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 changes to the agreed paediatric investigation plan and to the deferral

MHRA-100072-PIP01-21-M01

Scope of the Application

Active Substance(s)

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

Condition(s)

Prevention of coronavirus disease 2019 (COVID-19)

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

Intramuscular use

Name / Corporate name of the PIP applicant

AstraZeneca UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AstraZeneca UK Limited submitted to the licensing authority on 23/03/2021 15:46 GMT an application for a Modification

The procedure started on 28/05/2021 13:01 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:

The acceptance of change 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-100072-PIP01-21-M01

Of 14/12/2021 16:29 GMT

On the adopted decision for COVID-19 Vaccine (ChAdOx1-S [recombinant]) (MHRA-100072-PIP01-21-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 COVID-19 Vaccine (ChAdOx1-S [recombinant]), Solution for injection , Intramuscular use .

This decision is addressed to AstraZeneca UK Limited, 600 Capability Green, Luton, United Kingdom, LU1 3LU

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of coronavirus disease 2019 (COVID-19)

2.2 Indication(s) targeted by the PIP:

For active immunisation for the prevention of coronavirus disease 2019 (COVID-19).

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

All subsets of the paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	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 MHRA-100072-PIP01-21-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 years to less than 18 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:	31/12/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes