Tdap/Tdap-IPV used during pregnancy
Missing information	Limited information on use in pregnant women during1st trimester of pregnancy "Waning of protection" with regard to the acellular pertussis component of the vaccine

VI.2.2. Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

Table 2 - Important risks and missing information with corresponding risk minimization activities and additional pharmacovigilance activities if any: Important potential risks: Chorioamnionitis with Tdap/Tdap-IPV used during pregnancy

Important potential risks – Chorioamnionitis with Tdap/Tdap-IPV used during pregnancy	
Risk minimization measures	This safety concern is not listed in the SmPC section 4.8 due to insufficient evidence of causal relationship with vaccination. Chorioamnionitis is under close monitoring through routine Pharmacovigilance activities. **Routine risk minimization measures:** • Targeted Follow-up Questionnaire (TFQ) to better document cases • Periodic reviews of internal PV data and information on new studies on the topic. Communication in PBRERs **Additional risk minimization measures:** None
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** None

Table 3 - Important risks and missing information with corresponding risk minimization activities and additional pharmacovigilance activities if any: Missing information: Limited information on use in pregnant women during 1st trimester of pregnancy

Missing information – Limited information on use in pregnant women during 1st trimester of pregnancy	
Risk minimization measures	Data on pregnancy exposure are under monitoring through routine Pharmacovigilance activities. **Routine risk minimization measures:** SmPC: Labelled in section 4.6 **Additional risk minimization measures:** None
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** None

Table 4 - Important risks and missing information with corresponding risk minimization activities and additional pharmacovigilance activities if any: Missing information: "Waning of protection" with regard to the acellular pertussis component of the vaccine

Missing information – "Waning of protection" with regard to the acellular pertussis component of the vaccine	
Risk minimization measures	To date, vaccine failure is event under monitoring through routine Pharmacovigilance activities. **Routine risk minimization measures:** None **Additional risk minimization measures:** None
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** 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 REPEVAX.

VI.2.3.2. Other studies in post-authorization development plan

There are no studies required for REPEVAX.

REFERENCES

None