

EMA/775570/2018

European Medicines Agency decision P/0387/2018

of 6 December 2018

on the acceptance of a modification of an agreed paediatric investigation plan 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 (Yamagata lineage) / influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) [QIVc] (EMEA-002068-PIP01-16-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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on the acceptance of a modification of an agreed paediatric investigation plan 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 (Yamagata lineage) / influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) [QIVc] (EMA-002068-PIP01-16-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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/0209/2017 issued on 9 August 2017 and the decision P/0341/2017 issued on 16 November 2017,

Having regard to the application submitted by Seqirus UK Limited on 13 July 2018 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 19 October 2018, 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 and to the deferral.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

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 (H1N1) / 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) [QIVc], suspension for injection, intramuscular use, including changes to the deferral, 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 UK Limited, Point, 29 Market Street, SL6 8AA - Maidenhead, United Kingdom.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/496057/2018 **Corr**

London, 19 October 2018

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

EMA-002068-PIP01-16-M02

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 (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) [QIVc]

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 opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Seqirus UK Limited submitted to the European Medicines Agency on 13 July 2018 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/0209/2017 issued on 9 August 2017 and the decision P/0341/2017 issued on 16 November 2017.

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

The procedure started on 21 August 2018.



Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan and 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 and to the deferral 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 annexes 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

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

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	7	<i>Studies with cell-based trivalent influenza vaccine (TIVc)</i> Study 1: 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 to less than 18 years of age (V58P12).

		Study 2: Randomised, observer-blind, active-controlled trial to evaluate safety of cell-based trivalent influenza vaccine (TIVc) compared to egg-based trivalent influenza vaccine (Agridipal) in children from 3 to less than 18 years of age who are at risk for influenza-related complications (V58P15). Study 3: Randomised, observer-blind, active controlled trial to evaluate safety and tolerability of cell-based trivalent influenza vaccine (TIVc) compared to egg-based trivalent influenza vaccine (Fluvirin) in healthy children from 4 to less than 18 years of age (V58_31). Study 4: 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 to less than 48 months of age (V58_P16). <i>Studies with cell-based quadrivalent influenza vaccine (QIVc)</i> Study 5: Randomised, double-blind, active-controlled, non-inferiority trial to evaluate immunogenicity and safety of cell-based quadrivalent influenza vaccine (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 to less than 18 years age (V130_03). Study 6: Randomised, observer-blind, active-controlled trial to evaluate safety and immunogenicity of cell-based quadrivalent influenza vaccine (QIVc) compared to a quadrivalent authorised influenza vaccine in healthy children from 6 to less than 48 months of age (V130_10). Study 7: Randomised, observer-blind, controlled trial to evaluate efficacy, safety and immunogenicity of cell-based quadrivalent influenza vaccine (QIVc) compared to a non-influenza vaccine comparator in healthy children from 6 to less than 48 months of age (V130_14).
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:	No
Date of completion of the paediatric investigation plan:	By July 2021
Deferral for one or more measures contained in the paediatric investigation plan:	Yes