EMA/628699/2020

European Medicines Agency decision

P/0509/2020

of 22 December 2020

on the acceptance of a modification of an agreed paediatric investigation plan for cholera vaccine, live attenuated, oral (strain CVD 103-HgR) (Vaxchora) (EMEA-001490-PIP01-13-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/0286/2014 issued on 28 October 2014, and the decision P/0381/2018 issued on 7 December 2018,

Having regard to the application submitted by Emergent Netherlands B.V. on 5 August 2020 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 November 2020, 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 cholera vaccine, live attenuated, oral (strain CVD 103-HgR) (Vaxchora), powder for oral suspension, age-appropriate oral liquid dosage form, oral 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 Emergent Netherlands B.V., Strawinskylaan 411 - 1077XX Amsterdam, The Netherlands.

EMA/PDCO/440551/2020
Amsterdam, 13 November 2020

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

EMEA-001490-PIP01-13-M02

Scope of the application

Active substance(s):

Cholera vaccine, live attenuated, oral (strain CVD 103-HgR)

Invented name:

Vaxchora

Condition(s):

Prevention of cholera

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for oral suspension

Age-appropriate oral liquid dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Emergent Netherlands B.V.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Emergent Netherlands B.V. submitted to the European Medicines Agency on 5 August 2020 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0286/2014 issued on 28 October 2014 and the decision P/0381/2018 issued on 7 December 2018.

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

The procedure started on 15 September 2020.

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 the 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 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 cholera

The waiver applies to:

- the paediatric population from birth to less than 6 months of age;
- powder for oral suspension, oral use;
- on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric investigation plan

2.1. Condition:

Prevention of cholera

2.1.1. Indication(s) targeted by the PIP

Prophylaxis of disease caused by *V. cholerae* serogroup O1

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

From 6 months to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder for oral suspension

Age-appropriate oral liquid dosage form

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of an age-appropriate oral liquid dosage form for the paediatric subset from 6 months to less than 2 years of age
Non-clinical studies	0	Not applicable
Clinical studies	2	**Study 2** Double-blind, randomised, single dose, placebo-controlled trial to demonstrate that vibriocidal antibody seroconversion in children from 2 to less than 18 years of age is non-inferior as compared to adults following vaccination with cholera vaccine (PXVX-VC-200-006)

		Study 3 Double-blind, randomised, single dose, placebo-controlled trial to assess the safety and immunogenicity of cholera vaccine in children from 6 months to less than 2 years of age (EBSI-VC-200-008)
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 December 2023
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 cholera

Authorised indication(s):

- Vaxchora is indicated for active immunisation against disease caused by *Vibrio cholerae* serogroup O1 in adults and children aged 6 years and older.

Authorised pharmaceutical form(s):

Effervescent powder and powder for oral suspension

Authorised route(s) of administration:

Oral use