EMA/111601/2024

# European Medicines Agency decision

P/0088/2024

of 15 March 2024

on the agreement of a paediatric investigation plan and on the granting of a waiver for split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain/Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain/Split influenza virus, inactivated containing antigens equivalent to B-like strain (EMEA-003603-PIP01-24) 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 application submitted by Sanofi Winthrop Industrie on 28 February 2024 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 14 March 2024, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a waiver.

[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***

A paediatric investigation plan for split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain/Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain/Split influenza virus, inactivated containing antigens equivalent to B-like strain, suspension for injection, subcutaneous use intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

***Article 2***

A waiver for split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain/Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain/Split influenza virus, inactivated containing antigens equivalent to B-like strain, suspension for injection, subcutaneous use intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

***Article 3***

This decision is addressed to Sanofi Winthrop Industrie, 82 Avenue Raspail, 92250 – Gentilly, France.

EMA/PDCO/105302/2024
Amsterdam, 14 March 2024

# Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a waiver

EMEA-003603-PIP01-24

## Scope of the application

**Active substance(s):**

Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain/Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain/Split influenza virus, inactivated containing antigens equivalent to B-like strain

**Invented name and authorisation status:**

See Annex II

**Condition(s):**

Prevention of influenza disease

**Pharmaceutical form(s):**

Suspension for injection

**Route(s) of administration:**

Subcutaneous use

Intramuscular use

**Name/corporate name of the PIP applicant:**

Sanofi Winthrop Industrie

## Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Sanofi Winthrop Industrie submitted for agreement to the European Medicines Agency on 28 February 2024 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 7 March 2024.

## Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective in part or all of the paediatric population.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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 disease

The waiver applies to:

- Children from birth to less than 6 months of age;
- Suspension for injection; Subcutaneous use, Intramuscular use;

  on the grounds that the specific medicinal product is likely to be ineffective.

# 2. Paediatric investigation plan

## *2.1. Condition:*

Prevention of influenza disease

### 2.1.1. Indication(s) targeted by the PIP

Prevention of influenza disease

### 2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 6 months of age 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 (GQM04)**<br>Randomized, controlled, double-blind (for Quadrivalent influenza vaccine [QIV] lots), open (for allocation to QIV or Trivalent Influenza Vaccine [TIV]) safety and immunogenicity 4-arm trial in children from 9 years of age to less than 18 years of age (and adults).<br>**Study 2 (GQM05)**<br>Randomized, observer-blind (except for TIV groups), controlled, 4-arm trial of efficacy, safety and immunogenicity in healthy children from 6 months of age to less than 36 months of age not previously vaccinated against influenza. |

| | |
|---|---|
| | **Study 3 (GQM02)**<br><br>Randomized, double-blind, active-controlled, 3-arm immunogenicity and safety trial in children aged from 3 years of age to less than 9 years of age, previously vaccinated or unvaccinated against influenza. |
| Modelling and simulation analyses | Not applicable |
| Other studies | Not applicable |
| Extrapolation plan | 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 2018 |
| Deferral for one or more measures contained in the paediatric investigation plan: | No |

# Annex II

# Information about the authorised medicinal product

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

**The product is not authorised anywhere in the European Community.**