

EMA/324014/2019

European Medicines Agency decision

P/0219/2019

of 17 June 2019

on the acceptance of a modification of an agreed paediatric investigation plan for recombinant Influenza Hemagglutinin-strain A (H1N1 subtype) / recombinant Influenza Hemagglutinin-strain A (H3N2 subtype) / recombinant Influenza Hemagglutinin-strain B (Victoria lineage) / recombinant Influenza Hemagglutinin-strain B (Yamagata lineage) (RIV4) (EMEA-002418-PIP01-18-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/0088/2019 issued on 22 March 2019,

Having regard to the application submitted by Sanofi Pasteur on 16 April 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 29 May 2019, 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 recombinant Influenza Hemagglutinin-strain A (H1N1 subtype) / recombinant Influenza Hemagglutinin-strain A (H3N2 subtype) / recombinant Influenza Hemagglutinin-strain B (Victoria lineage) / recombinant Influenza Hemagglutinin-strain B (Yamagata lineage) (RIV4), solution for injection in pre-filled syringe, 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 Sanofi Pasteur, 14 Espace Henry Vallée, 69007 - Lyon, France.

EMA/PDCO/243143/2019
Amsterdam, 29 May 2019

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-002418-PIP01-18-M01

Scope of the application

Active substance(s):

Recombinant Influenza Hemagglutinin-strain A (H1N1 subtype) / Recombinant Influenza Hemagglutinin-strain A (H3N2 subtype) / Recombinant Influenza Hemagglutinin-strain B (Victoria lineage) / Recombinant Influenza Hemagglutinin-strain B (Yamagata lineage) (RIV4)

Condition(s):

Prevention of influenza infection

Pharmaceutical form(s):

Solution for injection in pre-filled syringe

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Sanofi Pasteur

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sanofi Pasteur submitted to the European Medicines Agency on 16 April 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/0088/2019 issued on 22 March 2019.

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

The procedure started on 30 April 2019.

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 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 annex 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 3 years of age;
- solution for injection in pre-filled syringe; intramuscular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

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 3 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection in pre-filled syringe

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	3	Study 1 (PSC08) Randomized, modified double-blind, active-controlled study to evaluate safety, reactogenicity and immunogenicity of Recombinant Influenza Hemagglutinin-strain A (H1N1 subtype) / Recombinant Influenza Hemagglutinin-strain A (H3N2 subtype) / Recombinant Influenza Hemagglutinin-strain B (Victoria lineage) / Recombinant Influenza Hemagglutinin-strain B (Yamagata lineage) (RIV4) or quadrivalent inactivated influenza vaccine (IIV4)

		Study 2 (LIO-04-16) Randomized, double-blind, active-controlled study to demonstrate non-inferiority, relative efficacy, and safety of recombinant Influenza Hemagglutinin-strain A (H1N1 subtype) / Recombinant Influenza Hemagglutinin-strain A (H3N2 subtype) / Recombinant Influenza Hemagglutinin-strain B (Victoria lineage) / Recombinant Influenza Hemagglutinin-strain B (Yamagata lineage) (RIV4) compared to quadrivalent inactivated influenza vaccine (IIV4) Study 3 (VAP0004) Randomized, double-blind, active-controlled study to demonstrate the non-inferiority, relative efficacy, and safety of recombinant Influenza Hemagglutinin-strain A (H1N1 subtype) / Recombinant Influenza Hemagglutinin-strain A (H3N2 subtype) / Recombinant Influenza Hemagglutinin-strain B (Victoria lineage) / Recombinant Influenza Hemagglutinin-strain B (Yamagata lineage) (RIV4) compared to quadrivalent inactivated influenza vaccine (IIV4)
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 November 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes