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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-100177-PIP01-21-M01

Scope of the Application

Active Substance(s)

INFLUENZA A/ (H1N1)-LIKE VIRUS ANTIGEN; INFLUENZA A/ (H3N2)-LIKE VIRUS ANTIGEN; INFLUENZA B/VICTORIA/2/87-LIKE VIRUS ANTIGEN; INFLUENZA B/ YAMAGATA/16/88-LIKE VIRUS ANTIGEN

Condition(s)

Prevention of influenza

Pharmaceutical Form(s)

Suspension for injection

Route(s) of Administration

Intramuscular use

Name / Corporate name of the PIP applicant

Seqirus UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Seqirus UK Limited submitted to the licensing authority on 14/07/2021 11:45 BST an application for a Modification

The procedure started on 03/12/2021 08:21 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 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-100177-PIP01-21-M01

Of 13/12/2021 12:16 GMT

On the adopted decision for INFLUENZA A/ (H1N1)-LIKE VIRUS ANTIGEN; INFLUENZA A/ (H3N2)-LIKE VIRUS ANTIGEN; INFLUENZA B/VICTORIA/2/87-LIKE VIRUS ANTIGEN; INFLUENZA B/YAMAGATA/16/88-LIKE VIRUS ANTIGEN (MHRA-100177-PIP01-21-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 INFLUENZA A/ (H1N1)-LIKE VIRUS ANTIGEN; INFLUENZA A/ (H3N2)-LIKE VIRUS ANTIGEN; INFLUENZA B/VICTORIA/2/87-LIKE VIRUS ANTIGEN; INFLUENZA B/YAMAGATA/16/88-LIKE VIRUS ANTIGEN, Suspension for injection , Intramuscular use .

This decision is addressed to Seqirus UK Limited, Point, 29 Market Street , Maidenhead, Berkshire, United Kingdom, SL6 8AA

ANNEX I

1. Waiver

1.1 Condition:

Prevention of influenza 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: 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):

Prevention of influenza

2.2 Indication(s) targeted by the PIP:

Prevention of influenza

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	7	x
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:	30/09/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes