PUBLIC SUMMARY OF THE RISK MANAGEMENT PLAN

PREVENAR 13 (PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE [13-VALENT, ADSORBED])

Marketing Authorization Number 60129

Suspension for i.m. injection in pre-filled syringe

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LIST OF ABBREVIATIONS

13vPnC	13-valent Pneumococcal Conjugate Vaccine
CRM	Cross-reactive material
EMA	European Medicines Agency
PSUR	Periodic Safety Update Report
RMP	Risk Management Plan
SmPC	Summary Of Product Characteristics

OVERVIEW

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them. The RMP summary for Prevenar 13 is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g., by mentioning risks occurring in populations or indications not included in the Swiss marketing authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Prevenar 13 in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorised by Swissmedic. Pfizer is fully responsible for the accuracy and correctness of the content of the published RMP summary of Prevenar 13.

SUMMARY OF RISK MANAGEMENT PLAN FOR PREVENAR 13 (PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE, 13-VALENT, ADSORBED)

This is a summary of the risk management plan (RMP) for Prevenar 13. The RMP details important risks of Prevenar 13, how these risks can be minimised, and how more information will be obtained about the Prevenar 13 risks and uncertainties (missing information).

Prevenar 13 summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how the vaccine should be used.

This summary of the RMP for Prevenar 13 should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Prevenar 13 RMP.

I. The Medicine and What It Is Used For

Prevenar 13 is authorised for

- Active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* in infants, children and adolescents from 6 weeks to 17 years of age.

- active immunisation for the prevention of invasive disease and pneumonia caused by *S. pneumoniae* in adults ≥18 years of age and the elderly.

(See SmPC for the full indication). It contains 2.2 µg of saccharide for all included serotypes, except for 4.4 µg of saccharide for serotype 6B, conjugated to CRM_{197} carrier protein as the active substance and adsorbed on aluminium phosphate. Adults and children aged 2 years and above should receive one single dose of the vaccine into the shoulder muscle, whereas in children below 2 years of age, the vaccine is given by injection into the thigh muscle.

Further information about the evaluation of 13vPnC benefits can be found in the vaccine EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Prevenar 13, together with measures to minimise such risks and the proposed studies for learning more about vaccine'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 public (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 events is collected continuously and regularly analysed, including PSUR 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 13vPnC is not yet available, it is listed under 'missing information' below.

II.A. List of Important Risks and Missing Information

There are no important identified/potential risks or missing information in safety concern list for Prevenar 13.

II.B. Summary of Important Risks and Missing Information

Not applicable.

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 Prevenar 13.

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

There are no post-authorisation studies required for Prevenar 13.