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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a waiver

MHRA-101495-PIP01-24

Scope of the Application

Active Substance(s)

Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain; Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain; Split influenza virus, inactivated containing antigens equivalent to B-like strain

Condition(s)

Prevention of influenza disease

Pharmaceutical Form(s)

Suspension for injection

Route(s) of Administration

SUBCUTANEOUS USE; 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 06/06/2024 14:53 BST an application for a

The procedure started on 02/07/2024 13:13 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-101495-PIP01-24

Of 03/09/2024 10:08 BST

On the adopted decision for Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain; Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain; Split influenza virus, inactivated containing antigens equivalent to B-like strain (MHRA-101495-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 for Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain; Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain; Split influenza virus, inactivated containing antigens equivalent to B-like strain, Suspension for injection , SUBCUTANEOUS USE, INTRAMUSCULAR .

This decision is addressed to Sanofi Winthrop Industrie, 82 Avenue Raspail, Gentilly, FRANCE, 92250

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 months of age Pharmaceutical form(s): Suspension for injection Route(s) of administration: SUBCUTANEOUS USE 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:

Prevention of influenza disease

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

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

2.4 Pharmaceutical Form(s):

Suspension 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	3	Study 1 (GQM04) Randomised, controlled, double-blind (for Quadrivalent influenza vaccine [QIV] lots), open (for allocation to QIV or Trivalent Influenza Vaccine [TIV]) safety and immunogenicity 4-arm trial in children from 9 years of age to less than 18 years of age (and adults). Study 2 (GQM05) Randomised, observer-blind (except for TIV groups), controlled, 4-arm trial of efficacy, safety and immunogenicity in healthy children from 6 months of age to less than 36 months of age not previously vaccinated against influenza. Study 3 (GQM02) Randomised, double-blind, active-controlled, 3-arm immunogenicity and safety trial in children from 3 years of age to less than 9 years of age, previously vaccinated or unvaccinated against influenza.
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:	31/12/2018
Deferral of one or more studies contained in the paediatric investigation plan:	No