I. Executive Summary

No SmPC and PL changes are proposed.

II. Recommendation [1]

The data from this study do not warrant any changes to the SmPC or PIL.

III. Introduction

On 6 February 2012, the MAH submitted a completed paediatric study for Prevenar, in accordance with Article 46 of Regulation (EC) No1901/2006, as amended, on medicinal products for paediatric use.

A short critical expert overview has also been provided.

The MAH stated that the submitted paediatric study does not influence the benefit risk for Prevenar and that there is no consequential regulatory action.

IV. Scientific Discussion

Information on the pharmaceutical formulation used in the study
In Europe, Prevenar (PCV7) is indicated for children aged 2 months to 5 year. Available commercial supply of PCV7 (routine use) was used in this study.

Clinical aspects

1. Introduction

The MAH submitted a final report for:

- B1841001 (0887X1-4596-RU) Prevenar POST-licensure Safety Study in Russia: Frequency of Fever Post Vaccination

2. Clinical study

- **Description**

Pfizer's 7-valent pneumococcal conjugate vaccine (PCV7, Prevenar®), indicated for the prevention of invasive disease caused by *Streptococcus pneumoniae*, was granted a license by the Russian Ministry of Health and Social Development (Roszdravnadzor) on 29 January 2009. As part of a postlicensure commitment requested by the Regulatory Authorities of the Russian Federation, Pfizer conducted a prospective, observational, non-interventional study of Prevenar in the context of the routine immunization schedules of the Russian Federation (Protocol 0887X1-4596-RU). The study has now been completed, and final data are available. The purpose of this Clinical Overview is to summarize the results of Study 0887X1-4596-RU.

- **Methods**

- Objective(s)

Primary
The primary objective of the study was to estimate the incidence of febrile reactions of ≥38°C to ≤39°C; >39°C to ≤40°C; >40°C occurring within 2 days following vaccination with Prevenar (PCV7) co-administered with other routine childhood vaccines under the conditions of routine daily use in the Russian Federation within the licensed indication.

Secondary
The secondary objective was to observe the frequency and severity of other local and/or systemic events and undesirable events and undesirable effects for two days after routine vaccination with PCV7.

[1] *The recommendation from section V can be copied in this section*