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-100070-PIP01-21

Scope of the Application

Active Substance(s)

molnupiravir

Condition(s)

Treatment of Coronavirus disease 2019 (COVID-19)

Pharmaceutical Form(s)

Age appropriate dosage form (Granules); Capsule, hard

Route(s) of Administration

Oral use, Enteral use

Name / Corporate name of the PIP applicant

Merck Sharp and Dohme (UK) Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Merck Sharp and Dohme (UK) Limited submitted to the licensing authority on 17/06/2021 08:45 BST an application for a Paediatric Investigation Plan

The procedure started on 06/07/2021 11:04 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 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-100070-PIP01-21

Of 06/09/2021 15:44 BST

On the adopted decision for molnupiravir (MHRA-100070-PIP01-21) 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 molnupiravir, Age appropriate dosage form (Granules); Capsule, hard , Oral use, Enteral use .

This decision is addressed to Merck Sharp and Dohme (UK) Limited, 120 Moorgate, London, United Kingdom, EC2M 6UR

ANNEX I

1. Waiver

1.1 Condition:

Not applicable.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of Coronavirus disease 2019 (COVID-19)

2.2 Indication(s) targeted by the PIP:

Treatment of Coronavirus disease 2019 (COVID-19) in paediatric patients 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):

Age appropriate dosage form (Granules); Capsule, hard

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1_ Development of an age-appropriate oral dosage form (granules) for the paediatric population from birth to less than 12 years of age
Non-Clinical Studies	1	Study 2_ Definitive juvenile toxicity study in rats
Clinical Studies	1	Study 3_ Open label, multicentre study to evaluate the pharmacokinetics, safety, and efficacy of molnupiravir (MK-4482) in children from birth to less than 18 years of age (including premature infants born at least at 32 weeks GA) with mild or moderate COVID-19.
Extrapolation, Modeling & Simulation Studies	2	Study 4_ Population PK modelling and PK-PD exposure-response study to select the molnupiravir (MK-4482) doses across weight bands for paediatric populations from birth to less than 18 years of age; Study 5_ Extrapolation study of efficacy and safety of molnupiravir (MK-4482) from adults to children from birth to less than 18 years of age with mild or moderate coronavirus disease 2019.
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