

EMA/472034/2018

European Medicines Agency decision

P/0260/2018

of 15 August 2018

on the acceptance of a modification of an agreed paediatric investigation plan for pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) (Foclivia and associated names), (EMA-001830-PIP01-15-M01) 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 726/2004¹,

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/0085/2016 issued on 18 March 2016,

Having regard to the application submitted by Seqirus S.r.l. on 6 April 2018 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 29 June 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.
- (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 pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) (Foclivia and associated names), 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 S.r.l., Via Fiorentina 1, 53100 - Siena, Italy.

EMA/PDCO/237319/2018

London, 29 June 2018

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-001830-PIP01-15-M01

Scope of the application

Active substance(s):

Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)

Invented name:

Foclivia and associated names

Condition(s):

Prevention of influenza infection

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Intramuscular use

Name / corporate name of the PIP applicant:

Seqirus S.r.l.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Seqirus S.r.l. submitted to the European Medicines Agency on 6 April 2018 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0085/2016 issued on 18 March 2016.

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

The procedure started on 2 May 2018.

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 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 infection

The waiver applies to:

- the paediatric population from birth to less than 2 months of age;
- suspension for injection, intramuscular use;
- on the grounds that the specific medicinal product is likely to be ineffective.

And to:

- the paediatric population from 2 months 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

Prophylaxis of influenza in an officially declared pandemic situation

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	2	Study 1 Randomized, controlled, observer-blind, single-centre study to evaluate the immunogenicity, safety and tolerability of two doses of FLUAD H5N1 (Aflunov) influenza vaccine in paediatric subjects from 6 months to less than 18 years of age (study V87P6, same as Study 1 of PIP EMEA-000599-PIP01-09-M04 and subsequent modification thereof). Study 2 Randomized, observer-blind, multicenter study to evaluate the immunogenicity and safety of several doses of antigen and MF59 adjuvant content in a monovalent H5N1 pandemic influenza vaccine in healthy paediatric subjects from 6 months to less than 9 years of age (study V87_30, same as Study 3 of PIP EMEA-000599-PIP01-09-M04 and subsequent modification thereof).
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 April 2022
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Prevention of influenza infection

Authorised indication(s):

- Prophylaxis of influenza in an officially declared pandemic situation.

Authorised pharmaceutical form(s):

Suspension for injection

Authorised route(s) of administration:

Intramuscular use