

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

[gov.uk/mhra](http://gov.uk/mhra)

## **Decision Cover Letter**

### **Decision of the licensing authority to:**

accept change(s) to the agreed paediatric investigation plan (MHRA-100347-PIP01-21)

MHRA-100347-PIP01-21-M01

### **Scope of the Application**

#### **Active Substance(s)**

Respiratory syncytial virus vaccine (bivalent, recombinant)

#### **Condition(s)**

Prevention of lower respiratory tract disease caused by respiratory syncytial virus 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 31/10/2025 06:19 GMT an application for a Modification

The procedure started on 12/02/2026 15:54 GMT

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 accept change(s) to the agreed paediatric investigation plan

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.

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

[gov.uk/mhra](http://gov.uk/mhra)

## Final Decision Letter

MHRA-100347-PIP01-21-M01

Of 03/03/2026 14:15 GMT

On the adopted decision for Respiratory syncytial virus vaccine (bivalent, recombinant) (MHRA-100347-PIP01-21-M01) 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 modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for Respiratory syncytial virus vaccine (bivalent, recombinant), Powder and solvent for solution for injection , INTRAMUSCULAR USE .

This decision is addressed to Pfizer Limited, Ramsgate Road, Sandwich, Kent, UNITED KINGDOM, CT139NJ

## 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 track 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) Deleted during procedure MHRA-100347-PIP01-21-M01. Study 2 (C3671008) Added during procedure MHRA-100347-PIP01-21-M01. Multicentre, randomised, double-blinded placebo-controlled trial in healthy pregnant individuals 49 years of age and younger to evaluate the safety of respiratory syncytial virus stabilised prefusion f subunit vaccine (RSVpreF) in maternal participants and their infants and the efficacy of RSVpreF in reducing the incidence of medically attended lower respiratory tract illness (MA-LRTI) and severe MA-LRTI due to RSV in infant participants.
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:

<b>Concerns on potential long term safety and efficacy issues in relation to paediatric use:</b>	No
<b>Date of completion of the paediatric investigation plan:</b>	31/10/2023
<b>Deferral of one or more studies contained in the paediatric investigation plan:</b>	No