

**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 and to the deferral

MHRA-100502-PIP01-22-M01

### **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 infection

#### **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 06/04/2022 23:07 BST an application for a Modification

The procedure started on 10/08/2022 17:55 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 and to the 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-100502-PIP01-22-M01

Of 19/09/2022 07:23 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-M01) 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-inferior 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 8 years 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 18 to less than 50 years of age.
<b>Extrapolation, Modeling &amp; Simulation Studies</b>	0	Not applicable
<b>Other Studies</b>	0	Not applicable
<b>Other Measures</b>	0	Not applicable

### 3. Follow-up, completion and deferral of a PIP:

<b>Concerns on potential long term safety and efficacy issues in relation to paediatric use:</b>	No
<b>Date of completion of the paediatric investigation plan:</b>	31/12/2023
<b>Deferral of one or more studies contained in the paediatric investigation plan:</b>	Yes