Medicines & Healthcare products Regulatory Agency

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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral

MHRA-100346-PIP01-21

Scope of the Application

Active Substance(s)

MOLNUPIRAVIR; MOLNUPIRAVIR

Condition(s)

Prevention of Coronavirus disease 2019 (COVID-19)

Pharmaceutical Form(s)

Capsules hard; Age appropriate oral dosage form (Granules), Capsules hard; Age appropriate oral dosage form (Granules)

Route(s) of Administration

Oral use, Oral 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 15/12/2021 09:04 GMT an application for a Paediatric Investigation Plan

The procedure started on 22/12/2021 12:21 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-100346-PIP01-21

Of 01/02/2022 09:10 GMT

On the adopted decision for MOLNUPIRAVIR (MHRA-100346-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, Capsules hard; Age appropriate oral dosage form (Granules) , Oral 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):

Prevention of Coronavirus disease 2019 (COVID-19)

2.2 Indication(s) targeted by the PIP:

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):

Age appropriate dosage form (Granules); Capsule, hard

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 (same as for MHRA-100070-PIP01-21) 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 (same as for MHRA-100070-PIP01-21) Definitive juvenile toxicity study in rats
Clinical Studies	1	Study 3 (same as for MHRA-100070-PIP01-21) 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 with coronavirus disease 2019 (COVID-19) and healthy children from birth to less than 18 years for the prevention of COVID-19. Study 5 Extrapolation study of efficacy and safety of molnupiravir (MK-4482) from healthy adult subjects to healthy paediatric patients from birth to less than 18 years of age for the prevention of COVID-19.
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