Summary of risk management plan for Apexxnar (20-valent Pneumococcal Polysaccharide Conjugate Vaccine [20vPnC])

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

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

This summary of the RMP for Apexxnar 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 Apexxnar's RMP.

I. The Medicine and What It Is Used For

Apexxnar 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.

Further information about the evaluation of Apexxnar's benefits can be found in Apexxnar's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage https://www.ema.europa.eu/en/medicines/human/EPAR/apexxnar.

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

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

II.A. List of Important Risks and Missing Information

Important risks of Apexxnar 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 Apexxnar. 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 Apexxnar.

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 Apexxnar:

- **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.