



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/22215/2025

European Medicines Agency decision P/0001/2025

of 28 January 2025

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for respiratory syncytial virus, prefusion F protein, virus-like particle / human metapneumovirus, prefusion F protein, virus-like particle (IVX-A12) (EMEA-003636-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.



European Medicines Agency decision

P/0001/2025

of 28 January 2025

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for respiratory syncytial virus, prefusion F protein, virus-like particle / human metapneumovirus, prefusion F protein, virus-like particle (IVX-A12) (EMEA-003636-PIP01-24) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by AstraZeneca AB on 29 April 2024 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 13 December 2024, 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.

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 respiratory syncytial virus, prefusion F protein, virus-like particle / human metapneumovirus, prefusion F protein, virus-like particle (IVX-A12), 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 respiratory syncytial virus, prefusion F protein, virus-like particle / human metapneumovirus, prefusion F protein, virus-like particle (IVX-A12), 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 respiratory syncytial virus, prefusion F protein, virus-like particle / human metapneumovirus, prefusion F protein, virus-like particle (IVX-A12), 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 AstraZeneca AB, SE-151 85 – Södertälje, Sweden.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/439690/2024 ¹ Corr
Amsterdam, 13 December 2024

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

EMA-003636-PIP01-24

Scope of the application

Active substance(s):

Respiratory syncytial virus, prefusion F protein, virus-like particle / Human metapneumovirus, prefusion F protein, virus-like particle (IVX-A12)

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of lower respiratory tract disease caused by respiratory syncytial virus or human metapneumovirus

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

AstraZeneca AB

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, AstraZeneca AB submitted for agreement to the European Medicines Agency on 29 April 2024 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 27 May 2024.

¹ 14 January 2025



Supplementary information was provided by the applicant on 9 September 2024. The applicant proposed modifications to the paediatric investigation plan.

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)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Paediatric Committee members of Liechtenstein and Norway agree 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 lower respiratory tract disease caused by respiratory syncytial virus or human metapneumovirus

The waiver applies to:

- the paediatric population from birth to less than 6 weeks of age;
- solution 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 lower respiratory tract disease caused by respiratory syncytial virus or human metapneumovirus

2.1.1. Indication(s) targeted by the PIP

Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV) or human metapneumovirus (hMPV)

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

From 6 weeks to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection, intramuscular use.

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Study 1 Part 1: Immunogenicity study in cotton rats to determine the dose and dosage of unadjuvanted IVX-A12 required to elicit a non-inferior neutralising antibody (nAb) response compared to adjuvanted IVX-A12 in naïve cotton rats Part 2: Challenge study in cotton rats to determine whether immunisation with IVX-A12 followed by RSV infection can lead to vaccine-associated enhanced respiratory disease

Clinical studies	<p>Study 2</p> <p>Modified double-blind, randomised, placebo-controlled trial to describe safety and immunogenicity of IVX-A12 in children from 6 weeks to less than 18 years of age</p> <p>Study 3</p> <p>Modified double-blind, randomised, placebo-controlled study to evaluate efficacy, safety, and immunogenicity of IVX-A12 in children from 6 weeks to less than 2 years of age</p> <p>Study 4</p> <p>Modified double-blind, randomised, placebo-controlled study to assess the immunogenicity and safety of IVX-A12 in children aged from 2 years to less than 5 years of age, and from 5 years to less than 18 years of age (at increased risk) when compared to children aged from 6 weeks to less than 2 years of age.</p> <p>Study 5</p> <p>Randomised, controlled, open-label study to assess the immunogenicity and safety of IVX-A12 in children from 6 weeks to less than 13 months of age when co-administered or sequentially administered with routine paediatric immunisations.</p> <p>Study 6</p> <p>Open-label study to evaluate the safety and immunogenicity of IVX-A12 in immunocompromised children from 6 weeks to less than 18 years of age.</p>
Modelling and simulation analyses	Not applicable
Other studies	Not applicable
Extrapolation plan	PIP Studies 3 and 4 are part of an extrapolation of efficacy plan covering the paediatric population from 6 weeks to less than 18 years of age, as agreed by the PDCO.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By March 2037
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