EMA/178725/2024

European Medicines Agency decision

P/0168/2024

of 6 May 2024

on the acceptance of a modification of an agreed paediatric investigation plan for influenza vaccine (surface antigen, inactivated, prepared in cell cultures) [QIVc] (Flucelvax Tetra), (EMEA-002068-PIP01-16-M05) 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 European Medicines Agency's decision P/0209/2017 issued on 9 August 2017, the decision P/0341/2017 issued on 16 November 2017, the decision P/0387/2018 issued on 6 December 2018, the decision P/0084/2020 issued on 18 March 2020 and the decision P/0492/2021 issued on 3 December 2021,

Having regard to the application submitted by Seqirus Netherlands on 6 December 2023 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 22 March 2024, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for influenza vaccine (surface antigen, inactivated, prepared in cell cultures) [QIVc] (Flucelvax Tetra), 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 Netherlands, Paasheuvelweg 28, 1105BJ - Amsterdam, The Netherlands.

EMA/PDCO/3696/2024
Amsterdam, 22 March 2024

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

EMEA-002068-PIP01-16-M05

Scope of the application

Active substance(s):

Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) [QIVc]

Invented name and authorisation status:

See Annex II

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 Netherlands

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Seqirus Netherlands submitted to the European Medicines Agency on 6 December 2023 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, the decision P/0341/2017 issued on 16 November 2017, the decision P/0387/2018 issued on 6 December 2018, the decision P/0084/2020 issued on 18 March 2020 and the decision P/0492/2021 issued on 3 December 2021.

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

The procedure started on 22 January 2024.

Scope of the modification

Some measures and 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 and to the deferral in the scope set out in the Annex I of this opinion.

   The Paediatric Committee member of Norway 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	**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 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 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). *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 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	Not applicable
Other studies	Not applicable
Other measures	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:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Prevention of influenza

Authorised indication(s):

- Prophylaxis of influenza in adults and children from 2 years of age.
  - Invented name(s): Flucelvax Tetra
  - Authorised pharmaceutical form(s): Suspension for injection
  - Authorised route(s) of administration: Intramuscular use
  - Authorised via centralised procedure.