MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-101028-PIP01-23-M01

Scope of the Application

Active Substance(s)

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

Condition(s)

Prevention of cholera

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 BioSolutions UK LTD

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Emergent BioSolutions UK LTD submitted to the licensing authority on 24/05/2023 14:24 BST an application for a Modification

The procedure started on 10/10/2023 09:46 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-101028-PIP01-23-M01

Of 20/10/2023 15:33 BST

On the adopted decision for Cholera vaccine, recombinant, live, oral (strain CVD 103-HgR) (MHRA-101028-PIP01-23-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for Cholera vaccine, recombinant, live, oral (strain CVD 103-HgR), Powder for oral suspension; Age-appropriate oral liquid dosage form , ORAL USE .

This decision is addressed to Emergent BioSolutions UK LTD, Building 3, Chiswick Park, 566 Chiswick high road, London, UNITED KINGDOM, W5 5YA

ANNEX I

1. Waiver

1.1 Condition:

Prevention of cholera The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 months of age Pharmaceutical form(s): Powder for oral suspension Age-appropriate oral liquid dosage form Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of cholera

2.2 Indication(s) targeted by the PIP:

Prophylaxis of disease caused by V. cholerae serogroup O1

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 6 months to less than 18 years of age

2.4 Pharmaceutical Form(s):

Powder for oral suspension Age-appropriate oral liquid dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	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 (PXVX-VC-200-006) Double-blind, randomised, single dose, placebo-controlled trial to demonstrate that vibriocidal antibody seroconversion in children from 2 years to less than 18 years of age is non-inferior as compared to adults following vaccination with cholera vaccine. Study 3 (EBSI-VC-200-008) Open label, single arm study to assess the safety and immunogenicity of one dose of the cholera vaccine in children from 6 months to less than 2 years of age.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	30/11/2024

Deferral of one or more studies contained in the paediatric investigation plan:	Yes