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

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100502-PIP01-22-M01)

MHRA-100502-PIP01-22-M02

Scope of the Application

Active Substance(s)

Recombinant Influenza Hemagglutinin-strain A (H1N1 subtype); Recombinant Influenza Hemagglutinin-strain A (H3N2 subtype); Recombinant Influenza Hemagglutinin-strain B (Victoria lineage); Recombinant Influenza Hemagglutinin-strain B (Yamagata lineage)

Condition(s)

Prevention of Influenza disease

Pharmaceutical Form(s)

Solution for injection in pre-filled syringe

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 22/04/2024 22:51 BST an application for a Modification

The procedure started on 04/06/2024 14:18 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 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.

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Final Decision Letter

MHRA-100502-PIP01-22-M02

Of 24/07/2024 16:28 BST

On the adopted decision for Recombinant Influenza Hemagglutinin-strain A (H1N1 subtype); Recombinant Influenza Hemagglutinin-strain A (H3N2 subtype); Recombinant Influenza Hemagglutinin-strain B (Victoria lineage); Recombinant Influenza Hemagglutinin-strain B (Yamagata lineage) (MHRA-100502-PIP01-22-M02) 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 Recombinant Influenza Hemagglutinin-strain A (H1N1 subtype); Recombinant Influenza Hemagglutinin-strain A (H3N2 subtype); Recombinant Influenza Hemagglutinin-strain B (Victoria lineage); Recombinant Influenza Hemagglutinin-strain B (Yamagata lineage), Solution for injection in pre-filled syringe , INTRAMUSCULAR USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Prevention of Influenza infection The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 3 years of age Pharmaceutical form(s): Solution for injection in pre-filled syringe Route(s) of administration: INTRAMUSCULAR USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of Influenza infection

2.2 Indication(s) targeted by the PIP:

Prevention of Influenza infection

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

The paediatric population from 3 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution for injection in pre-filled syringe

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	4	Study 1 Randomised, modified double-blind, active-controlled study to evaluate the safety, reactogenicity and immunogenicity of Recombinant Influenza Hemagglutinin-strain A (H1N1 subtype)/ Recombinant Influenza Hemagglutinin-strain A (H3N2 subtype) / Recombinant Influenza Hemagglutinin-strain B (Victoria lineage) / Recombinant Influenza Hemagglutinin-strain B (Yamagata lineage) (RIV4) or quadrivalent inactivated influenza vaccine (IIV4). Study 2 Randomised, double-blind, active-controlled study to demonstrate the non-inferiority, relative efficacy, and safety of Recombinant Influenza Hemagglutinin-strain A (H1N1 subtype)/ Recombinant Influenza Hemagglutinin-strain A (H3N2 subtype) / Recombinant Influenza Hemagglutinin-strain B (Victoria lineage)/ Recombinant Influenza Hemagglutinin-strain B (Yamagata lineage) (RIV4) compared to

		quadrivalent inactivated influenza vaccine (IIV4). Study 3 Deleted during procedure MHRA-100502-PIP01-22-M01. Study 4 (Added during procedure MHRA-100502-PIP01-22-M01) Randomised, modified double-blind, active-controlled study to demonstrate non-inferior immunogenicity of the Quadrivalent Recombinant Influenza Vaccine (RIV4) in participants aged 3 to less than 9 years of age compared to an egg-based Quadrivalent Inactivated Influenza Vaccine (IIV4). Study 5 (Added during procedure MHRA-100502-PIP01-22-M01) Randomised, open-label, uncontrolled study to demonstrate non-inferior immunogenicity of the Quadrivalent Recombinant Influenza Vaccine (RIV4) in children and adolescents from 9 years to less than 18 years of age compared to adults from 18 to less than 50 years 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:	31/12/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes