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

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral

MHRA-101210-PIP01-23

Scope of the Application

Active Substance(s)

Zapomeran

Condition(s)

Prevention of coronavirus disease 2019 (COVID-19)

Pharmaceutical Form(s)

Powder for dispersion for injection

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

Seqirus UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Seqirus UK Limited submitted to the licensing authority on 19/12/2023 21:16 GMT an application for a Paediatric Investigation Plan

The procedure started on 12/02/2024 12:47 GMT

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 agree a paediatric investigation plan and grant a 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-101210-PIP01-23

Of 23/04/2024 16:32 BST

On the adopted decision for Zapomeran (MHRA-101210-PIP01-23) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for Zapomeran, Powder for dispersion for injection , INTRAMUSCULAR USE .

This decision is addressed to Seqirus UK Limited, The Point, 29 Market Street, Maidenhead, UNITED KINGDOM, SL6 8AA

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:

Active immunisation for the prevention of COVID-19 caused by SARS-CoV-2 in individuals from birth to less than 18 years of age

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):

Powder for dispersion 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	2	Study 1 (ARCT-154-05) Randomised, observer-blind, controlled study to evaluate the safety, reactogenicity, and immunogenicity of zapomeran given as a primary series in children from birth to less than 5 years of age (primary series cohort) and as a booster vaccine in children and adolescents from 5 years to less than 18 years of age who have received an authorised COVID-19 mRNA vaccine as a primary series (booster cohort), for the prevention of COVID-19. Study 2 (ARCT-154-06) Open-label single arm study to evaluate the safety, reactogenicity, and immunogenicity of zapomeran given as a primary series in immunocompromised children from birth to less than 5 years of age (primary series cohort) and as a booster vaccine in immunocompromised children and adolescents from 5 years to less than 18 years of age who have received an authorised COVID-19 mRNA vaccine as a primary series (booster cohort), for the prevention of COVID-19.
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:	31/12/2032
Deferral of one or more studies contained in the paediatric investigation plan:	Yes