**MHRA**
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

**gov.uk/mhra**

# Decision Cover Letter

## Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-100347-PIP01-21

# Scope of the Application

## Active Substance(s)

Respiratory Syncytial Virus Stabilised Prefusion F Subunit Vaccine (RSVpreF, PF-06928316)

## Condition(s)

Prevention of lower respiratory track disease caused by RSV via maternal immunisation.

## Pharmaceutical Form(s)

Powder and solvent for solution for injection

## Route(s) of Administration

Intramuscular use

## Name / Corporate name of the PIP applicant

Pfizer Limited

## Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Pfizer Limited submitted to the licensing authority on 15/11/2021 09:58 GMT an application for a Paediatric Investigation Plan

The procedure started on 10/08/2022 17:48 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to agree a paediatric investigation plan and grant a deferral and grant a waiver

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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# Final Decision Letter

MHRA-100347-PIP01-21

Of 19/09/2022 09:47 BST

On the adopted decision for Respiratory Syncytial Virus Stabilised Prefusion F Subunit Vaccine (RSVpreF, PF-06928316) (MHRA-100347-PIP01-21) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for Respiratory Syncytial Virus Stabilised Prefusion F Subunit Vaccine (RSVpreF, PF-06928316), Powder and solvent for solution for injection , Intramuscular use .

This decision is addressed to Pfizer Limited, Ramsgate Road, Sandwich, Kent, Sandwich, United Kingdom, CT13 9NJ

# ANNEX I

## 1. Waiver

### 1.1 Condition:

| |
|---|
| Prevention of lower respiratory track disease caused by respiratory syncytial virus via maternal immunisation. The waiver applies / applied to: Paediatric Subset(s): Males from birth to less than 18 years of age and females from birth to before menarche Pharmaceutical form(s): Powder and solvent for solution for injection Route(s) of administration: Intramuscular use Reason for granting waiver: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s). |

## 2. Paediatric Investigation Plan:

### 2.1 Condition(s):

| |
|---|
| Prevention of lower respiratory track disease caused by respiratory syncytial virus via maternal immunisation. |

## 2.2 Indication(s) targeted by the PIP:

| |
|---|
| Prevention of lower respiratory tract disease caused by respiratory syncytial virus via maternal immunisation. |

## 2.3 Subset(s) of the paediatric population concerned by the paediatric development:

| |
|---|
| Females from menarche to less than 18 years of age |

## 2.4 Pharmaceutical Form(s):

| |
|---|
| Powder and solvent for solution for injection |

## 2.5 Studies:

| Study Type | Number of Studies | Study Description |
|---|---|---|
| **Quality Measures** | 0 | Not applicable. |
| **Non-Clinical Studies** | 0 | Not applicable. |
| **Clinical Studies** | 1 | Study 1 (C3671011) Multicentre, randomised, double-blind placebo-controlled trial to assess safety, tolerability and immunogenicity of respiratory syncytial virus stabilised prefusion F subunit vaccine (RSVpreF) in healthy non-pregnant girls from menarche to less than 18 years of age (and non-pregnant adult women). |
| **Extrapolation, Modeling & Simulation Studies** | 0 | Not applicable. |
| **Other Studies** | 0 | Not applicable. |
| **Other Measures** | 0 | Not applicable. |

## 3. Follow-up, completion and deferral of a PIP:

| | |
|---|---|
| **Concerns on potential long term safety and efficacy issues in relation to paediatric use:** | No |
| **Date of completion of the paediatric investigation plan:** | 31/03/2026 |
| **Deferral of one or more studies contained in the paediatric investigation plan:** | Yes |