Annex 2

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XX July 2024

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Lagevrio® ▼ (molnupiravir) 200 mg hard capsules – Extended Use Beyond Labelled Expiry Date.

Dear Healthcare Professional,

This letter is sent in agreement with the Medicines and Healthcare Products Regulatory Agency (MHRA).

We would like to inform you about the following:

Summary

- **There has been an extension to the shelf life of specific batch numbers of Lagevrio® 200 mg hard capsules, beyond the labelled expiry date by 6, 12 or 18 months.**
- **Affected batches for extended use of Lagevrio® 200 mg hard capsules are annexed to this communication.**
- **The extended use only applies to the batches of Lagevrio® 200 mg hard capsules listed in the annex on page 3.**
- **Patients can continue to use the Lagevrio® 200 mg hard capsules of these specified batches safely until the extended use by date as stated within the annex.**
- **This extended use does not apply to any other batch numbers of Lagevrio® 200 mg hard capsules not specified.**
- **Patients must continue to adhere to the labelled expiry date on any Lagevrio® 200 mg hard capsules not covered by the batch numbers within the annex.**

Further information on the extended use of the listed batches of Lagevrio® 200 mg hard capsules
The overall market supply of Lagevrio® 200 mg hard capsules is being managed by the Department of Health and Social Care (DHSC). Initial stock procured by the DHSC was labelled at the time of manufacture with the approved shelf life of 18 months at product release. The DHSC has since procured further stock with the approved shelf life of 24 and 30 months, at product release.

With supportive stability data MSD have subsequently gained approval from the MHRA to extend the expiry date to 36 months. Therefore, to enable the stock on hand to be utilised, the period that the 124 specified batches of Lagevrio® 200 mg hard capsules (listed in the annex) can be used has been extended by 6, 12 or 18 months beyond the labelled expiry date on the pack.

Batch numbers and labelled expiry dates are marked on the bottom-flap of the box and on the bottle label. This extended use of either 6, 12 or 18 months beyond the labelled expiry date for the specific batches is based on supportive stability data for Lagevrio® 200 mg hard capsules which has been approved by the MHRA. Lagevrio® 200 mg hard capsules of these specific batches can

continue to be administered as intended within the allowed extended use by date. The product should continue to be stored in accordance with the storage instructions in the Patient Information Leaflet.

Further information on recommendations to healthcare professionals
The healthcare professional should tell patients and caregivers about the extended use by date of the specified batches of Lagevrio® 200 mg hard capsules as listed within the annex. This does not apply to other batches of Lagevrio® 200 mg hard capsules not listed below.

Please show patients and caregivers where to find the batch numbers on their medication (on the end-flap of the box).

Please reassure patients and caregivers that their medication can be taken over the extended use period.

Please note the following:

- This product is considered authorised for supply in United Kingdom
- Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed. These can be found at www.medicines.org.uk/emc.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to patients receiving Lagevrio® 200 mg hard capsules of these specific batches.

Call for reporting
Healthcare professionals are asked to report suspected adverse reactions to the Coronavirus Yellow Card Scheme electronically. Report via the website https://coronavirus-yellowcard.mhra.gov.uk/, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effects can also be reported by calling 0800 731 6789 for free.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Lagevrio® ▼ is subject to additional monitoring identified by the black triangle. Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme.

Company contact point: If you require further information please contact medicalinformationuk@msd.com or call MSD Medical Information services on 0208 154 8000.

Yours sincerely,

Dr Christoph Hartmann

Country Medical Director
MSD UK

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Table 1: Affected batches for extended use of Lagevrio® 200 mg hard capsules

Batch no.	Labelled Expiry Date (end of the month)	Extended Use by Date (end of the month)
U035832, U035834, U035826, U035830, U035829, U035827	December 2022	June 2024
CKFWW, CKFWT, CKFXB, U035259, U035349, U035403, U035575, U035580, U035584, U035723, U036097, U036227, U036303, U036096, U036063	January 2023	July 2024
U038932, U038928, U039514, U038931, U039699, U038933, W003017, W001762, W002196, W002251, W002252, W003006, W003015, W001492, W001742, W001757, W001763, W002191, W002192, W002200, W002201, W002209, W003055, W003012	February 2023	August 2024
U040071, U040082, U040308, U040300, W001764, U040316, W002566, W002577, W002582, W003430, W003111, W003431	March 2023	September 2024
2644400, 2620967, 2620965, 2620959, 2644399, W003434, W005862, W005866, W005869, W005872, W005873, W006344, W006347, W006351, W006360, W006363, W006353, W006354, W006793, W006365, W006369, W006358, W006794, W006945	April 2023	October 2024
2620971, 2620975, 2620973, 2620969, 2620977, 2698245, 2678932, 2698247	May 2023	November 2024
W011781, W012460	August 2023	August 2024
W007695, W008022, W007683, W007684, W007693	October 2023	October 2024
W012394, W012403, W012408, W012538, W012585, W017279, 2698249	November 2023	November 2024
2689837, 2689839, 2689841, 2689845, 2689847, 2689851, 2843352, 2689855	December 2023	December 2024
W031114, W031120, W031127	August 2024	February 2025
W032935, W032936, W032940, W033244, W033245, W033246, W032594, W032598, W032911, W032934	September 2024	March 2025

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