EMA/149054/2022

European Medicines Agency decision

P/0100/2022

of 18 March 2022

on the acceptance of a modification of an agreed paediatric investigation plan for recombinant influenza hemagglutinin-strain A (H1N1 subtype)/recombinant influenza hemagglutininstrain A (H3N2 subtype)/recombinant influenza hemagglutinin-strain B (Victoria lineage)/recombinant influenza hemagglutinin-strain B (Yamagata lineage) (Supemtek), (EMEA-002418-PIP01-18-M02) 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/0088/2019 issued on 22 March 2019 and the decision P/0219/2019 issued on 17June 2019,

Having regard to the application submitted by Sanofi Pasteur on 19 November 2021 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 25 February 2022, 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 recombinant influenza hemagglutinin-strain A (H1N1 subtype)/recombinant influenza hemagglutininstrain A (H3N2 subtype)/recombinant influenza hemagglutinin-strain B (Victoria lineage)/recombinant influenza hemagglutinin-strain B (Yamagata lineage) (Supemtek), solution for injection in pre-filled syringe, 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 Sanofi Pasteur, 14 Espace Henry Vallée, 69007 Lyon, France.

EMA/PDCO/710095/2021
Amsterdam, 25 February 2022

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

EMEA-002418-PIP01-18-M02

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)

Invented name:

Supemtek

Condition(s):

Prevention of Influenza infection

Authorised indication(s):

See Annex II

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

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sanofi Pasteur submitted to the European Medicines Agency on 19 November 2021 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 and the decision P/0219/2019 issued on 17 June 2019.

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

The procedure started on 4 January 2022.

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 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 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	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**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)** *This study was deleted with procedure EMEA-002418-PIP01-18-M02* **Study 4 (VAP00026)** *This study was added with procedure EMEA-002418-PIP01-18-M02* Randomised, modified double-blind, active-controlled study to demonstrate non-inferior immunogenicity of the Quadrivalent Recombinant Influenza Vaccine (RIV4) in children from 3 years to less than 9 years of age, compared to an egg-based Quadrivalent Inactivated Influenza Vaccine (IIV4) **Study 5 (VAP00027)** *This study was added with procedure EMEA-002418-PIP01-18-M02* Randomised, open-label, uncontrolled study to demonstrate non-inferior immunogenicity of the Quadrivalent Recombinant Influenza Vaccine (RIV4) in children and adolescents from 9 years to less than 18 years of age compared to adults from 18 to less than 50 years of age.
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 December2023
Deferral for one or more measures 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

Authorised indication(s):

- Supemtek is indicated for active immunization for the prevention of influenza disease in adults.

Authorised pharmaceutical form(s):

Solution for injection in pre-filled syringe (injection)

Authorised route(s) of administration:

Intramuscular use