EMA/123854/2019

# European Medicines Agency decision

P/0057/2019

of 25 February 2019

on the acceptance of a modification of an agreed paediatric investigation plan for Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1) (EMEA-001715-PIP01-14-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

**Disclaimer**

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

**Only the English text is authentic.**

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# European Medicines Agency decision

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on the acceptance of a modification of an agreed paediatric investigation plan for Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1) (EMEA-001715-PIP01-14-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0172/2016 issued on 17 June 2016 and the decision P/0341/2018 issued on 8 November 2018,

Having regard to the application submitted by Seqirus Netherlands B.V. on 21 January 2019 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 12 February 2019, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

***Article 1***

Changes to the agreed paediatric investigation plan for Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1), suspension for injection, intramuscular use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

***Article 2***

This decision is addressed to Seqirus Netherlands B.V., Hullenbergweg, 89, 1101 CL – Amsterdam, The Netherlands.

EMA/PDCO/65234/2019
London, 12 February 2019

# Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-001715-PIP01-14-M02

## Scope of the application

**Active substance(s):**

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

**Condition(s):**

Prevention of influenza infection

**Pharmaceutical form(s):**

Suspension for injection

**Route(s) of administration:**

Intramuscular use

**Name/corporate name of the PIP applicant:**

Seqirus Netherlands B.V.

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Seqirus Netherlands B.V. submitted to the European Medicines Agency on 21 January 2019 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0172/2016 issued on 17 June 2016 and the decision P/0341/2018 issued on 8 November 2018.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 1 February 2019.

## Scope of the modification

Some measures or timelines of the Paediatric Investigation Plan have been modified.

## Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex and appendix.

# Annex I

# The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

# 1. Waiver

## *1.1. Condition*

Prevention of influenza infection

The waiver applies to:

- the paediatric population from birth to less than 6 months of age;
- suspension for injection, intramuscular use;
- 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*

Prevention of influenza infection

### 2.1.1. Indication(s) targeted by the PIP

Prevention of influenza infection

### 2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 6 months to less than 18 years of age

### 2.1.3. Pharmaceutical form(s)

Suspension for injection

### 2.1.4. Measures

| Area | Number of measures | Description |
|---|---|---|
| Quality-related studies | 0 | Not applicable |
| Non-clinical studies | 0 | Not applicable |
| Clinical studies | 5 | **Study 1**<br>Randomized, observer blind, stratified, group-sequential, multicentre study to assess the immunogenicity, efficacy and safety of an adjuvanted quadrivalent influenza vaccine (aQIV) compared to a licensed non-adjuvanted influenza vaccine, trivalent influenza vaccine (Fluzone; first season) or quadrivalent influenza vaccine (Fluzone Quadrivalent; second season), in children from 6 months to less than 6 years of age (V118_05). |

| | | |
|---|---|---|
| | | **Study 2**<br><br>Randomised, observer blind, 4-arm, multicentre extension study to assess the immunogenicity and safety of revaccination in children from 12 months to less than 7 years of age who were included in study V118_05 who receive either the same type of influenza vaccine (adjuvanted or non-adjuvanted) that they have received during the previous influenza season in parent trial V118_05 or the alternate form of vaccine (adjuvanted or non-adjuvanted). (V118_05E3).<br><br>**Study 3**<br><br>Randomized, observer-blind, dose-ranging, multicentre, incomplete factorial design study in unprimed healthy children from 6 months to less than 3 years of age to evaluate the safety, tolerability and immunogenicity of different combinations of two different doses of trivalent inactivated influenza vaccine, different doses of MF59 and/or a second influenza B strain.<br><br>**Study 4**<br><br>Randomised, observer blind, multicentre extension study to assess the immunogenicity and safety of revaccination with the adjuvanted quadrivalent influenza vaccine (aQIV) compared to the quadrivalent influenza vaccine (Fluzone Quadrivalent) in children from 12 months to less than 7 years of age who were included in study V118_05 (V118_05E1).<br><br>**Study 5**<br><br>Randomised, open-label, active-controlled, multicentre study to evaluate the immunogenicity and safety of 2 dose regimens of aQIV versus non-adjuvanted QIV (Fluzone) in immunocompromised (vaccine non-naïve) children from 6 months to less than 18 years of age (V118_09). |
| Extrapolation, modelling and simulation studies | 0 | Not applicable |
| Other studies | 0 | Not applicable |
| Other measures | 0 | Not applicable |

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

| | |
|---|---|
| Concerns on potential long term safety/efficacy issues in relation to paediatric use: | Yes |
| Date of completion of the paediatric investigation plan: | By September 2022 |
| Deferral for one or more measures contained in the paediatric investigation plan: | Yes |