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 (MHRA-100070-PIP01-21-M01) and grant a deferral

MHRA-100070-PIP01-21-M02

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

Name / Corporate name of the PIP applicant

Merck Sharp & Dohme (UK) Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Merck Sharp & Dohme (UK) Limited submitted to the licensing authority on 12/12/2025 10:49 GMT an application for a Modification

The procedure started on 08/01/2026 17:20 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 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-100070-PIP01-21-M02

Of 02/04/2026 13:23 BST

On the adopted decision for MOLNUPIRAVIR (MHRA-100070-PIP01-21-M02) 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 MOLNUPIRAVIR, Age-appropriate dosage form (Granules) Capsule, hard , ORAL USE .

This decision is addressed to Merck Sharp & 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:	31/10/2032
Deferral of one or more studies contained in the paediatric investigation plan:	Yes