

EMADOC-1700519818-1773555

## European Medicines Agency decision

EMA/PE/0000221589

of 25 November 2024

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 Tetra and associated names) 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<sup>1</sup>,

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<sup>2</sup>,

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, the decision P/0042/2022 issued on 10 February 2022 and the decision P/0219/2022 issued on 10 June 2022,

Having regard to the application submitted by Sanofi Pasteur on 8 July 2024 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 18 October 2024, 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.

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<sup>1</sup> OJ L 378, 27.12.2006, p.1, as amended.

<sup>2</sup> 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) (Eflueda Tetra and associated names), 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.

EMADOC-1700519818-1623643  
Amsterdam, 18 October 2024

## Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA/PE/0000221589

### 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 and authorisation status:

See Annex II

#### Condition(s):

Prevention of influenza infection

#### Pharmaceutical form(s):

Suspension for injection

#### 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 8 July 2024 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, the decision P/0042/2022 issued on 10 February 2022 and the decision P/0219/2022 issued on 10 June 2022.

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

The procedure started on 19 August 2024.

## 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 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 years 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	<b>Study 1 (QHD04)</b>  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

	<p>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</p> <p><b>Study 2 (QHD00014)</b> <i>deleted in modification</i> EMA/PE/0000221589</p> <p><b>Study 3 (QHD00015)</b> <i>deleted with procedure EMEA-002359-PIP01-18-M04</i></p> <p><b>Study 4 (QHD00020)</b> <i>deleted with procedure EMEA-002359-PIP01-18-M04</i></p> <p><b>Study 5 (QHD00022)</b> <i>deleted in modification</i> EMA/PE/0000221589</p> <p><b>Study 6 (QHD00026)</b> <i>deleted in modification</i> EMA/PE/0000221589</p>
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 September 2020
Deferral for one or more measures contained in the paediatric investigation plan:	Yes



## **Annex II**

### **Information about the authorised medicinal product**

***Information provided by the applicant:***

**Condition(s) and authorised indication(s)**

1. Prevention of influenza infection

Authorised indication(s):

- Active immunisation in adults 60 years of age and older for the prevention of influenza disease
  - Invented name(s): Efluelda Tetra and associated names
  - Authorised pharmaceutical form(s): Suspension for injection in pre-filled syringe
  - Authorised route(s) of administration: intramuscular use
  - Authorised via decentralised procedure