

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

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## Decision Cover Letter

### Decision of the licensing authority to:

grant a product specific waiver

MHRA-101761-PIP01-24

### Scope of the Application

#### Active Substance(s)

Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1); Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2); Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage)

#### Condition(s)

Prevention of influenza infection

#### Pharmaceutical Form(s)

Suspension for injection in pre-filled syringe

#### Route(s) of Administration

INTRAMUSCULAR USE

#### Name / Corporate name of the PIP applicant

Seqirus UK Ltd

#### Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Seqirus UK Ltd submitted to the licensing authority on 17/01/2025 22:08 GMT an application for a Waiver

The procedure started on 17/02/2025 17:49 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 grant a product specific 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-101761-PIP01-24

Of 30/04/2025 07:22 BST

On the adopted decision for Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1); Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2); Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) (MHRA-101761-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:

Granting a waiver in all age groups for the listed condition(s)

This decision applies to a Waiver for Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1); Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2); Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage), Suspension for injection in pre-filled syringe , INTRAMUSCULAR USE .

This decision is addressed to Seqirus UK Ltd, Point, 29 Market Street, , Maidenhead , UNITED KINGDOM, SL6 8AA

## ANNEX I

### 1. Waiver

#### 1.1 Condition:

Prevention of influenza infection The waiver applies / applied to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 years of age Pharmaceutical form(s): Suspension for injection in pre-filled syringe Route(s) of administration: INTRAMUSCULAR USE Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

### 2. Paediatric Investigation Plan:

#### 2.1 Condition(s):

Not Applicable
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**2.2 Indication(s) targeted by the PIP:**

Not Applicable
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**2.3 Subset(s) of the paediatric population concerned by the paediatric development:**

Not Applicable
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**2.4 Pharmaceutical Form(s):**

Not Applicable
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**2.5 Studies:**

Study Type	Number of Studies	Study Description
Quality Measures		
Non-Clinical Studies		
Clinical Studies		
Extrapolation, Modeling & Simulation Studies		
Other Studies		
Other Measures		

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

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	

