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 waiver

MHRA-101492-PIP01-24

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 (RIV3)

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 Winthrop Industrie

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Sanofi Winthrop Industrie submitted to the licensing authority on 25/05/2024 00:12 BST an application for a Paediatric Investigation Plan

The procedure started on 02/07/2024 13:26 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 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-101492-PIP01-24

Of 29/07/2024 07:05 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 (RIV3) (MHRA-101492-PIP01-24) 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 Recombinant Influenza Hemagglutinin-strain A (H1N1 subtype); Recombinant Influenza Hemagglutinin-strain A (H3N2 subtype); Recombinant Influenza Hemagglutinin-strain B (RIV3), Solution for injection in pre-filled syringe , INTRAMUSCULAR USE .

This decision is addressed to Sanofi Winthrop Industrie, 84 avenue Raspail, Gentilly, FRANCE, 94250

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 9 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 disease

2.2 Indication(s) targeted by the PIP:

Prevention of Influenza disease

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

The paediatric population from 9 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	2	Studies with quadrivalent influenza vaccine (QIV- RIV4) Study 1 (PSC08) Randomised, modified double-blind, active-controlled study to evaluate 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) (Quadrivalent Recombinant Influenza Hemagglutinin Vaccine: RIV4) or quadrivalent inactivated influenza vaccine (IIV4) in male and female children and adolescents from 6 years to less than 18 years of age. Study 2 (VAP00027) 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 years 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:	No