PUBLIC SUMMARY OF THE RISK MANAGEMENT PLAN

PREVENAR 20 (PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE [20-VALENT, ADSORBED])

Marketing Authorization Number 69222

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

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LIST OF ABBREVIATIONS

20vPnC	20-valent Pneumococcal Conjugate Vaccine
EU	European Union
IM	Intramuscular
PSUR	Periodic Safety Update Report
RMP	Risk Management Plan
SmPC	Summary Of Product Characteristics
US	United States

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 20 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 20 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 20.

SUMMARY OF RISK MANAGEMENT PLAN FOR PREVENAR 20 (20-VALENT PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE [20vPnC])

This is a summary of the risk management plan (RMP) for Prevenar 20. The RMP details important risks of Prevenar 20, how these risks can be minimised, and how more information will be obtained about Prevenar 20's risks and uncertainties (missing information).

Prevenar 20's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Prevenar 20 should be used.

Important new concerns or changes to the current ones will be included in updates of Prevenar 20's RMP.

I. The Medicine and What It Is Used For

Prevenar 20 is a vaccine for active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in individuals ≥18 years of age (see SmPC for the full indication). It contains pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) as the active substance, and it is given by IM route of administration.

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

Important risks of Prevenar 20, together with measures to minimise such risks and the proposed studies for learning more about Prevenar 20'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 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 Prevenar 20 is not yet available, it is listed under 'missing information' below.

II.A. List of Important Risks and Missing Information

Important risks of Prevenar 20 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 Prevenar 20. Potential

risks are concerns for which an association with the use of this vaccine 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).

There are no important identified/potential risks or missing information for Prevenar 20.

II.B. Summary of Important Risks

Not applicable.

II.C. Post-Authorisation Development Plan

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

The following post-authorisation efficacy studies are conditions of the marketing authorisation for Prevenar 20:

- **Study B7471015: A Phase 4 Study Using a Test-Negative Design to Evaluate the Effectiveness of a 20-valent Pneumococcal Conjugate Vaccine Against Vaccine-Type Radiologically Confirmed Community-Acquired Pneumonia in Adults ≥65 Years of Age in the US**

  Purpose of the study: Evaluate the effectiveness of 20vPnC against vaccine-type radiologically confirmed community acquired pneumonia in adults ≥65 years of age in the US.

- **Phase 4 Observational, Real-World Study of 20-valent Pneumococcal Conjugate Vaccine Effectiveness Against Vaccine-Type Community-Acquired Pneumonia in Europe**

  Purpose of the study: Evaluate the effectiveness of 20vPnC against hospitalised vaccine-type community acquired pneumonia in adults in the EU.

- **Phase 4 Observational, Real-World Study of 20-valent Pneumococcal Conjugate Vaccine Effectiveness Against Vaccine-Type Invasive Pneumococcal Disease in Europe.**

  Purpose of the study: Evaluate the effectiveness of 20vPnC against vaccine-type invasive pneumococcal disease in adults in the EU.

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

None.