EMA/28208/2024

European Medicines Agency decision

P/0072/2024

of 8 March 2024

on the acceptance of a modification of an agreed paediatric investigation plan for SARS-CoV2 prefusion spike delta TM (CoV-2 preS dTM) adjuvanted with AS03 (VidPrevtyn Beta), (EMEA-002915-PIP01-20-M03) 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/0072/2024

of 8 March 2024

on the acceptance of a modification of an agreed paediatric investigation plan for SARS-CoV2 prefusion spike delta TM (CoV-2 preS dTM) adjuvanted with AS03 (VidPrevtyn Beta), (EMEA-002915-PIP01-20-M03) 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 726/2004[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 European Medicines Agency's decision P/0201/2021 issued on 10 May 2021, and the decision P/0046/2022 issued on 14 February 2022,

Having regard to the application submitted by Sanofi Pasteur on 6 October 2023 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and proposing a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 January 2024, in accordance with Article 22 of Regulation (EC) No 1901/2006 and Article 11(1)(c),

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 on the granting of a waiver.

(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.

(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

Changes to the agreed paediatric investigation plan for SARS-CoV2 prefusion spike delta TM (CoV-2 preS dTM) adjuvanted with AS03 (VidPrevtyn Beta), solution and emulsion for emulsion for injection, intramuscular use, 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

A waiver for SARS-CoV2 prefusion spike delta TM (CoV-2 preS dTM) adjuvanted with AS03 (VidPrevtyn Beta), solution and emulsion for emulsion for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Sanofi Pasteur, 14 Espace Henry Vallée, 69007 – Lyon, France.

EMA/PDCO/479729/2023
Amsterdam, 19 January 2024

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan and on the granting of a product-specific waiver

EMEA-002915-PIP01-20-M03

Scope of the application

Active substance(s):

SARS-CoV2 prefusion spike delta TM (CoV-2 preS dTM) adjuvanted with AS03

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of coronavirus disease 2019 (COVID-19)

Pharmaceutical form(s):

Solution and emulsion for emulsion 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 6 October 2023 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0201/2021 issued on 10 May 2021, and the decision P/0046/2022 issued on 14 February 2022.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral and proposed a waiver for all subsets of the paediatric population.

The procedure started on 20 November 2023.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified. A waiver for a new paediatric subset has been added.

Opinion

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 and
- to grant a product-specific waiver for all subsets of the paediatric population 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, as set out in Annex I of this opinion.

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

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Prevention of coronavirus disease 2019 (COVID-19)

The waiver applies to:

- the paediatric population from birth to less than 18 years of age;
- solution and emulsion for emulsion for injection; intramuscular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Prevention of Coronavirus disease 2019 (COVID-19)

Authorised indication(s):

- VidPrevtyn Beta is indicated as a booster for active immunisation to prevent COVID-19 in adults who have previously received an mRNA or adenoviral vector COVID-19 vaccine
- Invented name: VidPrevtyn Beta
- Authorised pharmaceutical form(s): solution and emulsion for emulsion for injection
- Authorised route(s) of administration: intramuscular route
- Authorised via centralised procedure