EMA/563099/2022

European Medicines Agency decision

P/0219/2022

of 10 June 2022

on the acceptance of a modification of an agreed paediatric investigation plan for split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain, A/H3N2-like strain, B-like strain (Victoria lineage) and B-like strain (Yamagata lineage) (Efluelda and associated names), (EMEA-002359-PIP01-18-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.

European Medicines Agency decision

P/0219/2022

of 10 June 2022

on the acceptance of a modification of an agreed paediatric investigation plan for split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain, A/H3N2-like strain, B-like strain (Victoria lineage) and B-like strain (Yamagata lineage) (Efluelda and associated names), (EMEA-002359-PIP01-18-M05) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/0023/2019 issued on 4 January 2019, the decision P/0064/2020 issued on 20 February 2020, the decision P/0010/2021 issued on 18 January 2021 and the decision P/0042/2022 issued on 10 February 2022,

Having regard to the application submitted by Sanofi Pasteur on 18 February 2022 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 20 May 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.

(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, 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 split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain, A/H3N2-like strain, B-like strain (Victoria lineage) and B-like strain (Yamagata lineage) (Efluelda 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 Sanofi Pasteur, 14 Espace Henry Vallée, 69007 – Lyon, France.

EMA/PDCO/142390/2022
Amsterdam, 20 May 2022

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

EMEA-002359-PIP01-18-M05

Scope of the application

Active substance(s):

Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain, A/H3N2-like strain, B-like strain (Victoria lineage) and B-like strain (Yamagata lineage)

Invented name:

Efluelda 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:

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 18 February 2022 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/0023/2019 issued on 4 January 2019, the decision P/0064/2020 issued on 20 February 2020, the decision P/0010/2021 issued on 18 January 2021 and the decision P/0042/2022 issued on 10 February 2022.

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

The procedure started on 21 March 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 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 infection

The waiver applies to:

- the paediatric population from birth to less than 6 months of age and the immunocompetent paediatric population from 9 to less than 18 years of age;
- suspension for injection, 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 6 months to less than 9 years of age and only the immunocompromised paediatric population from 9 years 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	**Study 1 (QHD04)** Dose-finding, randomized, modified double-blind, active-controlled trial to evaluate safety and immunogenicity of 3 different doses of Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain, A/H3N2-like strain, B-like strain (Victoria lineage) and B-like strain (Yamagata lineage) (from here defined as: Quadrivalent influenza vaccine- high dose: QIV-HD) versus an unadjuvanted QIV-standard dose (QIV-SD) in healthy children from

	6 months to less than 9 years of age and an adjuvanted TIV-SD in a subset of healthy children from 6 to less than 24 months **Study 2 (QHD00014)** Randomized, modified double blind, active-controlled trial to demonstrate the superior clinical efficacy and immunogenicity of 1 or 2 doses of QIV-HD compared to standard-dose QIV (QIV-SD), and to describe the safety profile of QIV-HD in healthy children from 6 months to less than 3 years of age **Study 3 (QHD00015)** *Study deleted with procedure EMEA-002359-PIP01-18-M04* **Study 4 (QHD00020)** *Study deleted with procedure EMEA-002359-PIP01-18-M04* **Study 5 (QHD00022)** Randomized, blinding to be determined, active-controlled trial to evaluate immunogenicity and safety of QIV-HD versus QIV-SD in immunocompromised children and adolescents from 6 months to less than 18 years of age **Study 6 (QHD00026)** Open-label, uncontrolled trial to demonstrate non-inferior immunogenicity for each of the 4 influenza strains of QIV-HD in children from 3 years to less than 9 years of age previously unvaccinated against influenza, compared to children from 6 months to less than 3 years of age previously unvaccinated against influenza. *Study added with procedure EMEA-002359-PIP01-18-M04*
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 December 2027
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 disease

Authorised indication(s):

- Active immunisation in adults 60 years of age and older for the prevention of influenza disease.

Authorised pharmaceutical form(s):

Suspension for injection in pre-filled syringe

Authorised route(s) of administration:

Intramuscular route