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

Summary of risk management plan for ADACEL

This is a summary of the risk management plan (RMP) for ADACEL, COVAXIS, TRIAXIS and ADACEL BOOST referred as Tdap5. The RMP details important risks of Tdap5, how these risks can be minimized, and how more information will be obtained about Tdap5's risks and uncertainties (missing information).

Tdap5 summary of product characteristics (SmPC) provides essential information to healthcare professionals (HCPs) and patients on how Tdap5 should be used.

I. THE MEDICINE AND WHAT IT IS USED FOR

Tdap5 is approved for active immunization against tetanus, diphtheria and pertussis in persons 4 years of age and older as a booster following primary immunization and for use in pregnancy to prevent pertussis in newborns (see SmPC for the full indication). It contains diphtheria, tetanus, pertussis (acellular, component) as the active substance and it is given by intramuscular injection.

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

Important risks of Tdap5, together with measures to minimize such risks and the proposed studies for learning more about Tdap5'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 SmPC addressed to patients and HCPs;
- 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.

There are no important risks of Tetanus diphtheria acellular pertussis with 5 acellular pertussis components (Sanofi Pasteur) (Tdap5) 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.

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 Tdap5 is not yet available, it is listed under "missing information" outlined in the next section.

II.A List of important risks and missing information

Important risks of Tdap5 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 Tradename. 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 topics or certain populations for which there is no or limited data available 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 risk	None
Important potential risk	None
Missing information	None

II.B Summary of important risks

There are neither important identified or potential risks, nor missing information for Tdap5.

II.C Post-authorization development plan

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

The following study is conducted as a condition of the marketing authorization:

Table 2 - Studies which are conditions of the marketing authorization

Pregnancy registry
Purpose of the study: Obtain additional safety data in pregnant women and newborns exposed in postmarketing experience.

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

There are no studies required for COVAXIS.