

Deliveries of remdesivir (Veklury) from Gilead to the NMS

Document 1 - FOI 4920

Lot / Batch	Expiry	Date delivered	Quantity
C2000138-A	30/09/2024	13/08/2020	2785
C2000137-A	30/09/2024	1/09/2020	125
C2000137-A	30/09/2024	15/09/2020	5000
C2000141D2	31/07/2023	15/10/2020	5115
D20PV143D2	31/07/2023	28/10/2020	4885
C2000153D	30/09/2023	9/12/2020	7000
21090201M	31/01/2024	15/09/2021	27899
031983	31/05/2024	12/11/2021	24000
031983	31/05/2024	4/02/2022	2748
30023M	30/04/2024	18/02/2022	17280
30023M	30/04/2024	21/02/2022	11720
21090981D	30/09/2024	30/03/2022	28655
30023M	30/04/2024	30/03/2022	721
21101711D	30/11/2024	6/05/2022	26549
21091191D	30/11/2024	6/05/2022	29451
21091151D	31/10/2024	3/06/2022	29946
21101711D	30/11/2024	3/06/2022	2483
21101841D	30/11/2024	10/06/2022	6716
21101841D	30/11/2024	10/06/2022	22487
21101831D	30/11/2024	10/06/2022	29084
22100031D	31/12/2024	22/06/2022	29114
22100251D	28/02/2025	12/07/2022	29555
22100261D	28/02/2025	12/07/2022	29111
22090291D	28/02/2025	25/07/2022	16773
22090281D	28/02/2025	25/07/2022	28355
22100041D	31/12/2024	26/08/2022	29468
22090291D	28/02/2025	26/08/2022	12696
22100201D	31/01/2025	19/09/2022	28720
22105531D	30/04/2025	21/09/2022	23455
22100191D	31/01/2025	17/10/2022	28598
22090521D	30/04/2025	4/11/2022	29,008
22090511D	30/04/2025	11/11/2022	29,867
22090531D	30/04/2025	18/11/2022	23,508
22090611D	31/05/2025	6/12/2022	18,680
			641,557

Dispatched to DoH*	Quantity Dispatched to AU DoH	Batch
27/08/2021	5,169	JP9Y
1/10/2021	15,551	JP9Y
15/11/2021	4,606	UK3F
19/01/2022	7,763	SW3DT^
22/03/2022	3,251	SP5B
22/03/2022	287	KA9R-A
27/04/2022	15,971	XL5N
20/06/2022	12,179	4C9D
21/07/2022	10,537	926X
29/07/2022	21,677	9W6R
24/08/2022	23,400	9W6R
24/08/2022	3,888	B28L
9/09/2022	7,139	B28L

131,418

Dispatched to DoH*	Quantity Dispatched to DoH (Units)	Batch
4/03/2022	5000	CAAH
4/03/2022	134	CAAH
5/05/2022	10357	CAAP
27/05/2022	20509	CAAT
13/01/2023	6000	EVAL
	42,000	

Batch	Qty	Delivery date
FT4565	15540	27/01/2022
FT4889	6145	27/01/2022
FT5412	9600	2/02/2022
FT9972	30400	18/02/2022
FX7183	21000	18/03/2022
FX7184	20997	18/03/2022
GA8046	1600	14/04/2022
GA8765	11200	14/04/2022
GA8771	10873	14/04/2022
GA8046	41700	20/04/2022
GA8771	1600	20/04/2022
GC2932	10640	27/04/2022
FY1869	26168	29/04/2022
FY1870	26430	29/04/2022
FY1866	20088	2/05/2022
FY1871	19488	3/05/2022
FY1872	22752	5/05/2022
FY1868	11980	4/05/2022
FY1874	13116	13/05/2022
GD4586	12058	19/05/2022
GD4587	6696	19/05/2022
GC0803	15456	26/05/2022
GC5724	14208	26/05/2022
GC0805	10680	27/05/2022
GC2916	34047	27/05/2022
GD1180	23664	31/05/2022
GD1182	10368	3/06/2022
GD1184	22080	3/06/2022
GD3145	5028	3/06/2022
GC8173	2174	7/06/2022
GD1182	1920	7/06/2022
GD1184	5184	7/06/2022
GD3145	5184	7/06/2022
GC8173	24415	7/06/2022
GC0806	26736	17/06/2022
GC5729	25776	10/06/2022
GD4572	38060	14/06/2022
GC5725	25896	16/06/2022
GD1189	11352	16/06/2022
GD1179	26448	15/06/2022
GD1189	15552	15/06/2022
GC5722	25312	23/06/2022
GC5722	18	23/06/2022
GJ2966	26995	24/08/2022
GJ2959	26592	24/08/2022
GJ2966	21	24/08/2022
GJ2966	8	24/08/2022
GJ2963	26816	25/08/2022
GJ2970	25668	26/08/2022

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GJ2961	25920	25/08/2022
GJ2960	26700	26/08/2022
GJ2962	26016	26/08/2022
GJ2969	26232	8/09/2022
GJ2968	26492	8/09/2022
GJ2967	27065	8/09/2022
GJ7302	25920	19/09/2022
GR2928	16	31/01/2024

1000090

There were 74 units in total that were returned to Pfizer as the product was damaged.

To meet the contractual volume of 1,000,016 units, the last shipment of 16 units was delivered 21 December 2022.

Dispatched to DoH*	Quantity Dispatched to DoH (Doses)	Batch
27/10/2021	5000	N7557B03
9/12/2021	5000	N7582B03
		N7606B52
13/04/2022	5000	N7592B01
		N7614B04
	15,000	

BATCH	QUANTITY RECEIVED	DATE DELIVERED / RECEIVED
CKFWW	17,280	1/02/2022
CKGHW	59,971	4/02/2022
CKSFM	60,813	10/02/2022
CKFWV	26,207	11/02/2022
CKFXD	26,617	11/02/2022
CKFXF	26,784	11/02/2022
	217,672	

Pfizer Australia Pty Ltd
Level 17, 151 Clarence Street
Sydney, NSW 2000

11 January 2024

Dear Healthcare Professional,

**Shelf-life extension of PAXLOVID® (nirmatrelvir 150 mg/ritonavir 100 mg), film coated tablets
AUST R 377572**

We previously advised you that on 17 November 2022 a new shelf life for PAXLOVID had been approved in Australia by the Therapeutic Goods Administration (TGA).

The shelf life was extended from 18 months to 24 months and the storage condition of 'Store below 25 degrees Celsius' remains unchanged.

This letter provides an update on all delivered batches in Australia and their updated expiry dates.

This extension of the shelf life may be applied retrospectively to PAXLOVID batches manufactured prior to this approval. Cartons with an expiry date of August 2022 through to January 2024 printed on the carton or blisters may remain in use for a longer period beyond the printed expiry date, as long as the approved storage conditions have been maintained.

PAXLOVID is a co-packaged product consisting of nirmatrelvir and ritonavir tablets, which could have different production dates. For this reason, the updated expiry date cannot be calculated by adding 6 months or 12 months to the printed expiry date (that was determined based on the shelf life approved at the time of manufacturing) and must be determined by identifying the specific batch number in the list below:

<u>Batch Number</u>	<u>Printed Date</u>	<u>Updated Expiry Date</u>
FT4565; FT4889	08/2022	07/2023
FT5412	11/2022	07/2023
FT9972	12/2022	07/2023
FX7183; FX7184	01/2023	09/2023
FY1869; FY1870; FY1866; FY1871; FY1868; FY1872; FY1874	02/2023	11/2023
GA8046; GA8765; GA8771; GC2932; GC2916	02/2023	01/2024
GD4586; GD4587; GD3145; GC8173; GD4572	03/2023	01/2024
GD1179; GD1180	03/2023	11/2023
GC0803; GC5724; GC0805; GD1182; GC0806	03/2023	12/2023
GD1184; GC5725; GC5722	03/2023	02/2024

GC5729; GD1189	04/2023	02/2024
GJ2966; GJ2970; GJ2969; GJ2968; GJ2967	11/2023	03/2024
GJ2959; GJ7302; GJ2963; GJ2961; GJ2960; GJ2962	12/2023	03/2024
GR2928*	01/2024	05/2024

* This batch is a new addition to the table.

PLEASE REVIEW THE CURRENT AUSTRALIAN PRODUCT INFORMATION BEFORE PRESCRIBING OR DISPENSING.

The Australian Product Information and Consumer Medicine Information can be found at <https://www.tga.gov.au/>.

The PAXLOVID Australian Product Information for Healthcare professionals is also available by scanning the QR Code below:



Adverse Event Reporting

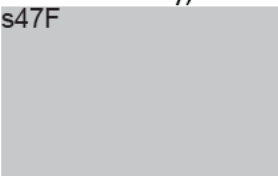


PAXLOVID is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems. Alternatively, any adverse events which are experienced with PAXLOVID can be reported to Pfizer on 1800 675 229 or by email to AUS.AEreporting@pfizer.com

Medical Enquiries

Please direct any medical enquiries to Pfizer Medical Information on: 1800 675 229 or via www.pfizermedicalinformation.com.au

Yours sincerely,
s47F



Pfizer Australia

MSD

Merck Sharp & Dohme (Australia) Pty Limited
ABN: 14 000 173 506
Level 1 - Building A, 26 Talavera Road
Macquarie Park NSW 2113
North Ryde Post Business Centre
Locked Bag 2234 North Ryde, NSW, 1670
T 02 8988 8000
F 02 8988 8001
msd-australia.com.au

23 September 2022

**LAGEVRIO® molnupiravir 200 mg Capsules – AUST R 372650****Extension to Shelf Life of Stock in Market**

Dear Healthcare Professional,

Merck Sharp & Dohme (Australia) Pty Limited (MSD) writes to inform you that on 20 September 2022 a new shelf life for LAGEVRIO was approved in Australia by the Therapeutic Goods Administration (TGA).

The shelf life of LAGEVRIO has been extended to 30 months. The storage conditions of 'Store below 30 degrees Celsius' remain unchanged. LAGEVRIO stock currently available in the Australian market is labelled with an expiry date of 18 months from the date of manufacture.

This 12-month extension may be applied retrospectively to LAGEVRIO product manufactured prior to this approval. Cartons and bottles with a labelled expiry date of January 2023 through to July 2023 may remain in use for 12 months beyond the labelled date, as long as the approved storage conditions have been maintained. Updated expiry dates are shown below.

Printed Expiry Date on Bottles and Cartons	Updated Expiry Date
January 2023	January 2024
May 2023	May 2024
June 2023	June 2024
July 2023	July 2024

**PLEASE REVIEW THE CURRENT AUSTRALIAN PRODUCT INFORMATION
BEFORE PRESCRIBING OR DISPENSING.**

Australian PI and CMI Can be Accessed via the Following

Scan the QR code shown below, or on the carton:



Adverse Event Reporting

▼ This medicine is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

Alternatively, any adverse events which are experienced with LAGEVRIO can be reported to MSD on 1800 818 553 or via email to DPOC.australia@msd.com.

Medical Enquiries

Should you require any further information, please contact MSD Medical Information on 1800 818 553 or via email to DPOC.australia@msd.com.

Yours sincerely,

A handwritten signature in black ink, reading "Gary Jankelowitz".

Dr Gary Jankelowitz

Australia and New Zealand Medical Director

T: (02) 8988 8246

M: 0414 795 284

Email: gary.jankelowitz@msd.com



Level 4, 436 Johnston Street
 Abbotsford VIC 3067
 PO Box 18095 Melbourne VIC 8003
 Australia

Tel +61 3 9721 6000
 Fax +61 3 8761 2442
www.gsk.com | www.au.gsk.com

6th June 2023

Dear Healthcare Professional,

Change in expiry date of specific batches in the Australian Government Department of Health and Aged Care National Medical Stockpile for Xevudy ▼ (sotrovimab) 500 mg/8 mL concentrated injection solution for infusion.

This communication is intended for Healthcare Professionals who administer Xevudy (sotrovimab) for the treatment of COVID-19.

The Therapeutic Goods Administration (TGA) has approved an extension to the shelf life and therefore the expiry date of the medicine. The shelf life has been extended from 18 months to 24 months. The storage conditions of 'Store between 2°C to 8°' remains unchanged.

This extension of the shelf life is not to be applied retrospectively to Xevudy (sotrovimab) batches manufactured prior to this approval, with the exception of stocks held in the National Medical Stockpile

The expiry date (EXP) has been extended beyond what is printed on the vial and carton label for the following batches:

Lot Number (LOT)	Printed Expiry Date (EXP)	Revised Expiry Date (EXP)
XL5N	Jul-2023	Jan-2024
4C9D	Jul-2023	Jan-2024
926X	Jul-2023	Jan-2024
9W6R	Aug-2023	Feb-2024
B28L	Nov-2023	May-2024

Action required by Healthcare Professionals:

- Please check the LOT number printed on the vial and carton label
- If the LOT number corresponds to a LOT number listed above it can be administered up to the final date of the month and year in the revised EXP date above
- Please follow the recommendations in the Australian Product Information (PI) when administering Xevudy (sotrovimab). The PI can be found at www.gsk.com.au/xevudy
- Please share this information with other healthcare personnel involved in the administration of Xevudy (sotrovimab)

Adverse Event Reporting

Xevudy▼ (sotrovimab) is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems. Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with Xevudy should be reported by healthcare professionals and patients to GSK Medical Information on 1800 033 109 or by email mel.australia-medinfo@gsk.com.

Medical Information

Medical enquiries for GSK products can be directed to GSK Medical Information on 1800 033 109. The Poisons Information Centre (phone 13 11 26) provides advice on the management of overdose.

Please forward this information to relevant staff members in your organisation.

Yours faithfully,

Alan Paul

Electronically signed by: Alan Paul
Reason: I am approving the content of
this document and authorize its issuance.
Date: Jun 6, 2023 22:51 GMT+10

Alan Paul
Country Medical Director
GlaxoSmithKline Australia Pty Ltd

s22

From: s22
Sent: Friday, 22 April 2022 10:52 AM
To: s47E(d) @health.gov.au; s22
Subject: FW: TGA extension of approved shelf-life for Roche's COVID-19 treatment RONAPREVE [SEC=OFFICIAL]

From: s22
Sent: Friday, 22 April 2022 10:52 AM
To: s22 ; s22 ; WAGNER, Jane ; s22 ; s22 ; SIMPSON, Andrew ; s22
Subject: TGA extension of approved shelf-life for Roche's COVID-19 treatment RONAPREVE [SEC=OFFICIAL]

All,

TGA has approved an extension to shelf-life for Roche's COVID-19 treatment, casirivimab + imdevimab (RONAPREVE) - the approved shelf-life is now **18 months**.

A web statement has been published: <https://www.tga.gov.au/extension-approved-shelf-life-casirivimab-imdevimab-ronapreve>

The public ARTG entry will be updated overnight and appear tomorrow.

Roche has been requested to provide an updated Dear HCP Letter.

Grateful if S/T can be informed, following their recent queries about expiry of stock on-hand.

Thanks,
s22

s22

Assistant Director - COVID-19 vaccine and treatment regulation

Medicines Regulation Division | TGA
Prescription Medicines Authorisation Branch
Australian Government Department of Health
T: 02 s22 | E: s22 @health.gov.au
Location: TGA, 136 Narrabundah Lane, Symonston ACT 2609
c/- PO Box 100, Woden ACT 2606, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

Please note that this email is intended only for the use of the addressee and may contain confidential or legally privileged information. If you receive this email in error, please notify the sender immediately and delete all copies of this email.

11 July 2022

Merck Sharp & Dohme (Australia) Pty Ltd

Commonwealth of Australia acting through the
Department of Health

Variation Deed

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THIS DOCUMENT IS
THE FREEDOM OF INFORMATION ACT
BY THE DEPARTMENT OF JUSTICE

Date

Parties

Merck Sharp & Dohme (Australia) Pty Ltd of Level 1, Building A 26 Talavera Road, Macquarie Park (MSD)

The Commonwealth of Australia acting through the Department of Health of Scarborough House, 1 Atlantic Street, Woden, Australian Capital Territory, Australia (Health)

Agreed terms

1 Definitions

1.1 This document

In this document these terms have the following meanings:

Original Document	The " <i>Supply and Purchase Agreement - Molnupiravir</i> " entered into between the parties dated 30 November 2021.
Restated Document	The Original Document as amended and restated in accordance with the " <i>Amendment and Restatement Deed – Supply and Purchase agreement - Molnupiravir</i> " executed 28 February 2022.
Variation Date	The date of this document.

1.2 Definitions in Original Document

Unless expressed to the contrary, terms defined in the Restated Document have the same meanings in this document.

2 Variation of Restated Document

2.1 Variations

On and from the Variation Date, the Restated Document is varied as follows:

- (a) The following definitions in clause 1.1 are replaced with the following:

Committed NMS Quantity means a total of 217,672 Patient Courses.

Committed PBS Quantity means a total of 232,328 Patient Courses

- (b) Clause 4.2 (a) is amended by amending the fourth row and removing the fifth row in the table under that clause so that the table is as follows:

NMS Tranche	Quantity of Patient Courses	NMS Delivery Period
First NMS Tranche	100,000	Any date within the 30 day period after the Product Approval Date but no earlier than 15 February 2022.
Second NMS Tranche	50,000	The period: <ul style="list-style-type: none"> (i) commencing on the Delivery date of the First NMS Tranche; and (ii) ending on the date that is 60 days after that date.
Third NMS Tranche	67,672	The period: <ul style="list-style-type: none"> (i) commencing on the delivery date for the Second NMS Tranche; and (ii) ending on the date that is 60 days after that date.

- (c) Clause 4.4(a) is replaced with the following:

Unless otherwise agreed in writing with Health, MSD must have available in the Territory the Committed PBS Quantity for dispensing to Patients only by Approved Suppliers, via CSO Distributors, as follows:

- (i) by 1 March 2022, 84,000 Patient Courses;
- (ii) by 1 July 2022, a further 66,000 Patient Courses; and
- (iii) by [1 August] 2022, a further 82,328 Patient Courses.

- (d) The table in clause 22.1(a) is replaced with the following:

Party name	Attention	Address (for hand delivery or delivery by courier or post)	Email address
MSD	Dylan Jones Nicola Richards	Level 1, Building A 26 Talavera Road Macquarie Park NSW 2113	dylan.jones@msd.com nicola.richards@msd.com

Health	Natasha Ploenges Assistant Secretary	Scarborough House 1 Atlantic Street Woden ACT 2606	Natasha.Ploenges@health.gov.au s47E(d) [REDACTED]@health.gov.au
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2.2 Restated Document continues

MSD and Health acknowledge and agree that the Restated Document as varied by this document continues in full force on and from the Variation Date.

3 Warranties and representations

3.1 Warranties

MSD represents and warrants that at the Variation Date:

- (a) it has capacity unconditionally to execute, deliver and comply with its obligations under this document;
- (b) it has taken all necessary action to authorise the unconditional execution and delivery of, and the compliance with, its obligations under this document; and
- (c) this document is a legal, valid and binding obligation and is enforceable against MSD by Health in accordance with its terms.

3.2 Survival of warranties

The warranties and representations in **clause 3.1** survive the execution of this document and the variation of the Restated Document.

4 General

4.1 Amendment

This document may only be varied or replaced by a document executed by the parties.

4.2 Legal costs

Except as expressly stated otherwise in this document, each party must pay its own legal and other costs and expenses of negotiating, preparing, executing and performing its obligations under this document.

4.3 Further steps

Each party must promptly do whatever any other party reasonably requires of it to give effect to this document and to perform its obligations under it.

4.4 Governing law and jurisdiction

- (a) This document is governed by and is to be construed in accordance with the laws applicable in New South Wales.
- (b) Each party irrevocably and unconditionally submits to the non-exclusive jurisdiction of the courts exercising jurisdiction in New South Wales and any courts which have jurisdiction to hear appeals from any of those courts and waives any right to object to any proceedings being brought in those courts.

4.5 Counterparts

This document may consist of a number of counterparts and, if so, the counterparts taken together constitute one document.

4.6 Effect of execution

This document is not binding on any party unless it or a counterpart has been duly executed by each person named as a party to this document.

4.7 Construction

Unless expressed to the contrary, in this document:

- (a) words in the singular include the plural and vice versa;
- (b) any gender includes the other genders;
- (c) if a word or phrase is defined its other grammatical forms have corresponding meanings;
- (d) 'includes' means includes without limitation;
- (e) no rule of construction will apply to a clause to the disadvantage of a party merely because that party put forward the clause or would otherwise benefit from it;
- (f) a reference to:
 - (i) a person includes a partnership, joint venture, unincorporated association, corporation and a government or statutory body or authority;
 - (ii) a person includes the person's legal personal representatives, successors, assigns and persons substituted by novation;
 - (iii) any legislation includes subordinate legislation under it and includes that legislation and subordinate legislation as modified or replaced;
 - (iv) an obligation includes a warranty or representation and a reference to a failure to comply with an obligation includes a breach of warranty or representation;
 - (v) a right includes a benefit, remedy, discretion or power;
 - (vi) time is to local time in Sydney;
 - (vii) '\$' or 'dollars' is a reference to Australian currency;

- (viii) this or any other document includes the document as novated, varied or replaced and despite any change in the identity of the parties;
 - (ix) writing includes any mode of representing or reproducing words in tangible and permanently visible form, and includes fax transmissions;
 - (x) this document includes all schedules and annexures to it; and
 - (xi) a clause, schedule or annexure is a reference to a clause, schedule or annexure, as the case may be, of this document; and
- (g) where time is to be calculated by reference to a day or event, that day or the day of that event is excluded.

4.8 Headings

Headings do not affect the interpretation of this document.

4.9 Deed

This document is a deed. Factors which might suggest otherwise are to be disregarded.

Execution

Executed as a deed.

**Executed by Merck Sharp & Dohme
(Australia) Pty Ltd**

s47F

.....
Secretary/Director

GEORGINA DIAB
.....
Name of Secretary/Director (print)

s47F

.....
Director

RAJIV SHARDA
.....
Name of Director (print)

**Executed for and on behalf of the
Commonwealth of Australia acting
through the Department of Health by its
duly authorised representative**

s47F

.....
Signature of Authorised Representative

Natasha Plaenges, Assistant Secretary, OHTA
.....
Name and Title of Authorised
Representative

s22

Witnessed by

s47F

17/11/22



Australian Government
Department of Health and Aged Care

Natasha Ploenges
 Assistant Secretary
 Office of Health Technology Assessment

Merck Sharp & Dohme Variation Deed for countersignature to shift 82,328 courses of Molnupiravir (Lagevrio®) from the National Medical Stockpile to the Pharmaceutical Benefits Scheme

1. Purpose

This Minute recommends that you:

- Countersign the Variation Deed (Agreement) to shift 82,328 treatment courses of Molnupiravir from National Medical Stockpile (NMS) to Pharmaceutical Benefits Scheme (PBS) supply chain (**Attachment A** refers).
 - NOTE that the Commonwealth of Australia through the Department of Health and Aged Care (Department) signed an agreement with Merck Sharp & Dohme (Australia) Pty Ltd (MSD) on 30 November 2021, to secure 300,000 treatment courses of molnupiravir (Lagevrio®) for NMS in 2022 (**Attachment B** refers).
 - NOTE that MSD delivered 217,672 courses to the NMS in February 2022.
 - NOTE that Lagevrio® was listed on the PBS from 1 March 2022 and its demand through the PBS supply chain increased after the expansion of its eligibility criteria on 11 July 2022. A further expansion was implemented on 1 November 2022.
 - NOTE that the current Agreement with MSD states that the total Committed NMS Quantity is 300,000 Patient Courses and the total Committed PBS Quantity is 150,000 Patient Courses. The Variation Deed would alter this to have a total Committed NMS Quantity of 217,672 Patient Courses and total Committed PBS Quantity of 232,328 Patient Courses. The total committed quantity of courses would remain at 450,000, with the redirection of 82,328 courses into the PBS to allow for greatest utilisation.
 - NOTE that MSD agreed to redirect the delivery of 82,328 NMS treatment courses to the PBS.
-
- Note the contract variation transfers the requirement to purchase the 82,328 treatment courses from the NMS to the PBS, this does have financial differences due to co-pays and pharmacy fees.
 - NOTE that there is no financial implication with MSD on this movement of 82,328 treatment courses from NMS to PBS.

- NOTE on 6 July 2022, Corrs Chambers Westgarth Partner provided legal clearance for the Variation Deed.

2. Background/Context

Lagevrio® is an oral antiviral treatment that inhibits viral DNA replication of the SARS-CoV-2 virus, it is a prescription-only, five-day course of oral medicine.

On 18 January 2022, Lagevrio® was approved by the Therapeutic Goods Administration for the treatment of COVID-19 in adults 18 years of age and older, who do not require initiation of supplemental oxygen due to COVID-19 and are at increased risk of progression to hospitalisation or death.

s47E(d)

3. Outcome of Evaluation/Value for money

For the week ending 6 November 2022, 271,010 prescriptions of Lagevrio® have been dispensed through the PBS. 128,827 courses have been deployed from the NMS,

Attachments:

- A. Variation Deed with MSD
- B. Advanced Purchase Agreement with MSD
- C. Approval letter from Prime Minister Albanese

4. Delegate Approvals

SIGN the Variation Deed (Agreement) to shift 82,328 treatment courses of Lagevrio® from the NMS to the PBS supply chain (Attachment A refers).	SIGNED/ NOT SIGNED
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