



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/304055/2023

## European Medicines Agency decision P/0255/2023

of 14 July 2023

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for modRNA encoding 4 influenza HA antigens (2 for influenza A and 2 for influenza B strains) (qIRV) (EMEA-003318-PIP01-22) 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 application submitted by Pfizer Europe MA EEIG on 9 September 2022 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 26 May 2023, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation 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 deferral 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 deferral.
- (4) It is therefore appropriate to adopt a decision granting a waiver.

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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**

A paediatric investigation plan for modRNA encoding 4 influenza HA antigens (2 for influenza A and 2 for influenza B strains) (qIRV), concentrate for solution for injection, 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 deferral for modRNA encoding 4 influenza HA antigens (2 for influenza A and 2 for influenza B strains) (qIRV), concentrate for solution for injection, 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**

A waiver for modRNA encoding 4 influenza HA antigens (2 for influenza A and 2 for influenza B strains) (qIRV), concentrate for solution for injection, 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 4**

This decision is addressed to Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 – Brussels, Belgium.



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/PDCO/88931/2023  
Amsterdam, 26 May 2023

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

EMA-003318-PIP01-22

### Scope of the application

#### Active substance(s):

modRNA encoding 4 influenza HA antigens (2 for influenza A and 2 for influenza B strains) (qIRV)

#### Invented name and authorisation status:

See Annex II

#### Condition(s):

Prevention of influenza disease

#### Pharmaceutical form(s):

Concentrate for solution for injection

#### Route(s) of administration:

Intramuscular use

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

Pfizer Europe MA EEIG

### Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Pfizer Europe MA EEIG submitted for agreement to the European Medicines Agency on 9 September 2022 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 17 October 2022.

Supplementary information was provided by the applicant on 17 February 2023.



## 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 deferral in accordance with Article 21 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 or unsafe in part or all of the paediatric population.
2. The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

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:

- the paediatric population from birth to 6 weeks of age;
- Concentrate for solution for injection; 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

Active immunisation for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine for children from 6 weeks of age to less than 18 years of age.

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

From 6 weeks of age to less than 18 years of age.

### 2.1.3. Pharmaceutical form(s)

Concentrate for solution for injection

### 2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	<b>Study 1</b> Observer-blind, active-controlled, safety, tolerability, and immunogenicity study of modRNA encoding 4 influenza HA antigens (2 for influenza A and 2 for influenza B strains) (qIRV) in children from 6 weeks of age to less than 18 years of age for the prevention of influenza disease. <b>Study 2</b> Randomized, observer- blind, efficacy, safety, and immunogenicity study of modRNA encoding 4 influenza HA antigens (2 for influenza A and 2 for

	influenza B strains) (qIRV) in children from 6 weeks of age to less than 18 years of age for the prevention of influenza disease.
Modelling and simulation studies	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 April 2029
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:***

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