EMA/176737/2024

European Medicines Agency decision

P/0181/2024

of 15 May 2024

on the agreement of a paediatric investigation plan and on the granting of a waiver 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 (Victoria lineage) (surface antigen, inactivated, prepared in cell cultures) (EMEA-003623-PIP01-24), 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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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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Seqirus Netherlands on 25 March 2024 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 26 April 2024, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a waiver.

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

Has adopted this decision:

Article 1

A 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 (Victoria lineage) (surface antigen, inactivated, prepared in cell cultures), suspension for injection in pre-filled syringe, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A waiver 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 (Victoria lineage) (surface antigen, inactivated, prepared in cell cultures), suspension for injection in pre-filled syringe, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Seqirus Netherlands, Paasheuvelweg 28, 1105BJ – Amsterdam, The Netherlands.

EMA/PDCO/141802/2024
Amsterdam, 26 April 2024

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a waiver

EMEA-003623-PIP01-24

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 (Victoria lineage) (surface antigen, inactivated, prepared in cell cultures)

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of influenza infection

Pharmaceutical form(s):

Suspension for injection in pre-filled syringe

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Seqirus Netherlands

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Seqirus Netherlands submitted for agreement to the European Medicines Agency on 25 March 2024 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 4 April 2024.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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

2. The measures and timelines of the agreed 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 infection

The waiver applies to:

- the paediatric population from birth to less than 6 months of age;
- suspension for injection in pre-filled syringe, 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 in pre-filled syringe

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	*Studies with cell-based trivalent influenza vaccine (TIVc)* **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 years 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 (Agrippal) in children from 3 years 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 years 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 years to less than 48 months of age (V58_P16). *Studies with cell-based quadrivalent influenza vaccine (QIVc)* **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 years 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 years 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 months to less than 48 months of age (V130_14).
Modelling and simulation analyses	Not applicable

Other studies	Not applicable
Extrapolation plan	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 April 2024
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.