

**MEMORANDUM FOR CONSIDERATION BY DIRECTOR OF OPERATIONS
UNDER DELEGATED AUTHORITY**

To: Director of Operations
From: Senior Therapeutic Group Manager/Team Leader - Te Papa
Date: 18 March 2022

Proposal to enter agreement with Pfizer New Zealand Limited for the supply of nirmatrelvir with ritonavir

Recommendations

It is recommended that having regard to the decision-making framework set out in Pharmac's Operating Policies and Procedures you exercise your delegated authority and:

resolve to approve the manufacturing and supply agreement dated 18 March 2022 with Pfizer New Zealand Limited (Pfizer) for the supply of 60,000 treatment courses of nirmatrelvir with ritonavir (brand name Paxlovid) for the treatment of COVID-19

resolve to approve the Purchase Order ([15121](#)) provided in Appendix Two for the supply of 60,000 treatment courses of nirmatrelvir with ritonavir (brand name Paxlovid) and note this would be provided to Pfizer on execution of this agreement and the separate indemnity described below

note that this proposal follows a decision by the [Pharmac Board of Directors in December 2021](#) to secure supply of 60,000 treatment courses of nirmatrelvir with ritonavir from Pfizer at a price of \$^{S 9(2)(b)(ii), 9(2)} per course

note there would be no changes to the financial impact associated with the supply of nirmatrelvir with ritonavir to New Zealand previously approved by the Chief Executive in [December 2021](#)

note that due to the urgency required to secure supply of nirmatrelvir with ritonavir, consultation on the proposal to secure supply was not undertaken. Consultation on the proposed access criteria for nirmatrelvir with ritonavir [closed on 2 March 2022](#) and any proposal in relation to the access criteria would be subject to a separate decision paper

s 9(2) (ba) (i)
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EXECUTIVE SUMMARY

- Negotiation of the manufacturing and supply agreement between Pfizer and Pharmac for the supply of nirmatrelvir with ritonavir has been completed (Appendix 1).
- It is proposed that Pharmac enter the manufacturing and supply agreement with Pfizer for the supply of nirmatrelvir with ritonavir by signing and returning a copy of the agreement (dated 18 March 2022).
- This proposal follows a decision in December 2021 to secure supply of 60,000 treatment courses at a total cost of \$^{s 9(2)(b)(ii), 9}_{(2)(b)(i), 9(2)}
- s 9(2) (ba) (i)
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s 9(2) (ba) (i)
- Pharmac's Legal Team and External Advisors (Bell Gully) have been extensively involved in the review of the terms in the manufacturing and supply agreement.
s 9(2) (b)(ii)
s 9(2) (b)(ii)

Why proposal should be considered by the Director of Operations under Delegated Authority

The decision to secure supply of 60,000 treatment courses of nirmatrelvir with ritonavir and its associated costs have already been approved by the the Pharmac Board of Directors, as part of a separate decision process in December 2021. Entering into the proposed agreement with Pfizer would give effect to this previous decision and:

- will not result in the Pharmaceutical budget or its future funding path being exceeded;
- is not inconsistent with previous Board decisions.

The Proposal

The proposal is to approve the manufacturing and supply agreement with Pfizer for the supply of 60,000 treatment courses of nirmatrelvir with ritonavir to New Zealand for the treatment of patients with mild to moderate COVID-19.

The access criteria that would apply to nirmatrelvir with ritonavir if the manufacturing and supply agreement is approved are in the process of being finalised following an open consultation process, which closed on 2 March 2022. Pharmac expects to notify the market and interested parties of access criteria within the next week.

s 9(2) (ba) (i)
s 9(2) (ba) (i)
s 9(2) (ba) (i)
s 9(2) (ba) (i)

Background

In September 2021 Pharmac and Pfizer began negotiations for nirmatrelvir with ritonavir, Pfizer’s oral antiviral treatment for mild to moderate COVID-19 to be supplied to New Zealand.

In December 2021 the Pharmac Board of Directors [approved a proposal](#) to secure supply of 60,000 treatment courses of nirmatrelvir with ritonavir from Pfizer for the treatment of COVID-19.

Following the Board’s approval to secure supply of nirmatrelvir with ritonavir, the Chief Executive signed a [Binding Term Sheet](#) with Pfizer for the supply 60,000 treatment courses of nirmatrelvir with ritonavir to be supplied to New Zealand. This Binding Term Sheet records the main terms to be negotiated between Pharmac and Pfizer for the supply of nirmatrelvir with ritonavir to New Zealand and recorded Pharmac and Pfizer’s intention to enter a definitive Agreement s 9(2) (b)(ii)

s 9(2) (b)(ii)

s 9(2) (ba) (i)
s 9(2) (ba) (i)
s 9(2) (ba) (i)
s 9(2) (ba) (i)

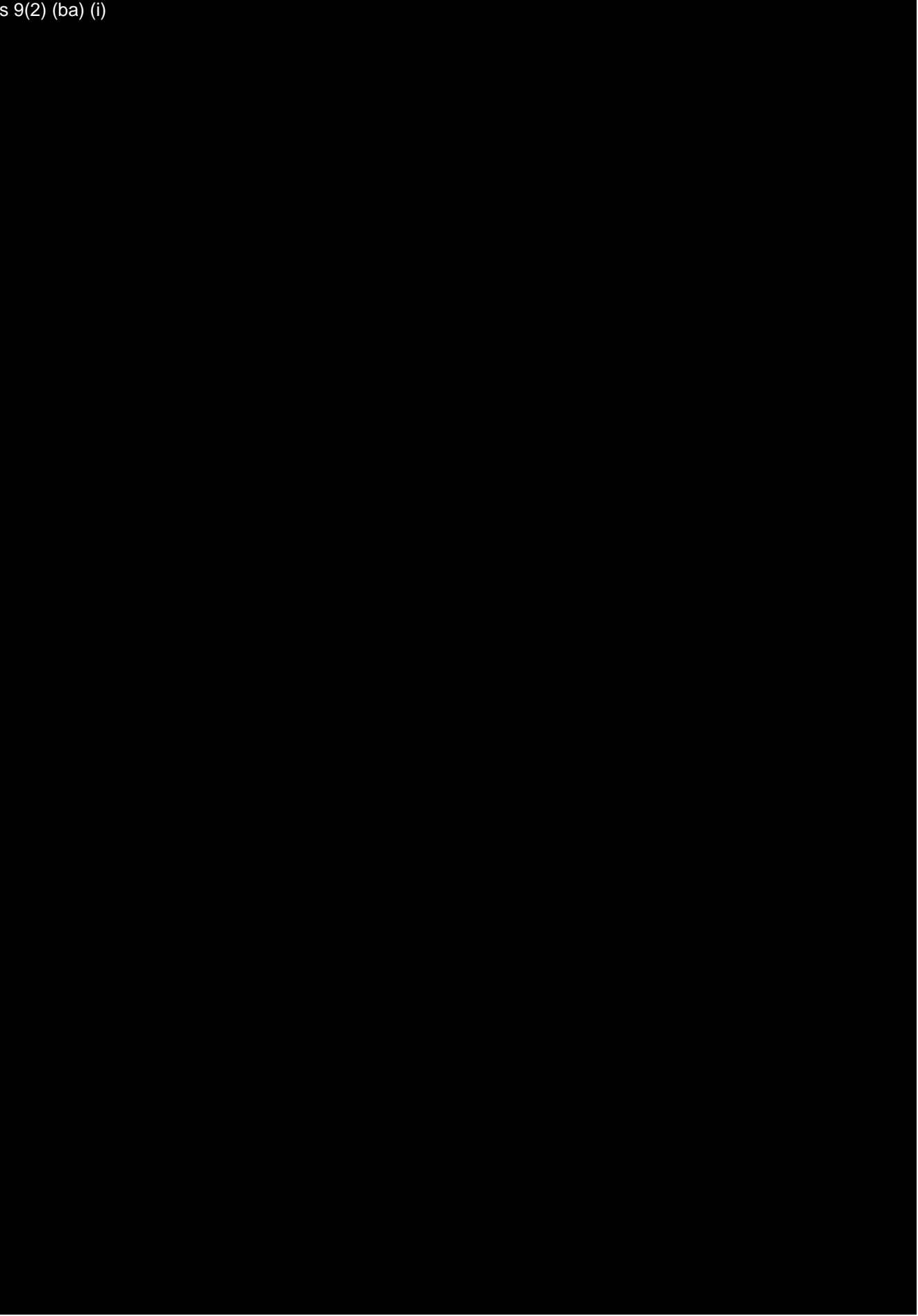
Negotiation of the final agreement

Following the signing of the Binding Terms Sheet Pharmac and Pfizer entered negotiations on the agreement for the supply of nirmatrelvir with ritonavir. The subsequent versions of the manufacturing and supply agreement, as a result of these negotiations, were extensively reviewed by Pharmac’s legal team and external legal advisor (Bell Gully). Pharmac’s legal team has also completed a comprehensive review of this paper.

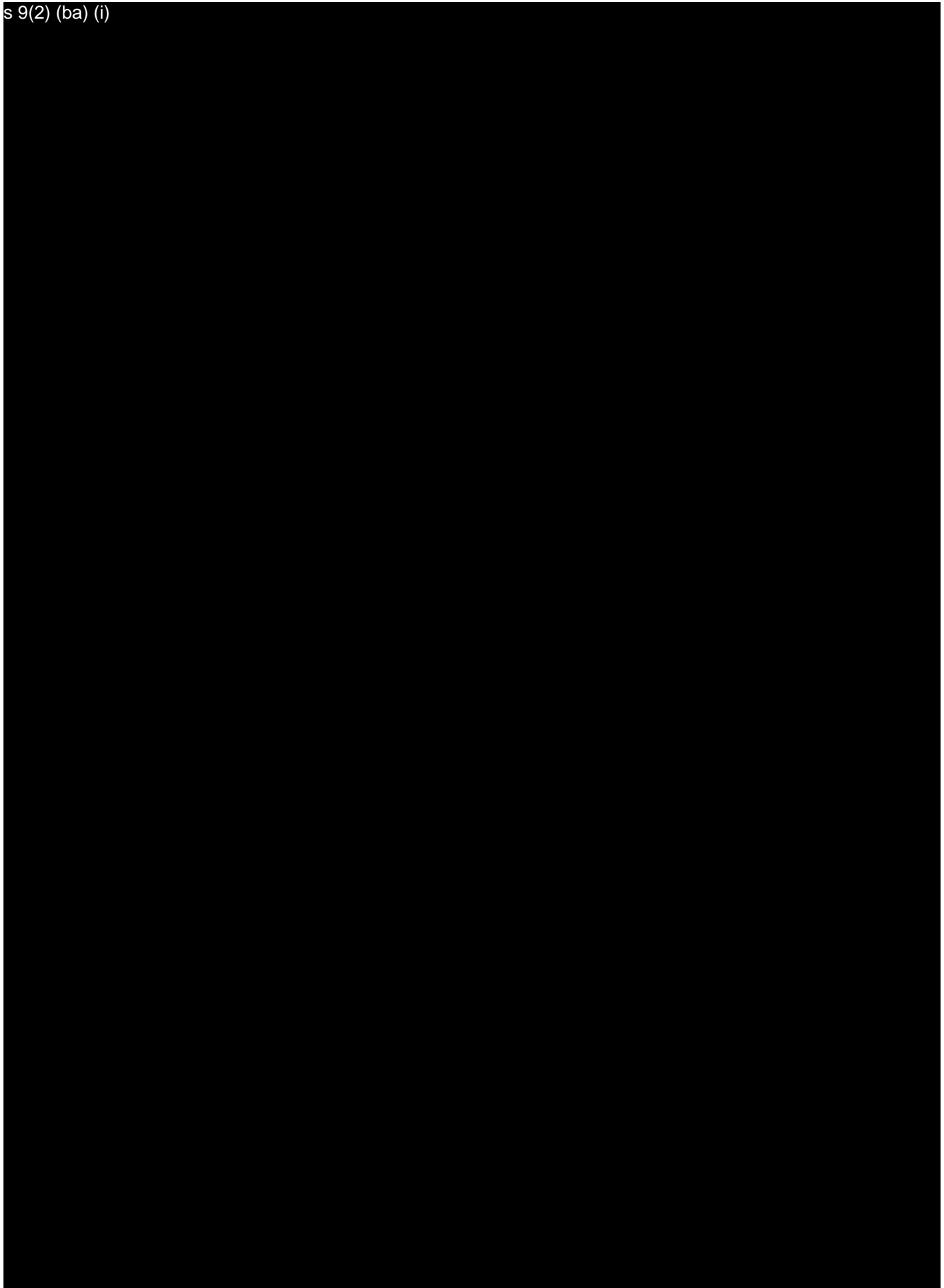
The key terms of the manufacturing and supply agreement are set out in the table below:

s 9(2) (ba) (i)


s 9(2) (ba) (i)



s 9(2) (ba) (i)



s 9(2) (ba) (i)



Risk Implications

Pharmac staff have identified the following key risks and associated mitigations if the manufacturing and supply agreement for the supply of nirmatrelvir with ritonavir is approved.

Risks

| Description | Mitigation |
|--|---|
| s 9(2) (ba) (i) | s 9(2) (ba) (i) |
| Pfizer is unable to meet, or makes changes to the delivery schedule for nirmatrelvir with ritonavir, resulting in a delay to nirmatrelvir with ritonavir being available to New Zealanders | <p>s 9(2) (ba) (i) s 9(2) (ba) (i)</p> <p>Pharmac staff have been working closely with Pfizer to ensure nirmatrelvir with ritonavir is available in New Zealand as soon as possible. Based on recent communications we anticipate that supply in April 2022 could be achieved if the required conditions are met. Based on the collaborative approach between Pharmac and Pfizer that has been taken to secure supply, we consider the risk of Pfizer making the decision to delay shipments planned for Quarter Two (Calendar Year) to New Zealand is low.</p> |
| Nirmatrelvir with ritonavir is not used for the treatment of COVID-19 either because of a lack of effectiveness or concerns regarding drug/drug interactions resulting in treatment courses being wasted | <p>Evidence for nirmatrelvir with ritonavir for the treatment of COVID-19 continues to emerge. Pharmac's COVID-19 Treatments Advisory Group has appraised the available evidence for nirmatrelvir with ritonavir and has recommended it for funding for the treatment of COVID-19. In addition, the Group has noted that due to its mechanism of action nirmatrelvir with ritonavir is expected to retain effectiveness against current and future Variants of Concern.</p> <p>s 9(2) (ba) (i) s 9(2) (ba) (i) s 9(2) (ba) (i) s 9(2) (ba) (i) s 9(2) (ba) (i)</p> <p>s 9(2) (ba) (i) s 9(2) (ba) (i) s 9(2) (ba) (i) Pharmac staff consider it is unlikely that any of the purchased treatments will remain unused.</p> <p>To manage the risks associated with drug/drug interactions associated with ritonavir Pharmac has engaged He Ako Hiringato produce resources to assist clinicians to make appropriate treatment decisions.</p> |
| s 9(2) (ba) (i) | s 9(2) (ba) (i) |

| Description | Mitigation |
|------------------------|---|
| <p>s 9(2) (ba) (i)</p> | <p>s 9(2) (ba) (i)</p> <p>Nirmatrelvir with ritonavir is the second oral antiviral treatment that Pharmac is contracting for. Pharmac and MSD have recently reached an agreement with MSD for the supply of 60,000 treatment courses of its oral antiviral treatment for COVID-19 (Molnupiravir). Molnupiravir is expected to be available in New Zealand from mid-April 2022 at the earliest subject to Medsafe approval, this means that in the event that the agreement with Pfizer for the supply of nirmatrelvir with ritonavir is not progressed people with COVID-19 in the community would likely still have access to an oral antiviral treatment in 2022; however, the number of patients that could be treated would be significantly reduced.</p> |

Pharmac staff view

On balance Pharmac staff are supportive of the proposal to approve the manufacturing and supply agreement between Pharmac and Pfizer for the supply of nirmatrelvir with ritonavir and note the following key points in support of this position:

- Entering into this manufacturing and supply agreement with Pfizer would ensure supply of an oral antiviral treatment for patients with mild to moderate COVID-19 in New Zealand. This would provide a treatment for patients with COVID-19 in the community and would help to ensure that DHB Hospitals are not overwhelmed caring for patients with COVID-19.
- If this manufacturing and supply agreement is progressed it is expected that nirmatrelvir with ritonavir would be the first oral antiviral treatment available in New Zealand.
- Entering into this manufacturing and supply agreement would support Pharmac's approach of securing a portfolio of treatments for COVID-19 and would legally bind Pfizer to supply its treatment to New Zealand.

• s 9(2) (ba) (i)

Implementation and Communication

Section 49(b) of the New Zealand Public Health and Disability Act 2000 requires Pharmac to take measures to inform the public, groups and individuals of Pharmac's decisions concerning the pharmaceutical schedule. Accordingly, if the recommendations contained in this paper are adopted, Pharmac staff will take the following measures to inform the public, groups and individuals of that decision:

- The decision to enter into the manufacturing and supply agreement with Pfizer for the supply of nirmatrelvir with ritonavir would be communicated to inform the public, groups and individuals at the time of communicating the decision regarding the access criteria for nirmatrelvir with ritonavir and molnupiravir. This is expected mid-March 2022.
- He Ako Hiringa has also been engaged by Pharmac to produce resources for healthcare professionals regarding nirmatrelvir with ritonavir.
- Implementation activities would be further described in the decision paper regarding access criteria to oral antiviral treatments.

Factors for Consideration

An assessment of the decision to fund nirmatrelvir with ritonavir against Pharmac's Factors for Consideration is provided in the December 2021 decision paper to secure supply of nirmatrelvir with ritonavir.

MEMORANDUM FOR CONSIDERATION BY DIRECTOR OF OPERATIONS UNDER DELEGATED AUTHORITY

To: Director of Operations
From: Senior Therapeutic Group Manager/Team Leader – Te Papa
Date: September 2022

Purchase Order for 40,000 treatment courses of Paxlovid

Recommendations

It is recommended that having regard to the decision-making framework set out in Pharmac's Operating Policies and Procedures you exercise your delegated authority and:

resolve to approve the Purchase Order (15122) provided in Appendix One for the purchase of 40,000 treatment courses of nirmatrelvir with ritonavir (Paxlovid), to be supplied to New Zealand.

note that this purchase order follows a decision by the Pharmac Board to approve a proposal by Pharmac staff to secure an additional 40,000 courses of Paxlovid via an agreement amendment dated 29 August 2022

note that this purchase order is required by Pfizer to secure supply of the 40,000 Paxlovid treatment courses for New Zealand

note that the 40,000 Paxlovid treatment courses would be expected to arrive in New Zealand in September 2022 and would be supplied with a shelf life of 18 months from the date of manufacture

note that the agreement amendment also includes provisions for two additional orders of Paxlovid of up to 20,000 treatment courses each at Pharmac's discretion

note that if these additional orders were exercised, they would be subject to a separate decision and purchase order

note that the Purchase Order would have a financial impact of \$ [redacted] s 9(2)(b)(ii), 9(2)(ba)(i) & 9(2)(i) and would be recovered from COVID-19 treatment funds

note that the cost associated with this Purchase Order has been approved as part of the previous decision by the Pharmac Board in August 2022 to secure supply of an additional 40,000 treatment courses of Paxlovid

[redacted]
s 9(2) (ba) (i)
s 9(2) (ba) (i)
s 9(2) (ba) (i)

Paxlovid Purchase Order – September 2022

Purchase order for 40,000 treatment courses of Paxlovid for New Zealand

| PO | Pharmaceutical/Item | Supplier | Quantity | Price (NZD) | Gross Cost (NZD, ex GST) | Agreement Date | Anticipated Delivery Date | Forecast stock on hand at delivery (months) |
|-------|---------------------|----------|----------|--------------|--------------------------|----------------|---------------------------|---|
| 15122 | Paxlovid | Pfizer | 40,000 | \$ s 9(2)(b) | \$ S 9(2)(b)(ii), 9 | 29 August 2022 | September 2022 | 10* |

*Based on average monthly Paxlovid dispensing since 1 July 2022

Comment:

Purpose:
 The purpose of this Purchase Order is to secure supply of 40,000 treatment courses of Paxlovid to New Zealand. s 9(2) (b)(ii)
 s 9(2) (b)(ii) If this Purchase Order is progressed, it is expected that the 40,000 treatment courses would be available in New Zealand this month (September 2022).

Background:
 This proposal follows a [decision by the Pharmac Board in September 2022](#) to secure supply 40,000 treatment courses of Paxlovid for the treatment of COVID-19 in New Zealand. This decision followed the negotiation of an amendment to Pharmac’s original 18 March Agreement for the supply of Paxlovid to New Zealand to secure an additional 40,000 courses. The volume of 40,000 courses was informed by available COVID-19 funding for therapeutics available for the 2023/24 financial year. Further rationale for the Purchase of Paxlovid is provided in this decision paper.

s 9(2) (ba) (i)
 s 9(2) (ba) (i)
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 s 9(2) (ba) (i)

Shelf life:
 Based on recent correspondence with Pfizer, we understand that Medsafe has recently approved a shelf-life extension for Paxlovid from the date of manufacture from 12 to 18 months. Pharmac understands that this extension to the shelf life, will apply to the 40,000 courses of Paxlovid that would be secured by this Purchase Order, any future orders for Paxlovid placed by Pharmac, and would also apply retrospectively to courses of Paxlovid that have already arrived in New Zealand and are currently being used in the treatment of COVID-19. We understand that for stock that is currently available over labelling would be required to meet regulatory requirements associated with the increased shelf life for this stock. This increase to the shelf life for Paxlovid would provide additional time for the courses that have been secured to be used. We will consider how to implement this for existing stock, working with Pfizer and the COVID-19 Care in the Community team at Te Whatu Ora and will ensure that stock with the shortest dating is used first. We understand that Pfizer expects to submit data for further Paxlovid shelf-life extensions to Medsafe as it becomes available.

Access criteria and expected uptake:
 Since Paxlovid was first funded in April 2022 Pharmac has made a number of updates to the access criteria for antiviral treatments (including Paxlovid) to support greater uptake, particularly amongst groups most at risk of severe COVID-19 infection in New Zealand including Māori and Pacific People. This includes updates in [March 2022](#), [April 2022](#) and [July 2022](#).

| PO | Pharmaceutical/Item | Supplier | Quantity | Price (NZD) | Gross Cost (NZD, ex GST) | Agreement Date | Anticipated Delivery Date | Forecast stock on hand at delivery (months) |
|---|---------------------|----------|----------|-------------|--------------------------|----------------|---------------------------|---|
| <p>Each of these updates resulted in increases in the number of eligible people and were intended to increase uptake of antiviral treatments. As at 4 September 2022, 34,847 courses of oral antivirals have been dispensed. 22,829 (approximately 66%) were Paxlovid and 12,018 (approximately 34%) were molnupiravir.</p> <p>Increased uptake of COVID-19 oral antiviral treatments has also been supported by recent changes made by Manatū Hauora - Ministry of Health including a temporary reclassification of Paxlovid and molnupiravir as 'Pharmacist Only' medicines, which allows them to be dispensed by pharmacists to eligible people without a prescription.</p> <p>Pharmac staff are also proposing a further change to the access criteria for COVID-19 antiviral treatments, which are proposed to be implemented from mid-September 2022. This proposal is subject to a separate decision paper which is currently under review with Pharmac staff. If approved this proposal would result in a significant increase in the size of the eligible population and consequently, would be expected to result in increased uptake of COVID-19 antivirals.</p> <p>At the highest levels of dispensing for oral antivirals experienced to date (approximately 1,000 packs per day), the 40,000 packs proposed to be secured would last approximately 1.3 months. We consider it is important to secure this additional stock to help manage the risk of future COVID-19 outbreaks in New Zealand.</p> | | | | | | | | |

Appendix One: Purchase Order

Purchase order for 40,000 treatment courses of Paxlovid for New Zealand

To: Pfizer New Zealand Limited

Level 17, 151 Clarence Street
Sydney, NSW 2000
Australia

Attention: S 9(2)(a)

Purchase

Purchase Order Number 15122
Date 9 September 2022
pharmaceutical Nirmatrelvir with ritonavir (Paxlovid)
For the treatment of COVID-19 (tablets)
Quantity (doses) 40,000
Value of Order \$S 9(2)(b)(ii),

Delivery

Delivery Date September 2022
Delivery Address Pharmacy Retailing NZ Limited (ProPharma) 54 Carbine Road, Mount Wellington
Auckland 1060
Contacts S 9(2)(a)
S 9(2)(a)
S 9(2)(a)

Invoice & Terms of Trade

Invoice Address Pharmac
PO Box 10-254
Wellington 6143
New Zealand
Contacts Graham Durston - Finance Manager, email: S 9(2)(a)
Josh Wiles - Therapeutic Group Manager, email: S 9(2)(a)
Phone S 9(2)(a)
Terms of Trade Terms of trade per the 29 August 2022 Amendment Agreement between Pharmac
and Pfizer for the supply of Paxlovid

Authorisation



Lisa Williams – Director of Operations, Pharmac

**MEMORANDUM FOR CONSIDERATION BY CHIEF EXECUTIVE
UNDER DELEGATED AUTHORITY**

To: Chief Executive
From: Senior Therapeutic Group Manager/Team Leader – Te Papa
Date: December 2022

Purchase Order for 20,000 treatment courses of Paxlovid

Recommendations

It is recommended that having regard to the decision-making framework set out in Pharmac's Operating Policies and Procedures you exercise your delegated authority and:

resolve to approve the Purchase Order (15123) provided in Appendix One for the purchase of 20,000 treatment courses of nirmatrelvir with ritonavir (Paxlovid), to be supplied to New Zealand.

resolve to direct Pharmac staff to inform Pfizer that Pharmac wishes to retain the option to secure supply of s 9(2) (b)(ii) subject to budget availability in 2023.

note that this proposal follows a decision by the Pharmac Board to [delegate decision making](#) for the purchase of 20,000 courses of nirmatrelvir with ritonavir to the Chief Executive.

note that this proposal follows previous decisions by the Pharmac Board to approve a proposal by Pharmac staff to [secure an additional 40,000 courses of nirmatrelvir with ritonavir](#) via an agreement amendment dated 29 August 2022.

s 9(2) (b)(ii)

s 9(2) (b)(ii)

note s 9(2) (b)(ii)

s 9(2) (b)(ii)

however Pfizer has noted if an order is received prior to the summer break it will work towards delivery in February 2022.

note that this proposal is required to ensure ongoing supply of nirmatrelvir with ritonavir.

note that the Purchase Order associated with this proposal would have a financial impact of s 9(2)(b)(ii), 9(2)(ba)(i) & s 9(2)(i) and would be recovered from COVID-19 treatment funds and there is sufficient funding available for this purchase.

| SUMMARY OF PHARMACEUTICAL | | | |
|--|---|--|---|
| Brand Name | Paxlovid | Chemical Name | Nirmatrelvir with ritonavir |
| Indications | Mild to moderate COVID-19 | Presentation | Oral |
| Therapeutic Group | Infections – Agents for systemic use, protease inhibitors | Currently recommended dosage | Nirmatrelvir with ritonavir for five days |
| Supplier | Pfizer New Zealand Limited | | |
| Current Subsidy | NA | Proposed Restriction | Access Criteria |
| Proposed Subsidy | S 9(2)(b)(ii), 9(2)(ba)(i) & 9(2)(j) | Approved by Medsafe for this indication | Yes |
| | February 2023 | | |
| Number of Patients† | 20,000 | | |
| Net Cost to Covid-19 Fund | S 9(2)(b)(ii), 9(2)(ba)(i) & 9(2)(j) | | |
| Net Cost to DHBs (1-year NPV, 8%) | S 9(2)(b)(ii), 9(2)(ba)(i) & 9(2)(j) | | |

Notes:

1. Net Cost to COVID-19 Fund
2. All pharmaceutical costs are ex-manufacturer
3. All costs are ex-GST

Why proposal should be considered by the Chief Executive under Delegated Authority

The proposal involves a purchasing decision that has an estimated Financial Impact of greater than S 9(2) (ba) (i)

On 2 December 2022 the Pharmac Board resolved to delegate decision making for this proposal to the Chief Executive, to allow a timely decision to be made on this proposal.

Executive summary

- Paxlovid has been available in New Zealand for people with COVID-19 who are at risk of severe illness following infection since April 2022.
- Paxlovid is the most widely dispensed treatment for COVID-19 in New Zealand and this is expected to continue in future due to emerging evidence that other available oral antiviral treatments (molnupiravir) may not be as effective as first reported and the emergence of variants of COVID-19 that are not susceptible to the currently available monoclonal antibody treatment (tixagevimab with cilgavimab).
- 20,000 courses available to Pharmac under its [August 2022 agreement](#) with Pfizer are proposed to be secured. Any additional future orders would be expected to require additional funding.
- Current case numbers continue to rise and there continues to be significant concerns about the future trajectory of COVID-19 in New Zealand. This proposal would ensure continued availability of nirmatrelvir with ritonavir into 2023.
- Public consultation was not undertaken on this proposal as it is a continuation of existing arrangements.

Purpose

- The purpose of this paper is to seek your approval to secure supply of 20,000 courses of Paxlovid for the treatment of COVID-19 in New Zealand.

Proposal

- It is proposed that Pharmac would s 9(2) (b)(ii) [redacted] s 9(2) (b)(ii) [redacted] and secure supply on an additional 20,000 courses of nirmatrelvir with ritonavir (Paxlovid) s 9(2) (ba) (i) [redacted] s 9(2) (ba) (i) [redacted] It is intended that securing this stock would provide ongoing supply of nirmatrelvir with ritonavir through early 2023.
- s 9(2) (ba) (i) [redacted]
s 9(2) (ba) (i) [redacted]
s 9(2) (ba) (i) [redacted]
- s 9(2) (ba) (i) [redacted]
s 9(2) (ba) (i) [redacted]
s 9(2) (ba) (i) [redacted]

Background

- Nirmatrelvir with ritonavir has been available in New Zealand subject to access criteria since April 2022. An initial volume of 60,000 courses was secured and in August 2022 an additional purchase of 40,000 courses of nirmatrelvir with ritonavir was made. s 9(2) (b)(ii)
s 9(2) (b)(ii)
- As noted in other papers prepared by Pharmac staff, Pharmac has adopted a portfolio approach to securing COVID-19 Treatments for New Zealand. Nirmatrelvir with ritonavir is one of three antivirals currently available in New Zealand for the treatment of COVID-19. The others are remdesivir and molnupiravir. Remdesivir is an infusion, while molnupiravir, like nirmatrelvir with ritonavir is an oral antiviral.
- All three of the currently available antiviral treatments are funded subject to the same access criteria, with the exception of remdesivir which is also funded for the treatment of people hospitalised with COVID-19 in Te Whatu Ora Hospitals which require supplementary oxygen.
- The use of oral treatments, nirmatrelvir with ritonavir and molnupiravir, has been higher than remdesivir which has largely been limited to people hospitalised with COVID-19.
- Nirmatrelvir with ritonavir has been the most popular of the oral antiviral treatments due to available evidence that suggests it may be more effective than molnupiravir. To reflect this, there is a [note in the access criteria](#), which emphasises that other antiviral treatments should be considered if nirmatrelvir with ritonavir is unsuitable.
- Preliminary data from the [PANORAMIC trial undertaken in the United Kingdom](#) have recently been released, which have raised further concerns about the effectiveness of molnupiravir and the relative benefits associated with its use. Results of this trial have not been published yet, but it is expected that they may result in further increases in the use of nirmatrelvir with ritonavir relative to molnupiravir.

COVID-19-current trends and dispensing rates

- Of the 100,000 courses of nirmatrelvir with ritonavir that have been delivered to New Zealand so far, approximately 60,000 have been dispensed and a further 13,000 courses are available at pharmacies. The remaining 27,000 courses are available at the wholesaler (Propharma).
- Since October 2022 COVID-19 cases began increasing again in New Zealand, following a period of declining numbers. Over the past week there has been approximately 40,000 COVID-19 cases and an average of approximately 1200 courses of oral antivirals distributed each day. Approximately 70% of these (900 courses per day) have been Paxlovid. Assuming that dispensing rates remain constant the 40,000 available Paxlovid courses would be expected to last approximately 1.5 months. Noting this and the considerable uncertainty

about future COVID-19 cases we consider it is timely to secure Pharmac's next order of nirmatrelvir with ritonavir.

- The uncertainty regarding future COVID-19 cases and the impact of this on the uptake of antiviral treatments is compounded by growing uncertainty about the effectiveness of molnupiravir against COVID-19 and the emergence of variants of COVID-19 that are not susceptible to current monoclonal antibody treatments (tixagevimab with cilgavimab). These factors together would be expected to result in increased demand for nirmatrelvir with ritonavir.

Volume of courses to be secured

- We have proposed that 20,000 courses of Paxlovid be secured through this proposal. s 9(2) (ba) (i)
s 9(2) (ba) (i)
s 9(2) (ba) (i)
- s 9(2) (ba) (i)
s 9(2) (ba) (i)
s 9(2) (ba) (i) There is sufficient funding available to support this proposal with approximately s 9(2) (ba) (i) of committed COVID-19 treatment costs this financial year, with approximately s 9(2) (ba) (i) still available (total COVID-19 treatment funds available this financial year being \$s 9(2) (ba) (i), as per July 2022 Briefing to Ministers [HR20221191]. s 9(2) (ba) (i)
s 9(2) (ba) (i)
s 9(2) (ba) (i) Staff expect to confirm future funding requirements for COVID-19 treatments in early 2023.
- s 9(2) (ba) (i)
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s 9(2) (ba) (i)
- In light of evidence emerging from the PANORAMIC Trial and advice from Pharmac's COVID-19 Treatments Advisory Group we are not currently proposing to secure additional molnupiravir beyond the 60,000 courses that have already been secured. The final 10,000 courses of this order are expected to arrive in January 2023.

Clinical Advice received

Pharmac staff have sought advice from the COVID-19 Treatments Advisory Group regarding nirmatrelvir with ritonavir on a number of occasions.

The Advisory Group has noted that due to nirmatrelvir with ritonavir's mechanism of action, it is expected to retain efficacy against future variants of COVID-19.

On 31 October 2022 Advice was sought from the COVID-19 Treatments Advisory Group regarding molnupiravir for the treatment of COVID-19 following release of preliminary results from the PANORAMIC Trial.

The Advisory Group reconfirmed its previous position that nirmatrelvir with ritonavir and remdesivir are the preferred antiviral treatments for COVID-19 in New Zealand due to available evidence suggesting greater efficacy.

The Advisory Group strengthened this position noting that molnupiravir should only be retained for people who cannot receive nirmatrelvir with ritonavir for strong clinical reasons, and treatment with molnupiravir may offer benefit for some people who would otherwise receive no treatment.

A record of this discussion is undergoing review. [A draft is available here.](#)

Advisor Conflicts of Interest

All declared conflict(s) of interest for any clinical advisors who contributed to the above advice, and actions taken to manage the conflict(s), are recorded in the relevant records.

Risks

- The 20,000 courses may not be sufficient or may be delivered too late (mid-February 2023) to meet New Zealand's needs during the current wave of cases. To manage this, we would work with Pfizer to progress the delivery of the 20,000 courses as soon as possible to New Zealand. Providing the purchase order associated with this decision to Pfizer as soon as possible will aid these conversations.
- It is important to note that the arm of the PANORAMIC Trial evaluating the effectiveness of nirmatrelvir with ritonavir in the treatment of COVID-19 is underway and there is a risk that like molnupiravir, nirmatrelvir with ritonavir may be found to be less effective than previously thought. The portfolio approach to securing supply of COVID-19 acknowledges that not all treatments secured are expected to be effective against all variants of COVID-19. However, it is important to make decisions based on the evidence available, which currently supports the effectiveness of nirmatrelvir with ritonavir. This proposal would secure supply of a limited volume of nirmatrelvir with ritonavir (20,000 courses) which would allow Pharmac's losses to be limited if future results for nirmatrelvir with ritonavir are unfavourable.

Implementation planning and approach

- This proposal would ensure a currently available treatment for COVID-19 would remain available. No changes have been proposed to access criteria or distribution arrangements. Consequently, it is considered that specific implementation activities would not be required.

- For the reasons noted above a public consultation has not been undertaken on this proposal. Pharmac retains the option to undertake public consultation as required at any point in the future.

Equity considerations and Factors for Consideration

- The Equity implications and analysis of the Factors for Consideration resulting from the availability of nirmatrelvir with ritonavir have been discussed in the [December 2021 decision paper](#) to secure supply of nirmatrelvir with ritonavir and the [September 2022 decision paper](#) amend the access criteria to antiviral treatments for COVID-19. We consider that these assessments remain valid and provide further justification for this proposal.

Appendix One: Purchase Order

Purchase order for 20,000 treatment courses of Paxlovid for New Zealand

To: Pfizer New Zealand Limited

Level 17, 151 Clarence Street
Sydney, NSW 2000
Australia

Attention: S 9(2)(a)

Purchase

Purchase Order Number 15123
Date 16 December 2022
pharmaceutical Nirmatrelvir with ritonavir (Paxlovid)
For the treatment of COVID-19 (tablets)
Quantity (doses) 20,000
Value of Order \$ S 9(2) (ba)

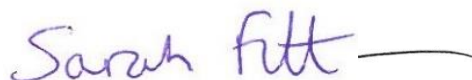
Delivery

Delivery Date February – March 2023
Delivery Address Pharmacy Retailing NZ Limited (ProPharma) 54 Carbine Road, Mount Wellington
Auckland 1060
Contacts S 9(2)(a)
S 9(2)(a)
S 9(2)(a)

Invoice & Terms of Trade

Invoice Address Pharmac
PO Box 10-254
Wellington 6143
New Zealand
Contacts Graham Durston - Finance Manager, email: S 9(2)(a)
Josh Wiles – Therapeutic Group Manager, email: S 9(2)(a)
Phone S 9(2)(a)
Terms of Trade Terms of trade per the 29 August 2022 Amendment Agreement between Pharmac
and Pfizer for the supply of Paxlovid

Authorisation



Sarah Fitt – Chief Executive, Pharmac

MEMORANDUM FOR CONSIDERATION BY CHIEF EXECUTIVE UNDER DELEGATED AUTHORITY

To: Chief Executive
From: Senior Therapeutic Group Manager/Team Leader – Te Papa
Date: March 2023

Purchase Order for 15,048 treatment courses of Paxlovid

Recommendations

It is recommended that having regard to the decision-making framework set out in Pharmac's Operating Policies and Procedures you exercise your delegated authority and:

resolve to approve the agreement amendment dated 3 March 2023 provided in Appendix One for the purchase of 15,048 treatment courses of nirmatrelvir with ritonavir

resolve to approve the Purchase Order (15131) provided in Appendix Two for the purchase of this stock to be supplied to New Zealand.

note that this proposal follows a decision by the Pharmac Board to [delegate decision making](#) for the purchase of 15,048 courses of nirmatrelvir with ritonavir to the Chief Executive.

note that supply of these 15,048 courses would be secured by entering an amendment to the 18 March 2022 agreement with Pfizer for the supply of nirmatrelvir with ritonavir.

note s 9(2) (ba) (i) [REDACTED]
s 9(2) (ba) (i) [REDACTED] Pfizer has noted it would work with Pharmac to provide supply as soon as it is able.

note that the Purchase Order associated with this proposal would have a financial impact of \$s 9(2) (ba) (i) [REDACTED] and would be recovered from COVID-19 treatment funds and there is sufficient funding available for this purchase.

| SUMMARY OF PHARMACEUTICAL | | | |
|--|---|--|---|
| Brand Name | Paxlovid | Chemical Name | Nirmatrelvir with ritonavir |
| Indications | Mild to moderate COVID-19 | Presentation | Oral |
| Therapeutic Group | Infections – Agents for systemic use, protease inhibitors | Currently recommended dosage | Nirmatrelvir with ritonavir twice daily for five days |
| Supplier | Pfizer New Zealand Limited | | |
| Current Subsidy | NA | Proposed Restriction | Access Criteria |
| Proposed Subsidy | S 9(2)(b)(ii), 9(2)(ba)(i) & 9(2)(j) | Approved by Medsafe for this indication | Yes |
| | February 2023 | | |
| Number of Patients† | 15,048 | | |
| Net Cost to Covid-19 Fund | S 9(2)(b)(ii), 9(2)(ba)(i) & 9(2)(j) | | |
| Net Cost to DHBs (1-year NPV, 8%) | S 9(2)(b)(ii), 9(2)(ba)(i) & 9(2)(j) | | |

Notes:

1. Net Cost to COVID-19 Fund
2. All pharmaceutical costs are ex-manufacturer
3. All costs are ex-GST

Why proposal should be considered by the Chief Executive under Delegated Authority

The proposal involves a purchasing decision that has an estimated Financial Impact of greater than S 9(2) (ba) (i)

On 24 February 2023 the Pharmac Board resolved to delegate decision making for this proposal to the Chief Executive, to allow a timely decision to be made on this proposal.

Executive summary

- Nirmatrelvir with ritonavir has been available in New Zealand for people with COVID-19 who are at risk of severe illness following infection since April 2022.
- Nirmatrelvir with ritonavir is the most widely dispensed treatment for COVID-19 in New Zealand and this is expected to continue due to emerging evidence that the other available oral antiviral treatment (molnupiravir) does not appear to be as effective as first reported.
- 15,048 courses of nirmatrelvir with ritonavir are proposed to be secured via an amendment agreement with Pfizer. This stock would be secured with the remaining available COVID-19 funding in the 2022/23 budget.
- Following the 2022 December peak in COVID-19 cases, active cases continue to decline. Securing this stock would help ensure continued supply until the budget position for COVID-19 Treatments in the 2023/2024 financial year is clear.
- Public consultation was not undertaken on this proposal as it is a continuation of existing arrangements.

Purpose

- The purpose of this paper is to seek your approval to secure supply of 15,048 courses of nirmatrelvir with ritonavir for the treatment of COVID-19 in New Zealand.

Proposal

- It is proposed that Pharmac would enter an agreement amendment with Pfizer to secure supply of 15,048 courses of nirmatrelvir with ritonavir. The terms and conditions of this amendment, including the price per course would be the same as Pharmac's existing agreement with Pfizer.

- s 9(2) (ba) (i) [REDACTED]
s 9(2) (ba) (i) [REDACTED]
s 9(2) (ba) (i) [REDACTED]

- s 9(2) (ba) (i) [REDACTED]
s 9(2) (ba) (i) [REDACTED]
s 9(2) (ba) (i) [REDACTED]
s 9(2) (ba) (i) [REDACTED]

- s 9(2) (ba) (i) [REDACTED]

- s 9(2) (ba) (i) [REDACTED] from the receipt of an invoice to the delivery of stock to New Zealand. This means stock would be expected to arrive in New Zealand in May 2023.

Pfizer has noted that once an invoice has been received it would work with Pharmac to reduce the lead time to supply as much as possible.

Background

- Nirmatrelvir with ritonavir has been available in New Zealand subject to access criteria since April 2022. An initial volume of 60,000 courses was secured and in August 2022 an additional purchase of 40,000 courses of nirmatrelvir with ritonavir was made. In December 2022, s 9(2) (b)(ii) [REDACTED]
s 9(2) (b)(ii) [REDACTED]
s 9(2) (b)(ii) [REDACTED]
- Nirmatrelvir with ritonavir has been the most popular of the oral antiviral treatments due to available evidence that suggests it may be more effective than molnupiravir.
- The PANORAMIC Trial has recently been published, which reports that molnupiravir did not reduce the risk of hospitalisation and death in a vaccinated population where Omicron is the dominant variant of circulating COVID-19.
- This data was considered by Pharmac's COVID-19 Advisory Group in February 2023. Records of this meeting are being drafted, however, based on feedback from the Advisory Group it is expected that changes will be made to molnupiravir access, which would result in increased uptake of nirmatrelvir with ritonavir.

Volume of courses to be secured

- We have proposed that 15,048 courses of nirmatrelvir with ritonavir be secured through this proposal. This volume has been informed by both Pfizer's pallet volumes for nirmatrelvir with ritonavir and available budget in the COVID-19 Treatments Fund for 2022/23. There is sufficient funding available to support this proposal. Based on currently committed cost, approximately \$s 9(2) (ba) [REDACTED] will be remaining in the COVID-19 Fund for unforeseen expenses. We are in the process of confirming the 2023/24 budget for COVID-19 Treatments, which would be available from 1 July 2023.
- s 9(2) (ba) (i) [REDACTED]
s 9(2) (ba) (i) [REDACTED]
s 9(2) (ba) (i) [REDACTED]

Clinical Advice received

Pharmac staff have sought advice from the COVID-19 Treatments Advisory Group regarding nirmatrelvir with ritonavir and COVID-19 antivirals on a number of occasions.

The Advisory Group has noted that due to nirmatrelvir with ritonavir's mechanism of action, it is expected to retain efficacy against future variants of COVID-19.

Most recently, at its 14 February 2023 meeting advice was sought from the COVID-19 Treatments Advisory Group regarding the position of molnupiravir in New Zealand's portfolio of treatments. Records of the discussion are being finalised. In summary the Group noted the publication of results of the PANORAMIC Trial and recommended that molnupiravir should not continue to be available for the treatment of COVID-19 in New Zealand.

Advisor Conflicts of Interest

All declared conflict(s) of interest for any clinical advisors who contributed to the above advice, and actions taken to manage the conflict(s), are recorded in the relevant records.

Risks

- There are approximately 36,000 courses of Paxlovid available in New Zealand. Although COVID-19 case numbers are currently declining, there is a possibility that if cases increased to similar levels seen at the December 2022 peak (over 20,000 courses dispensed on one month) the remaining stock and the proposed purchase of 15,048 courses may not be sufficient to meet demand until additional COVID-19 treatment funding is confirmed and available for the 2023/24 financial year. Noting that current COVID-19 case numbers are low compared to previous months and the expected trajectory of cases over the coming months, this outcome is not considered likely.
- It is important to note that the arm of the PANORAMIC Trial evaluating the effectiveness of nirmatrelvir with ritonavir in the treatment of COVID-19 is underway and there is a risk that like molnupiravir, nirmatrelvir with ritonavir may be found to be less effective than previously thought. The portfolio approach to securing supply of COVID-19 acknowledges that not all treatments secured are expected to be effective against all variants of COVID-19. However, it is important to make decisions based on the evidence available, which currently supports the effectiveness of nirmatrelvir with ritonavir. This proposal would secure supply of a limited volume of nirmatrelvir with ritonavir (15,048 courses) which would allow Pharmac's losses to be limited if future results for nirmatrelvir with ritonavir are unfavourable.

Implementation planning and approach

- This proposal would ensure a currently available treatment for COVID-19 would remain available. No changes have been proposed to access criteria or distribution arrangements. Consequently, it is considered that specific implementation activities would not be required.
- For the reasons noted above a public consultation has not been undertaken on this proposal. Pharmac retains the option to undertake public consultation as required at any point in the future.

Equity considerations and Factors for Consideration

- The Equity implications and analysis of the Factors for Consideration resulting from the availability of nirmatrelvir with ritonavir have been discussed in the [December 2021 decision paper](#) to secure supply of nirmatrelvir with ritonavir and the [September 2022 decision paper](#) amend the access criteria to antiviral treatments for COVID-19. We consider that these assessments remain valid and provide further justification for this proposal.

Appendix One: Purchase Order

Purchase order for 15,048 treatment courses of Paxlovid for New Zealand

To: Pfizer New Zealand Limited

Level 17, 151 Clarence Street
Sydney, NSW 2000
Australia

Attention: S 9(2)(a)

Purchase

Purchase Order Number 15131
Date 3 March 2023
pharmaceutical Nirmatrelvir with ritonavir (Paxlovid)
For the treatment of COVID-19 (tablets)
Quantity (doses) 15,048
Value of Order \$S 9(2) (ba)

Delivery

Delivery Date March – May 2023
Delivery Address Pharmacy Retailing NZ Limited (ProPharma) 54 Carbine Road, Mount Wellington
Auckland 1060
Contacts S 9(2)(a)
S 9(2)(a)
S 9(2)(a)

Invoice & Terms of Trade

Invoice Address Pharmac
PO Box 10-254
Wellington 6143
New Zealand
Contacts Graham Durston - Finance Manager, email: S 9(2)(a)
Josh Wiles– Therapeutic Group Manager, email: S 9(2)(a)
Phone S 9(2)(a)
Terms of Trade Terms of trade per the 3 March 2023 Amendment Agreement between Pharmac and
Pfizer for the supply of nirmatrelvir with ritoanvir

Authorisation



Sarah Fitt – Chief Executive, Pharmac

**MEMORANDUM FOR CONSIDERATION BY CHIEF EXECUTIVE
UNDER DELEGATED AUTHORITY**

To: Chief Executive
From: Senior Therapeutic Group Manager/Team Leader – Te Papa
Date: May 2023

Purchase Order for 36,000 treatment courses of nirmatrelvir with ritonavir

Recommendations

It is recommended that having regard to the decision-making framework set out in Pharmac's Operating Policies and Procedures you exercise your delegated authority and:

resolve to approve the agreement amendment dated 1 May 2023 provided in Appendix One for the purchase of 36,000 treatment courses of nirmatrelvir with ritonavir

resolve to approve the Purchase Order (15132) provided in Appendix Two for the purchase of this stock to be supplied to New Zealand.

note that this proposal follows a decision by the Pharmac Board to [delegate decision making](#) for the purchase of up to 36,000 courses of nirmatrelvir with ritonavir to the Chief Executive.

note that supply of these 36,000 courses would be secured by entering an amendment to the 18 March 2022 agreement with Pfizer for the supply of nirmatrelvir with ritonavir.

note that Pfizer has confirmed that if a purchase order is provided delivery for the full volume of courses could occur in June 2023.

note that the Purchase Order associated with this proposal would have a financial impact of \$ 9(2) (ba) (i) (NZD) and would be recovered from COVID-19 treatment funds. There is sufficient funding available for this purchase following the Ministerial approval of an additional \$ 9(2) (ba) of COVID-19 treatment funding for the current financial year.

| SUMMARY OF PHARMACEUTICAL | | | |
|--|---|--|---|
| Brand Name | Paxlovid | Chemical Name | Nirmatrelvir with ritonavir |
| Indications | Mild to moderate COVID-19 | Presentation | Oral |
| Therapeutic Group | Infections – Agents for systemic use, protease inhibitors | Currently recommended dosage | Nirmatrelvir with ritonavir twice daily for five days |
| Supplier | Pfizer New Zealand Limited | | |
| Current Subsidy | NA | Proposed Restriction | Access Criteria |
| Proposed Subsidy | § 9(2) (ba) (i) | Approved by Medsafe for this indication | Yes |
| | February 2023 | | |
| Number of Patients† | 36,000 | | |
| Net Cost to Covid-19 Fund | § 9(2) (ba) | | |
| Net Cost to DHBs (1-year NPV, 8%) | § 9(2) (ba) (i) | | |

Notes:

1. Net Cost to COVID-19 Fund
2. All pharmaceutical costs are ex-manufacturer
3. All costs are ex-GST

Why proposal should be considered by the Chief Executive under Delegated Authority

The proposal involves a purchasing decision that has an estimated Financial Impact of greater than \$§ 9(2) (ba).

On 31 March 2023 the Pharmac Board resolved to delegate decision making for this proposal to the Chief Executive, to allow a timely decision to be made on this proposal once additional funding was confirmed.

Executive summary

- Nirmatrelvir with ritonavir has been available in New Zealand for people with COVID-19 who are at risk of severe illness following infection since April 2022.
- Nirmatrelvir with ritonavir is the most widely dispensed treatment for COVID-19 in New Zealand. Manatū Hauora's COVID-19 Therapeutic Technical Advisory Group has recently released a position statement recommending that molnupiravir is not used for the treatment of COVID-19 in New Zealand and treatment guidelines have been updated to reflect this. This has caused a relative increase in the use of nirmatrelvir with ritonavir, which is expected to continue.
- 36,000 courses of nirmatrelvir with ritonavir are proposed to be secured via an amendment agreement with Pfizer. This stock would be secured with the remaining available COVID-19 funding in the 2022/23 budget.
- Following declining case numbers from the December 2022 peak, case numbers have been increasing over the last few weeks and are expected to continue rising over the next month heading into winter. Last week there were 10,852 cases of COVID-19 reported in New Zealand.
- As of 26 April 2023, there are approximately 3,763 courses available at Propharma and 11,958 courses available at pharmacies. The remaining ~14,000 courses from Pharmac's March 2023 order are expected to arrive in New Zealand in the next few weeks. For the past month weekly dispensing volumes have ranged between 2,500 and 3,000 courses.
- Public consultation was not undertaken on this proposal as it is a continuation of existing arrangements.

Purpose

The purpose of this paper is to seek your approval to secure supply of 36,000 courses of nirmatrelvir with ritonavir for the treatment of COVID-19 in New Zealand.

Proposal

- It is proposed that Pharmac would enter an agreement amendment with Pfizer to secure supply of 36,000 courses of nirmatrelvir with ritonavir. The terms and conditions of this amendment, including the price per course would be the same as Pharmac's existing agreement with Pfizer.
- s 9(2) (ba) (i) from the receipt of an invoice to the delivery of stock to New Zealand. This means stock would be expected to arrive in New Zealand in May 2023. Pfizer has noted that if a purchase order is provided to it in the next few weeks, it would be able to supply stock to New Zealand in June 2023.
- The proposed 36,000 courses are intended to ensure that stock of nirmatrelvir with ritonavir is available from 1 July 2023 and to allow time for additional courses to be ordered and arrive in New Zealand as required.

Background

- Nirmatrelvir with ritonavir has been available in New Zealand subject to access criteria since April 2022. An initial volume of 60,000 courses was secured and in August 2022 an additional purchase of 40,000 courses of nirmatrelvir with ritonavir was made. In December 2022, s 9(2) (b)(ii) the August 2022 s 9(2) (b)(ii) was exercised for a further 20,000 courses. The most recent purchase order for 15,048 courses was provided to Pfizer in March 2023 and the remaining ~14,000 courses from this order are expected to arrive in New Zealand in the next one/two weeks.
- Nirmatrelvir with ritonavir has been the most widely used of the oral antiviral treatments due to available evidence that suggests it may be more effective than molnupiravir. Based on this evidence Manatū Hauora's COVID-19 Therapeutic Technical Advisory Group has recently released a position statement recommending that molnupiravir is not used for the treatment of COVID-19 in New Zealand and treatment guidelines have been updated to reflect this. This has resulted in significant decreases in the use of molnupiravir and an increase in the use of nirmatrelvir with ritonavir.
- Pharmac is currently [consulting](#) to consider the future role of molnupiravir in New Zealand's treatment portfolio. This consultation remains open for feedback until 2 May 2023, however, it is expected that low dispensing rates for molnupiravir are likely to remain.

Volume of courses to be secured

- We have proposed that 36,000 courses of nirmatrelvir with ritonavir be secured through this proposal. This volume has been informed by Pharmac's estimate of the volume of courses that could be required during the first quarter of the 2023/24 financial year.
- s 9(2) (ba) (i)
s 9(2) (ba) (i)
s 9(2) (ba) (i) | s 9(2) (ba) (i)
s 9(2) (ba) (i)
- s 9(2) (j)

Clinical Advice received

Pharmac staff have sought advice from the COVID-19 Treatments Advisory Group regarding nirmatrelvir with ritonavir and COVID-19 antivirals on a number of occasions.

The Advisory Group has noted that due to nirmatrelvir with ritonavir's mechanism of action, it is expected to retain efficacy against future variants of COVID-19.

Most recently, at its 14 February 2023 meeting advice was sought from the COVID-19 Treatments Advisory Group regarding the position of molnupiravir in New Zealand's portfolio of treatments. Records of the discussion are being finalised. In summary the Group noted the publication of results of the PANORMAIC Trial and recommended that molnupiravir should not continue to be available for the treatment of COVID-19 in New Zealand.

In response to this feedback received from the COVID-19 Treatments Advisory Group, Pharmac is undertaking a public consultation to seek feedback on the ongoing role of molnupiravir in New Zealand's portfolio of COVID-19 Treatments. This consultation remains open until close of business on 2 May 2023.

Advisor Conflicts of Interest

All declared conflict(s) of interest for any clinical advisors who contributed to the above advice, and actions taken to manage the conflict(s), are recorded in the relevant records.

Risks

- As of 26 April 2023, there are approximately 15,721 courses of nirmatrelvir with ritonavir available in New Zealand, with an additional ~14,000 courses expected to arrive in the next month. With case numbers rising there is a risk that if cases increased to similar levels seen at the December 2022 peak for an extended period (over 20,000 courses dispensed on one month) the available stock (including the proposed 36,000 packs) may not be sufficient to meet high levels of demand until FYR 2023/24 COVID-19 treatment funding is confirmed and additional stock has arrived in the country (noting that Pfizer's lead time to supply could be as long as three months). COVID-19 modelling, currently predicts that future waves of COVID-19 would be expected to be smaller than previous waves. Therefore, this risk is considered manageable. Pfizer has also noted it would work with Pharmac to bring orders forward as much as possible if needed.
- A new variant of COVID-19 that is more transmissible and or results in more severe illness than currently circulating variants may emerge. Working with Te Whatu Ora and Manatū Hauora, Pharmac staff continue to monitor the COVID-19 pandemic in New Zealand, including the emergence of new COVID-19 variants. If a more transmissible variant or a variant that resulted in more severe illness was to emerge, Pharmac would review the access criteria for COVID-19 treatments and consider changes based on feedback from the COVID-19 Treatments Advisory Group. We would also work with the Treasury if it was expected that additional funding would be required.
- The arm of the PANORAMIC Trial evaluating the effectiveness of nirmatrelvir with ritonavir in the treatment of COVID-19 is underway and there is a risk that like molnupiravir, nirmatrelvir with ritonavir may be found to be less effective than previously thought. The portfolio approach to securing supply of COVID-19 acknowledges that not all treatments secured are expected to be effective against all variants of COVID-19. However, it is important to make decisions based on the evidence available, which currently supports the effectiveness of nirmatrelvir with ritonavir. This proposal would secure supply of one further delivery of nirmatrelvir with ritonavir (36,000 courses) which would allow Pharmac's losses to be limited if future results for nirmatrelvir with ritonavir are unfavourable.
- Additional COVID-19 treatments may emerge which are more effective than nirmatrelvir with ritonavir in the treatment of COVID-19. Pharmac's portfolio approach to the management of COVID-19 treatments is intended to help manage this risk enabling Pharmac to purchase a range of treatments. Pharmac continues to review emerging COVID-19 Treatments and would manage any budget provided by the Government for COVID-19 Treatments to purchase new treatments if required.

Implementation planning and approach

- This proposal would ensure a currently available treatment for COVID-19 would remain available. No changes have been proposed to access criteria or distribution arrangements. Consequently, it is considered that specific implementation activities would not be required.
- For the reasons noted above a public consultation has not been undertaken on this proposal. Pharmac retains the option to undertake public consultation as required at any point in the future.

Equity considerations and Factors for Consideration

- The Equity implications and analysis of the Factors for Consideration resulting from the availability of nirmatrelvir with ritonavir have been discussed in the [December 2021 decision paper](#) to secure supply of nirmatrelvir with ritonavir and the [September 2022 decision paper](#) amend the access criteria to antiviral treatments for COVID-19. We consider that these assessments remain valid and provide further justification for this proposal.

Appendix One: Purchase Order

Purchase order for 36,000 treatment courses of Paxlovid for New Zealand

To: Pfizer New Zealand Limited

Level 17, 151 Clarence Street
Sydney, NSW 2000
Australia

Attention: S 9(2)(a)

Purchase

Purchase Order Number 15132
Date 1 May 2023
pharmaceutical Nirmatrelvir with ritonavir (Paxlovid)
For the treatment of COVID-19 (tablets)
Quantity (doses) 36,000
Value of Order \$s 9(2) (ba)

Delivery

Delivery Date June 2023
Delivery Address Pharmacy Retailing NZ Limited (ProPharma) 54 Carbine Road, Mount Wellington
Auckland 1060
Contacts S 9(2)(a)
S 9(2)(a)
S 9(2)(a)

Invoice & Terms of Trade

Invoice Address Pharmac
PO Box 10-254
Wellington 6143
New Zealand
Contacts Graham Durston - Finance Manager, email: S 9(2)(a)
Josh Wiles – Therapeutic Group Manager, email: S 9(2)(a)
Phone +64 4 831 5016
Terms of Trade Terms of trade per the 1 May 2023 Amendment Agreement between Pharmac and
Pfizer for the supply of nirmatrelvir with ritoanvir

Authorisation

Sarah Fitt – Chief Executive, Pharmac