Provisional Consent to the Distribution of a New Medicine

Pursuant to section 23(1) of the Medicines Act 1981, the Minister of Health hereby provisionally consents to the sale, supply or use in New Zealand of the new medicine set out in the Schedule hereto:

Schedule

Product:	**Lagevrio**
Active Ingredient:	Molnupiravir 200mg
Dosage Form:	Capsule
New Zealand Sponsor:	Merck Sharp & Dohme (New Zealand) Limited
Manufacturers:	MSD International GmbH (Puerto Rico Branch) LLC, Las Piedras, Puerto Rico Patheon Inc, Whitby Operations, Ontario, Canada Patheon Pharmaceuticals Inc, Ohio, United States of America

Provisional consent is granted for a period of two years.

This consent is given subject to the following conditions.

The New Zealand Sponsor must fulfil the following obligations within the timelines specified, which may be altered by mutual agreement with Medsafe:

1. Provide confirmatory clinical trial data as identified in the sponsor’s plan to submit comprehensive safety and efficacy data within six years from consent being granted within five working days of any reports being produced.
2. Provide updates regarding the clinical activity, efficacy, and effectiveness against the current and future Variants of Concern and Variants of Interest identified by the World Health Organization (WHO) within five working days of any reports being produced.
3. Provide further data relating to safety and efficacy in immunocompromised subjects, pregnant women, lactating mothers, paediatric subjects, patients with hepatic impairment as well as additional pharmacology and long-term safety data and information relating to post-market safety and efficacy studies within five working days of any reports being produced.
4. Provide the results from any non-sponsor led clinical studies involving Lagevrio within five working days of any reports being produced.
5. Provide results from a germ cell mutagenicity study in transgenic Fischer Big Blue rats. Due date: 31 July 2023.
6. Provide results of the 6-month Tg RasH2 mouse carcinogenicity study. Due date: 30 September 2022.
7. Provide results from the 7-month follow-up of the MOVe-OUT (P002) study. Due date: 31 December 2022.

Dated this 14th day of April 2022.

CHRIS JAMES, Group Manager, Medsafe, Ministry of Health (pursuant to delegation given by the Minister of Health on 11 September 2013).

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