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 deferral

MHRA-101268-PIP01-23

Scope of the Application

Active Substance(s)

Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A/H5N1

Condition(s)

Prevention of pandemic 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 30/01/2024 14:25 GMT an application for a Paediatric Investigation Plan

The procedure started on 12/02/2024 12:57 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 agree a paediatric investigation plan and grant a 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-101268-PIP01-23

Of 25/04/2024 14:12 BST

On the adopted decision for Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A/H5N1 (MHRA-101268-PIP01-23) 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 Paediatric Investigation Plan for Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A/H5N1, Suspension for injection , INTRAMUSCULAR USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of pandemic influenza

2.2 Indication(s) targeted by the PIP:

Prevention of pandemic influenza

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

The paediatric population from birth 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	4	Study 1 (V89_11) Randomised, observer-blind study to evaluate safety, tolerability and immunogenicity of 2 different dosages of influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A/H5N1 (aH5N1c) in paediatric subjects from 6 months to less than 18 years of age. Study 2 Randomised, observer-blind, multi-centre study to evaluate safety and immunogenicity of 2 dosage levels of MF59-adjuvanted A/H5 pandemic vaccine in paediatric subjects from 6 months to less than 9 years of age. Study 3 Two stage, randomised, observer-blind study to evaluate safety and immunogenicity of four different dosages of MF59-adjuvanted A/Hx pandemic vaccine in children from 6 months to less than 9 years of age. Study 4 Open-label, multicentre study to evaluate the immunogenicity and safety of a 2-dose series of MF59 adjuvanted, A/H5 or A/Hx vaccine in healthy infants below 6 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:	
Deferral of one or more studies contained in the paediatric investigation plan:	Yes: Not later than 24 months after the declaration by the WHO an Influenza A/H5 or A/Hx virus pandemic.