PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for *Synflorix*

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

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

This summary of the RMP for *Synflorix* 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 *Synflorix* 's RMP.

I. The medicine and what it is used for

Synflorix is a vaccine that contains parts of the bacterium Streptococcus pneumoniae (S. pneumoniae, also called pneumococcus). It is used to protect infants and children aged between 6 weeks and 5 years against invasive disease, pneumonia (infection of the lungs) and acute otitis media (infection of the middle ear) caused by S. pneumoniae. Invasive disease results from the bacterium spreading through the body causing serious infections such as septicemia (blood infection), meningitis (infection of the membranes around the brain and spine) and pneumonia. (see SmPC for the full indication).

Further information about the evaluation of *Synflorix*'s benefits can be found in *Synflorix*'s 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 characterize the risks

Based on Guideline on good pharmacovigilance practices (GVP) – Module V (Rev 2) EMA/838713/2011 Rev 2, the previously listed safety concerns have been reviewed. *Synflorix* is a well-established vaccine with more than 10 years of post-marketing experience with an extensive worldwide patient exposure and there is no need for further risk minimisation activities and/or further evaluation as part of the PV plan for any of the previously listed safety concerns (i.e. important identified or potential risks, important identified interactions and missing information), the company is therefore proposing to remove all of them in this EU RMP. The important identified or potential risks, and missing information are however considered to require continued monitoring in the Periodic Benefit Risk Evaluation Report (PBRER).

II.A List of important risks and missing information

Not applicable.

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

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 *Synflorix*

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

There are no more studies required for *Synflorix*