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 (MHRA-100177-PIP01-21-M01) and to the deferral

MHRA-100177-PIP01-21-M02

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 17/04/2023 11:23 BST an application for a Modification

The procedure started on 16/05/2023 16:50 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-100177-PIP01-21-M02

Of 17/05/2023 15:58 BST

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-M02) 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	Study 1 (V58P12) Randomised, observer-blind, active controlled trial to evaluate immunogenicity, tolerability and safety of cell-based trivalent influenza vaccine (TIVc) compared to egg-based trivalent influenza vaccine (Fluvirin) in healthy children from 3 years to less than 18 years of age. Study 2 (V58P15) Randomised, observer-blind, active-controlled trial to evaluate safety of cell-based trivalent influenza vaccine (TIVc) compared to egg-based trivalent influenza vaccine (Agrippal) in children from 3 years to less than 18 years of age who are at risk for influenza-related complications. Study 3 (V58_31) Randomised, observer-blind, active controlled trial to evaluate safety and tolerability of TIVc compared to Fluvirin in healthy children from 4 years to less than 18 years of age. Study 4 (V58_P16) Randomised, observer-blind, active controlled

		trial to evaluate immunogenicity and safety of 3 dose levels of cell-based trivalent influenza vaccine (TIVc) compared to egg-based trivalent influenza vaccine (Fluzone) in healthy children from 6 months to less than 48 months of age. Study 5 (V130_03) Randomised, double-blind, active-controlled, non-inferiority trial to evaluate immunogenicity and safety of QIVc compared to cell-based trivalent influenza vaccines containing either the WHO-recommended B-strain (TIV1c) or the B-strain from the alternate lineage (TIV2c) in healthy children from 4 months to less than 18 years age. Study 6 (V130_10) Randomised, observer-blind, active-controlled trial to evaluate safety and immunogenicity of QIVc compared to a quadrivalent authorised influenza vaccine in healthy children from 6 months to less than 48 months of age. Study 7 (V130_14) Randomised, observer-blind, controlled trial to evaluate efficacy, safety and immunogenicity of QIVc compared to a non-influenza vaccine comparator in healthy children from 6 months to less than 48 months 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:	31/07/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes