MHRA
10 South Colonnade
Canary Wharf
London
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-100242-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 tract disease caused by respiratory syncytial virus.

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 31/08/2021 15:28 BST an application for a Paediatric Investigation Plan

The procedure started on 07/07/2022 14:19 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-100242-PIP01-21

Of 19/10/2022 17:10 BST

On the adopted decision for Respiratory Syncytial Virus Stabilised Prefusion F Subunit Vaccine (RSVpreF, PF-06928316) (MHRA-100242-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, United Kingdom, CT13 9NJ

ANNEX I

1. Waiver

1.1 Condition:

Prevention of lower respiratory tract disease caused by respiratory syncytial virus. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age 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 specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of lower respiratory tract disease caused by respiratory syncytial virus.

2.2 Indication(s) targeted by the PIP:

Prevention of lower respiratory tract disease caused by respiratory syncytial virus.

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

The paediatric population from 2 years 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	2	Study 1 (C3671016) Randomised controlled study of safety, tolerability and immunogenicity of respiratory syncytial virus stabilised prefusion F subunit vaccine (RSVpreF) in children from 2 years to less than 18 years of age for the prevention of lower respiratory tract illness (LRTI) caused by respiratory syncytial virus. Study 2 (C3671017) Open-label study of safety, tolerability, and immunogenicity of respiratory syncytial virus stabilised prefusion F subunit vaccine (RSVpreF) in immunocompromised children from 2 years to less than 18 years of age for prevention of RSV-associated medically-attended lower respiratory tract illness (MA LRTI).
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:	31/12/2025
Deferral of one or more studies contained in the paediatric investigation plan:	Yes