PART VI SUMMARY OF THE RISK MANAGEMENT PLAN BY PRODUCT

Summary of risk management plan for Pneumovax™ 23 (Pneumococcal polysaccharide vaccine)

This is a summary of the risk management plan (RMP) for Pneumovax™ 23. The RMP details important risks of Pneumovax™ 23 and how more information will be obtained about Pneumovax™ 23's risks and uncertainties (missing information).

Pneumovax™ 23's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Pneumovax™ 23 should be used.

Important new concerns or changes to the current ones will be included in updates of Pneumovax™ 23's RMP.

I. The Medicine and What It is Used For

Pneumovax™ 23 is an authorised pneumococcal polysaccharide vaccine recommended for active immunisation against disease caused by the pneumococcal serotypes included in the vaccine. The vaccine is recommended for individuals 2 years of age or older in whom there is an increased risk of morbidity and mortality from pneumococcal disease. The specific at risk categories of persons to be immunised are to be determined on the basis of official recommendations (see SmPC for the full indication). It contains pneumococcal polysaccharide vaccine as the active substance and it is given by intramuscular (IM) or subcutaneous (SC) injection.

II. Risks Associated With the Medicine and Activities to Minimise Or Further Characterise the Risks

Important risks of Pneumovax™ 23, together with measures to minimise such risks and the proposed studies for learning more about Pneumovax™ 23's risks, are outlined below.

Measures to minimise 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 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 minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR 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

Important risks of Pneumovax™ 23 are risks that need special risk management activities to further investigate or minimise 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 Pneumovax™ 23. 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 (e.g. on the long-term use of the medicine).

Pneumovax™23 has been marketed for over 35 years since 1983 and over 291 million doses have been distributed during that time. The safety profile has been well-characterised during that time and adverse events that have been reported from clinical trials, non-interventional studies and post-approval safety surveillance analysis are included in the SmPC. There are no studies planned or warranted to further characterise any identified or potential risk that would alter the established risk-benefit profile for Pneumovax23. There are also no additional risk minimisation activities planned or warranted beyond communication of the safety profile in the SmPC and the Patient Leaflet. As such there are no important safety concerns (important identified or potential risks or missing information) for which prospective additional risk management is to be planned. Therefore, there are not important identified or potential risks or missing information associated with Pneumovax23 to be addressed in the RMP.

In conclusion, continued spontaneous safety surveillance and labeling are considered sufficient to monitor the safety profile and provide routine risk minimisation.

Table II.A.1: List of Important Risks and Missing Information

List of Important Risks and Missing Information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of Important Risks

The safety information in the proposed Prescribing Information is aligned to the reference medicinal product. There are no identified risks, potential risks, or missing information in this RMP.

II.C Post-Authorisation Development Plan

II.C.1 Studies Which are Conditions of the Marketing Authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Pneumovax™ 23.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Pneumovax™ 23.