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05th December 2022

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Lagevrio® ▼ 200 mg hard capsules (molnupiravir) – 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 lot (batch) numbers of Lagevrio® 200 mg hard capsules, beyond the labelled expiry date by 6 or 12 months (depending on the shelf life of the specific batch).
- 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.
- Patients can continue to use the Lagevrio® 200 mg hard capsules of these specified lots 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 lots 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 months, at product release.

With supportive stability data MSD have subsequently gained approval from the MHRA to extend the expiry date to 30 months. Therefore, to enable the stock on hand to be utilised,

the period that the 109 specified batches of Lagevrio® 200 mg hard capsules (listed in the annex) can be used has been extended by 6 or 12 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 or 12 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 will continue to work safely and as intended within the allowed extended use by date. The Lagevrio® 200 mg hard capsules 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 direct the patient to the online patient guidance available at <https://www.gov.uk/government/publications/expiry-date-of-lagevrio-molnupiravir-antiviral-medication-extended> and tell patients and caregivers about the extended use by date of the specified lots 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.

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 and will continue to work safely 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.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to patients.

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/](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, SystemOne, 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 about Lagevrio® please contact medicalinformationuk@msd.com or call MSD Medical Information services on 0208 1548000. The SmPC and Patient Information Leaflet are also available at www.medicines.org.uk/emc.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Dilruwan Herath', with a horizontal line underneath.

Dr Dilruwan Chaminda Herath

Country Medical Director
MSD UK

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

Lot (batch) no.	Labelled Expiry Date (end of the month)	Extended Use by Date (end of the month)
U035832	December 2022	December 2023
U035834	December 2022	December 2023
U035826	December 2022	December 2023
CKFWW	January 2023	January 2024
CKFWT	January 2023	January 2024
CKFXB	January 2023	January 2024
U035259	January 2023	January 2024
U035349	January 2023	January 2024
U035403	January 2023	January 2024
U035575	January 2023	January 2024
U035580	January 2023	January 2024
U035584	January 2023	January 2024
U035723	January 2023	January 2024
U036097	January 2023	January 2024
U036227	January 2023	January 2024
U036303	January 2023	January 2024
U036096	January 2023	January 2024
U036063	January 2023	January 2024
U038932	February 2023	February 2024
U038928	February 2023	February 2024
U039514	February 2023	February 2024
U038931	February 2023	February 2024
U039699	February 2023	February 2024
U038933	February 2023	February 2024
W003017	February 2023	February 2024
W001762	February 2023	February 2024
W002196	February 2023	February 2024
W002251	February 2023	February 2024
W002252	February 2023	February 2024
W003006	February 2023	February 2024
W003015	February 2023	February 2024
W001492	February 2023	February 2024
W001742	February 2023	February 2024
W001757	February 2023	February 2024
W001763	February 2023	February 2024
W002191	February 2023	February 2024
W002192	February 2023	February 2024
W002200	February 2023	February 2024
W002201	February 2023	February 2024
W002209	February 2023	February 2024

W003055	February 2023	February 2024
W003012	February 2023	February 2024
U040071	March 2023	March 2024
U040082	March 2023	March 2024
U040308	March 2023	March 2024
U040300	March 2023	March 2024
W001764	March 2023	March 2024
U040316	March 2023	March 2024
W002566	March 2023	March 2024
W002577	March 2023	March 2024
W002582	March 2023	March 2024
W003430	March 2023	March 2024
W003111	March 2023	March 2024
W003431	March 2023	March 2024
2644400	April 2023	April 2024
2620967	April 2023	April 2024
2620965	April 2023	April 2024
2620959	April 2023	April 2024
2644399	April 2023	April 2024
W003434	April 2023	April 2024
W005862	April 2023	April 2024
W005866	April 2023	April 2024
W005869	April 2023	April 2024
W005872	April 2023	April 2024
W005873	April 2023	April 2024
W006344	April 2023	April 2024
W006347	April 2023	April 2024
W006351	April 2023	April 2024
W006360	April 2023	April 2024
W006363	April 2023	April 2024
W006353	April 2023	April 2024
W006354	April 2023	April 2024
W006793	April 2023	April 2024
W006365	April 2023	April 2024
W006369	April 2023	April 2024
W006358	April 2023	April 2024
W006794	April 2023	April 2024
W006945	April 2023	April 2024
2620971	May 2023	May 2024
2620975	May 2023	May 2024
2620973	May 2023	May 2024
2620969	May 2023	May 2024
2620977	May 2023	May 2024
2698245	May 2023	May 2024
2678932	May 2023	May 2024

2698247	May 2023	May 2024
W011781	August 2023	February 2024
W012460	August 2023	February 2024
W007695	October 2023	April 2024
W008022	October 2023	April 2024
W012394	November 2023	May 2024
W012403	November 2023	May 2024
W012408	November 2023	May 2024
W012538	November 2023	May 2024
W012585	November 2023	May 2024
W017279	November 2023	May 2024
2698249	November 2023	May 2024
2689837	December 2023	June 2024
2689839	December 2023	June 2024
2689841	December 2023	June 2024
2689845	December 2023	June 2024
W007683	December 2023	June 2024
W007684	December 2023	June 2024
W007693	December 2023	June 2024
2689847	December 2023	June 2024
2689851	December 2023	June 2024
2843352	December 2023	June 2024
2689855	December 2023	June 2024
2843352	December 2023	June 2024