EMA/233132/2020

European Medicines Agency decision

P/0189/2020

of 15 May 2020

on the acceptance of a modification of an agreed paediatric investigation plan for influenza virus surface antigens - A/turkey/Turkey/1/05 (H5N1) (Aflunov and associated names), (EMEA-000599-PIP01-09-M07) 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 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/150/2009 issued on 5 August 2009, the decision P/211/2010 issued on 29 October 2010, the decision P/132/2011 issued on 8 June 2011, the decision P/0230/2014 issued on 5 September 2014, the decision P/0057/2017 issued on 17 March 2017 and the decision P/0249/2018 issued on 15 August 2018,

Having regard to the application submitted by Seqirus S.r.l. on 10 December 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 27 March 2020, 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 - A/turkey/Turkey/1/05 (H5N1) (Aflunov and associated names), 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 S.r.l., Via del Pozzo 3/A S.Martino, 53035 - Monteriggioni (SI), Italy.

EMA/PDCO/15547/2020
Amsterdam, 27 March 2020

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

EMEA-000599-PIP01-09-M07

Scope of the application

Active substance(s):

Influenza virus surface antigens - A/turkey/Turkey/1/05 (H5N1)

Invented name:

Aflunov and associated names

Condition(s):

Prevention of influenza

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 10 December 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/150/2009 issued on 5 August 2009, the decision P/211/2010 issued on 29 October 2010, the decision P/132/2011 issued on 8 June 2011, the decision P/0230/2014 issued on 5 September 2014, the decision P/0057/2017 issued on 17 March 2017 and the decision P/0249/2018 issued on 15 August 2018.

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

The procedure started on 28 January 2020.

Scope of the modification

Some 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 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:

- neonates and infants 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:

- infants from 2 months to less than 6 months of age;
- suspension for injection, intramuscular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing measures.

2. Paediatric Investigation Plan

2.1. Condition:

Prevention of influenza

2.1.1. Indication(s) targeted by the PIP

Prevention of influenza

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, intramuscular use

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable
Non-clinical	0	Not applicable

Clinical	2	**Study 1:** A Randomised, Controlled, Observer-blind, Single-center Study to Evaluate the Immunogenicity, Safety and Tolerability of Two Doses of FLUAD H5N1 (Aflunov) Influenza Vaccine in Subjects aged from 6 months to less than 18 years. (V87P6) *This study is the same as study 1 of the 'Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)' PIP EMEA-001830-PIP01-15 and subsequent modifications thereof* **Study 2:** Deleted in EMEA-000599-PIP01-09-M05 **Study 3:** 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 18 years of age. (V87_30) *This study is the same as study 2 of the 'Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)' PIP EMEA-001830-PIP01-15 and subsequent modifications thereof*

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 October 2022
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s)

1. Prevention of influenza infection

Authorised indications:

- Active immunisation against H5N1 subtype of Influenza A virus.

  This indication is based on immunogenicity data from healthy subjects from the age of 18 years onwards following administration of two doses of the vaccine containing A/turkey/Turkey/1/05 (H5N1)-like strain (see sections 4.4 and 5.1).

  Aflunov should be used in accordance with official recommendations.

Authorised pharmaceutical form(s):

Suspension for injection

Authorised route(s) of administration:

Intramuscular use