EMA/707190/2021

European Medicines Agency decision

P/0559/2021

of 27 December 2021

on the acceptance of a modification of an agreed paediatric investigation plan for COVID-19 vaccine (ChAdOx1-S [recombinant]) (Vaxzevria), (EMEA-002862-PIP01-20-M02) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0003/2021 issued on 5 January 2021 and decision P/0266/2021 issued on 7 July 2021,

Having regard to the application submitted by AstraZeneca AB on 13 September 2021 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 12 November 2021, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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 to the deferral.

(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.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for COVID-19 vaccine (ChAdOx1-S [recombinant]) (Vaxzevria), suspension 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

This decision is addressed to AstraZeneca AB, Södertälje, SE-151-85 – Södertälje, Sweden.

EMA/PDCO/560574/2021
Amsterdam, 12 November 2021

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-002862-PIP01-20-M02

Scope of the application

Active substance(s):

COVID-19 vaccine (ChAdOx1-S [recombinant])

Invented name:

Vaxzevria

Condition(s):

Prevention of coronavirus disease 2019 (COVID-19)

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

AstraZeneca AB

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, AstraZeneca AB submitted to the European Medicines Agency on 13 September 2021 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0003/2021 issued on 5 January 2021 and decision P/0266/2021 issued on 7 July 2021.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 19 October 2021.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. 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 in the scope set out in Annex I of this opinion.

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

2. The measures and timelines of the paediatric investigation plan 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

Not applicable

2. Paediatric investigation plan

2.1. Condition:

Prevention of coronavirus disease 2019 (COVID-19)

2.1.1. Indication(s) targeted by the PIP

For active immunization of individuals for the prevention of coronavirus disease 2019 (COVID-19)

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Suspension for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	4	**Study 1 (D8110C00002 part A)** Randomised, dose-finding, observer-blind, controlled study to evaluate the safety and immunogenicity of COVID-19 vaccine (ChAdOx1-S [recombinant]) (Vaxzevria) for prevention of COVID-19 in children from birth to less than 12 years of age **Study 2 (D8110C00002 Part B)** Randomised, observer-blind, controlled study to evaluate the safety and immunogenicity of COVID-19 vaccine (ChAdOx1-S [recombinant]) (Vaxzevria) for prevention of COVID-19 in children from birth to less than 12 years of age **Study 3** Open label, uncontrolled, safety and immunogenicity study of COVID-19 vaccine (ChAdOx1-S [recombinant]) (Vaxzevria) for the prevention of COVID-19 in immunocompromised children and adolescents from birth to less than 18 years of age

		Study 4 (D8110C0004) **Added in procedure EMEA-002862-PIP01-20-M01** Randomised, observer-blind, controlled study to evaluate the safety and immunogenicity of COVID-19 vaccine (ChAdOx1-S [recombinant]) (Vaxzevria) for prevention of COVID-19 in adolescents from 12 to less than 18 years of age
Extrapolation, modelling and simulation studies	0	Not applicable
Other studies	0	Not applicable
Other measures	0	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 July 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

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

Authorised indication(s):

- Vaxzevria is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 18 years of age and older

Authorised pharmaceutical form(s):

Suspension for injection

Intramuscular use

Authorised route(s) of administration:

Intramuscular use