

EMA/57360/2024

European Medicines Agency decision P/0045/2024

of 9 February 2024

on the agreement of a paediatric investigation plan and on the granting of a waiver for influenza Virus Type B, Victoria lineage / Influenza Virus Type A, H3N2 / Influenza Virus Type A, H1N1 (EMEA-003589-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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on the agreement of a paediatric investigation plan and on the granting of a waiver for Influenza Virus Type B, Victoria lineage / Influenza Virus Type A, H3N2 / Influenza Virus Type A, H1N1 (EMEA-003589-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 5 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 9 February 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 Influenza Virus Type B, Victoria lineage / Influenza Virus Type A, H3N2 / Influenza Virus Type A, H1N1, nasal spray, suspension, nasal 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 Influenza Virus Type B, Victoria lineage / Influenza Virus Type A, H3N2 / Influenza Virus Type A, H1N1, nasal spray, suspension, nasal 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 AstraZeneca AB, 151 85 – Sodertalje, Sweden.

EMA/PDCO/52408/2024
Amsterdam, 8 February 2024

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

EMA-003589-PIP01-24

Scope of the application

Active substance(s):

Influenza virus type B, Victoria lineage / Influenza virus type A, H3N2 / Influenza virus type A, H1N1

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of influenza infection

Pharmaceutical form(s):

Nasal spray, suspension

Route(s) of administration:

Nasal 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 5 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 6 February 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 or unsafe in part or all of the paediatric population.

The Paediatric Committee members of Norway and Liechtenstein 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 influenza infection

The waiver applies to:

- the children from birth to less than 2 years of age;
- for nasal spray for nasal use;
- on the grounds that the specific medicinal product is likely to be unsafe.

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 2 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Nasal spray for nasal use

2.1.4. Studies

Area	Description
Quality	Not applicable
Non-clinical	Not applicable
Clinical	Study 1 Randomised, double-blind, active controlled, multicenter study to assess the safety and immunogenicity of Q/LAIV in comparison with two formulations of FluMist in children from 2 to less than 18 years of age

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By March 2013
Deferral for one or more studies 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.