MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
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-100723-PIP01-22

Scope of the Application

Active Substance(s)

Wisconsin modRNA (PF-07829855); Austria modRNA (PF-07872963); Darwin modRNA (PF-07871853); Phuket modRNA (PF-07836259)

Condition(s)

Prevention of influenza disease

Pharmaceutical Form(s)

Concentrate 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 03/11/2022 13:58 GMT an application for a Paediatric Investigation Plan

The procedure started on 27/03/2023 10:02 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-100723-PIP01-22

Of 03/06/2024 09:05 BST

On the adopted decision for Wisconsin modRNA (PF-07829855); Austria modRNA (PF-07872963); Darwin modRNA (PF-07871853); Phuket modRNA (PF-07836259) (MHRA-100723-PIP01-22) 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 Wisconsin modRNA (PF-07829855); Austria modRNA (PF-07872963); Darwin modRNA (PF-07871853); Phuket modRNA (PF-07836259), Concentrate for solution for injection , INTRAMUSCULAR USE .

This decision is addressed to Pfizer Limited, Ramsgate Road, Sandwich, Kent, UNITED KINGDOM, CT13 9NJ

ANNEX I

1. Waiver

1.1 Condition:

Prevention of influenza disease The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 weeks of age Pharmaceutical form(s): Concentrate 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 ineffective.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of influenza disease

2.2 Indication(s) targeted by the PIP:

Active immunisation for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine for children from 6 weeks to less than 18 years of age.

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

The paediatric population from 6 weeks to less than 18 years of age

2.4 Pharmaceutical Form(s):

Concentrate 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 Observer-blind, active-controlled, safety, tolerability, and immunogenicity study of modRNA encoding 4 influenza HA antigens (2 for influenza A and 2 for influenza B strains) (qIRV) in children from 6 weeks of age to less than 18 years of age for the prevention of influenza disease. Study 2 Randomised, observer- blind, efficacy, safety, and immunogenicity study of modRNA encoding 4 influenza HA antigens (2 for influenza A and 2 for influenza B strains) (qIRV) in children from 6 weeks of age to less than 18 years of age for the prevention of influenza disease.
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:	30/04/2029

Deferral of one or more studies contained in the paediatric investigation plan:	Yes