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

MHRA-100680-PIP01-22

Scope of the Application

Active Substance(s)

Influenza recombinant H7 haemagglutinin

Condition(s)

Prevention of influenza infection

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

Sanofi Pasteur

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Sanofi Pasteur submitted to the licensing authority on 12/09/2022 14:28 BST an application for a Paediatric Investigation Plan

The procedure started on 09/03/2023 17:29 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 agree a paediatric investigation plan and grant a deferral

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-100680-PIP01-22

Of 18/12/2023 15:13 GMT

On the adopted decision for Influenza recombinant H7 haemagglutinin (MHRA-100680-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 Influenza recombinant H7 haemagglutinin, Solution for injection , INTRAMUSCULAR USE .

This decision is addressed to Sanofi Pasteur , 14 Espace Henry Vallée, Lyon, FRANCE, 69007

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of influenza infection

2.2 Indication(s) targeted by the PIP:

Prophylaxis of influenza in an officially declared pandemic situation

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

The paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

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 (VAM00003) Randomised, double-blind, placebo-controlled, multi-centre study to assess safety and immunogenicity of an adjuvanted recombinant hemagglutinin pandemic influenza vaccine candidate compared to placebo in children from 6 months to less than 18 years of age. Study 2 (VAM00006) Open label, multi-centre study to assess safety and immunogenicity of an adjuvanted recombinant hemagglutinin pandemic influenza vaccine candidate in children from birth to less than 6 months of age.
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:	31/12/2026
Deferral of one or more studies contained in the paediatric investigation plan:	Yes