

## MEMORANDUM FOR CONSIDERATION BY DIRECTOR OF OPERATIONS

To: Director of Operations  
From: Manager Pharmaceutical Funding  
Date: September 2020

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### Procurement of emergency stock of remdesivir for use in New Zealand

#### 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 31 August 2020 Stock Agreement with Gilead Sciences (NZ);

**note** that the Stock Agreement for this Pharmaceutical is required to secure supply as the global supply of remdesivir is constrained;

**note** that the number of vials secured and the total impact to the CPB are confidential and they cannot be disclosed to the public.

SUMMARY OF PHARMACEUTICAL			
<b>Brand Name</b>	Veklury	<b>Chemical Name</b>	Remdesivir
		<b>Presentation</b>	100 mg/20 ml concentrate solution for Injection and/or 100 mg powder for Injection
<b>Therapeutic Group</b>	Infections	<b>Application Date</b>	N/A
<b>MOH Restrictions</b>	Not yet classified <sup>1</sup>		
<b>List price</b>	\$578.72 per vial <sup>2</sup>		
<b>Market data</b>	<b>YE 30 June 2021</b>	<b>YE 30 June 2022</b>	<b>YE 30 June 2023</b>
<b>Number of patients</b>	Wi		
<b>Net cost of pharmaceutical to Combined Pharmaceutical Budget<sup>3</sup></b>	\$ Withheld <sup>4</sup>		

Notes:

1. Remdesivir has not been considered for the Medsafe classification database. Australian Register of Therapeutic Goods indicates that Veklury has been classified as S4 (Prescription medicine) on the Poison Schedule.
2. Non-negotiable global price for Veklury is set at US\$390 per vial. Total cost of remdesivir is based on assumption of USD-NZD exchange rate 1.484 as at 1600hrs on 31 August 2020.
3. Net cost of pharmaceutical to Combined Pharmaceutical Budget represents the sum of the total cost of remdesivir and the relevant wholesaler service fee. Pharmaceutical cost is expressed ex manufacturer, excluding GST.
4. The number of vials secured for New Zealand, and therefore the total impact to the CPB, is strictly confidential and should not be disclosed to the public.

## Background

- In July 2020, PHARMAC staff initiated discussion with Gilead Sciences, Australia & New Zealand (Gilead) about the possibility of securing a small supply of remdesivir for New Zealand.
- Remdesivir is a novel antiviral agent that has been identified as a possible treatment for hospitalised COVID-19 patients with respiratory complications in intensive care units (ICU).
- Although Gilead initially indicated that it was unable to supply remdesivir before the end of the calendar year, it subsequently agreed to make available [With] vials of remdesivir shortly after the re-emergence of COVID-19 community transmission in New Zealand in August 2020. [With] vials would be sufficient to treat [Withheld under] depending on disease severity.
- PHARMAC staff have engaged with Medsafe and facilitated discussions between Gilead and Medsafe to determine the most appropriate regulatory pathway for the supply of remdesivir in New Zealand. It was agreed that it would not be possible to obtain provisional consent, so supply under Section 29 of the Medicines Act would be the best pathway. While Medsafe does not actively encourage supply under S29, it was comfortable with S29 supply in this situation and worked with Gilead to ensure all S29 requirements would be met.

## Proposal

- Enter into a stock guarantee Agreement with Gilead Sciences (NZ) would secure [With] vials of remdesivir as an emergency stock for use in hospitalised COVID-19 patients in New Zealand. Supply would be under Section 29 of the Medicines Act. The net cost of pharmaceutical to CPB would be approximately [Withheld under]
- We do not propose to list remdesivir on the Pharmaceutical Schedule, rather we would let DHBs know that a small volume of stock is available for urgent use.
- Onelink would issue a purchase order to Gilead and PHARMAC would pay the resulting invoice on delivery of stock to Onelink (which would occur at the end of September 2020). ADHB and other DHBs would order stock from Onelink as required, in the event that they had COVID-19 patients in ICU who meets pre-set criteria established by PHARMAC (this will be the subject of a subsequent memo).

## Confidentiality

- It is important to note that, under the Confidentiality clause of the Agreement (Annex Two, Clause 1), the number of vials secured is strictly confidential. Furthermore, the total impact to the CPB should also not be disclosed to the public as it is widely known that the global cost per vial is set at US\$390.

## **Health Need**

### *Disease/illness/Need of the person*

Coronavirus disease 2019 (COVID-19) is an infectious acute respiratory disease caused by a novel coronavirus. The clinical presentation is generally that of a respiratory infection with a symptom severity ranging from a mild common cold-like illness to a severe viral pneumonia leading to acute respiratory distress syndrome that is potentially fatal. Severe viral pneumonia patients are treated in intensive care setting and can be considered for oxygenation and ventilation.

### *Availability and suitability of existing treatments*

A number of other existing pharmaceuticals have been considered as potential treatments for severe COVID-19 patients; however, there is limited or no evidence to support their use.

### *Government health priorities*

COVID-19 is not one of the Government health priorities; however, the Government has allocated significant funds to manage the consequences and to respond to the COVID-19 pandemic in New Zealand.

## **Health Benefit**

### *Summary of the pharmaceutical*

Remdesivir is a novel antiviral agent that has been identified as one of the possible pharmaceuticals that can be used to treat hospitalised COVID-19 patients with respiratory complications. In the latest results published on the Journal of the American Medical Association shows that in the randomised, open-label, phase 3 trial (n=584) with moderate COVID-19, patients randomised to a 5-day course of remdesivir had a statistically significant difference in clinical status compared with standard care. It is an antiviral that was initially investigated to treat patients infected with Ebola virus.

### *Clinical advice*

Clinical advice has not been sought from the Pharmacology and Therapeutic Advisory Committee (PTAC) or relevant Subcommittees at this time. It is intended to seek advice about the clinical access criteria for the use of remdesivir from PTAC, the Anti-Infective Subcommittee of PTAC, PHARMAC's Critical Care Advisory Group and from the Ministry of Health's clinical subgroup of their Technical Advisory Group in the coming weeks and then proposed criteria would be brought to the Director of Operations for a decision.

Clinical access criteria would then be communicated to DHB hospitals prior to the distribution of remdesivir.

### *Consequences for the health system*

A Procurement Pharmacist at Auckland DHB has been consulted to ensure the arrangement is feasible. It was recommended that PHARMAC work with OneLink as they are the contracted wholesaler for Auckland DHB, and they are also experienced in procuring unapproved pharmaceuticals on behalf of the DHB.

OneLink has indicated that the arrangement is feasible, and that it is confident in meeting the legal requirements of importing and distributing unapproved medicines in New Zealand. PHARMAC staff are considering if a separate agreement with Onelink is required.

## **PTAC View**

### **Advisor Conflicts of Interest**

The recommendations in this paper do not rely on PTAC or Subcommittee advice

## Suitability

### *Physical details of the pharmaceutical and registration status*

There are two different formulations of remdesivir:

- 100 mg powder for injection. A vial contains 100 mg of remdesivir. After reconstitution, each vial contains 5 mg/ml of remdesivir solution.
- 100 mg/20 ml concentrate for injection. A vial contains 100 mg of remdesivir. Each ml of concentrate contains 5 ml of remdesivir.

The delivery under this Agreement would consist of [With] vials of either or a mix of the above formulations.

The recommended dosage of remdesivir in patients 12 years of age and older and weighing at least 40 kg is:

Day 1 - a single loading dose of remdesivir 200 mg given by intravenous infusion

Day 2 onwards - 100 mg given once-daily by intravenous infusion

The total duration of treatment should be at least 5 days and not more than 10 days. This would equate to between 6 and 12 vials per patient – such that [With] vials would be sufficient to treat approximately [With] patients in New Zealand.

Remdesivir does not have Medsafe approval for distribution in New Zealand. It has been approved under emergency authorisations or provisional consent in other jurisdictions. Remdesivir has been granted emergency authorisation in Australia.

Although granting provisional consent would be the preferred regulatory pathway for the emergency supply of remdesivir, Gilead has advised it does not have the regulatory team capacity to provide the necessary documentation at this time.

Medsafe advised that supply under Section 29 would be acceptable in this circumstance. The stock guarantee agreement with Gilead would require that Gilead makes the necessary regulatory submission as soon as practicable.

## Costs and Savings

### *Calculations*

The non-negotiable global price for remdesivir (Veklury) is US\$390 per vial.

The total cost of remdesivir is based on assumption of USD-NZD exchange rate 1.484 as at 1600hrs on 31 August 2020.

[Withheld under section 9(2)(b)(ii), 9(2)(ba)(i), and 9(2)(j)]

The total one-off payment to Gilead for the stock, once delivered to Onelink, would be [Withheld under section 9(2)(b)(ii), 9(2)(ba)(i), and 9(2)(j)]

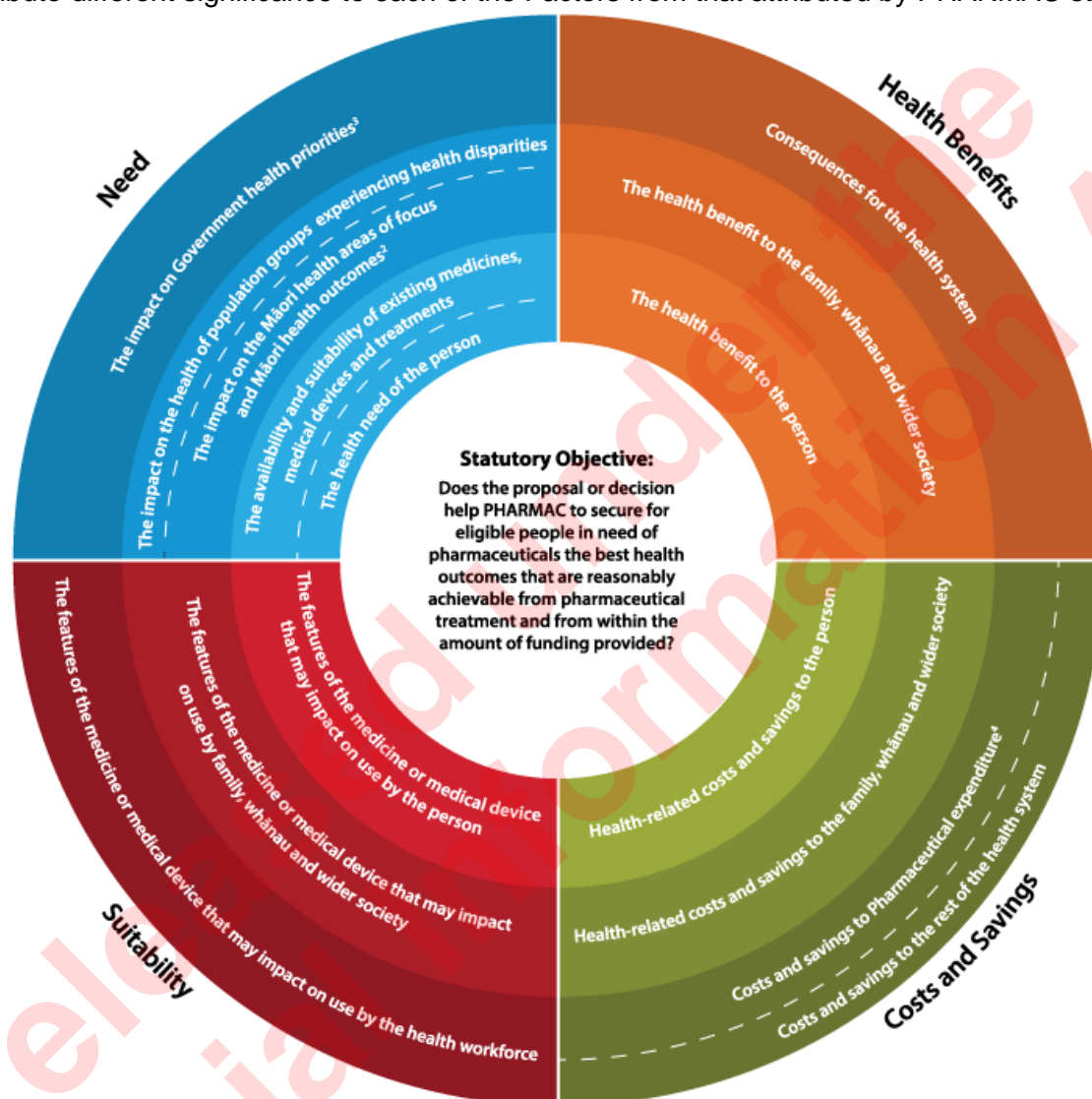
### *Costs and savings to pharmaceutical expenditure*

The net cost of pharmaceutical to CPB would be [Withheld under section 9(2)(b)(ii), 9(2)(ba)(i), and 9(2)(j)]



## Factors for Consideration

This paper sets out PHARMAC staff's assessment of the proposal using the Factors for Consideration in the [Operating Policies and Procedures](#). Some Factors may be more or less relevant (or may not be relevant at all) depending on the type and nature of the decision being made and, therefore, judgement is always required. The Decision Maker is not bound to accept PHARMAC staff's assessment of the proposal under the Factors for Consideration and may attribute different significance to each of the Factors from that attributed by PHARMAC staff.



### Footnotes

<sup>1</sup> The person receiving the medicine or medical device must be an eligible person, as set out in the [Health and Disability Services Eligibility Direction 2011](#) under Section 32 of the [New Zealand Public Health and Disability Services Act 2000](#).

<sup>2</sup> The current Māori health areas of focus are set out in PHARMAC's [Te Whaioranga Strategy](#).

<sup>3</sup> Government health priorities are currently communicated to PHARMAC by the Minister of Health's [Letter of Expectations](#).

<sup>4</sup> Pharmaceutical expenditure includes the impact on the Combined Pharmaceutical Budget (CPB) and / or DHB hospital budgets (as appropriate).

<sup>5</sup> Please note PHARMAC's Factors for Consideration schematic currently does not explicitly refer to the health needs of family, whānau and wider society, but this Factor should be considered alongside those depicted in the schematic.

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

**To:** Director of Operations  
**From:** Manager Pharmaceutical Funding  
**Date:** September 2021

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### Procurement of additional stock of remdesivir for use in New Zealand

#### 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 direct Pharmac staff to extend the current agreement dated 31 August 2020 between Pharmac and Gilead Sciences, Australia & New Zealand via exchange of emails to include an additional **Withh** vials of remdesivir;

**resolve** to approve the Purchase Order ([15106](#)) provided in Appendix One for the supply of **Withh** vials of remdesivir;

**note** that the price for remdesivir has increased to \$586.78 NZD per vial from \$578.72 paid previously;

**note** that remdesivir is used in the treatment of patients hospitalised with COVID-19, it is anticipated that a portion of this stock would be used to treat patients from the current outbreak and the remaining stock would be held to treat eligible patients who may be hospitalised with COVID-19 in the future.;

**note** that the number of vials secured and the total impact to the CPB are confidential and they cannot be disclosed to the public;

**note** that the costs would be recovered from COVID-19 funds.



SUMMARY OF PHARMACEUTICAL						
Brand name		Verklury		Chemical name		Remdesivir
Therapeutic Group		Oncology agents and Immunosuppressants		Presentation		Inj 100 mg vial
Supplier		Gilead		Pharmaceutical type		Restriction change
MoH Restriction		Not yet classified		Application date		01-September-2022
Market data		YE 30 June 2022	YE 30 June 2023	YE 30 June 2024	YE 30 June 2025	YE 30 June 2026
Number of patients		167	0	0	0	0
Community Pharmaceutical Expenditure	Subsidy (gross)	Withheld	\$0	\$0	\$0	\$0
	Net cost of community pharmaceuticals	Withheld	\$0	\$0	\$0	\$0
	Net present value (NPV)	Withheld				
TOTAL – Combined Pharmaceutical Budget	Net cost to CPB	Withheld				
	Net present value	Withheld				
Other DHB costs	Net other costs to DHBs	\$0	\$0	\$0	\$0	\$0
	Net present value (NPV)	\$0				
TOTAL	Total cost to DHBs	Withheld	\$0	\$0	\$0	\$0
	Net present value (NPV)	Withheld				

Notes:

1. Number of patients affected = number of new patients in each financial year.
2. Subsidy (gross) = forecast of all spending on remdesivir at current subsidy.
3. Net cost to CPB = forecast of all spending on remdesivir at the agreed price. This would be recovered from COVID-19 funds.
4. Net other DHB costs = There are likely to be minimal additional administration costs associated with remdesivir use for treatment of COVID-19.
5. Total cost to DHBs = Net cost to the Schedule plus net cost to DHBs.
6. All costs are expressed ex manufacturer, excluding GST
7. NPV is calculated over 5 years using an annual discount rate of 8%
8. Calculations in [A1525229](#)

## EXECUTIVE SUMMARY

- Remdesivir is a novel antiviral agent that is used in the treatment of patients hospitalised with COVID-19
- In August 2020 Pharmac entered into an agreement with Gilead Sciences, Australia & New Zealand for the supply of [With] vials of remdesivir. The terms of this agreement allow additional stock to be ordered by mutual agreement.
- Based on the current August 2021 outbreak of COVID-19 in New Zealand and the possibility of future outbreaks it is recommended that this agreement be extended to include an additional [Withh] vials, sufficient to treat [Withh] patients.
- It is estimated that this proposal would have a cost of [Withheld under section] to the Combined Pharmaceuticals Budget. This expenditure would be recovered from COVID-19 funds.

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

The proposal involves a Schedule change that has an estimated Financial Impact (NPV) of less than \$10,000,000 and:

- will not result in the Pharmaceutical budget or its future funding path being exceeded;
- is not inconsistent with previous Board decisions; and
- is not considered contentious by Pharmac staff; and
- approves a stock purchase order.

## The Proposal

It is proposed to extend the [existing agreement dated 31 August 2020](#) between Gilead Sciences, Australia & New Zealand (Gilead) and Pharmac for the supply of remdesivir to include an additional **Withh** vials to be used for the treatment of patients hospitalised with COVID-19.

Remdesivir would continue to be supplied under the terms of the 31 August 2021 agreement, which is based on Pharmac's standard terms of listing and includes the following terms of supply:

- Stock is to be ordered by Onelink at the price specified in Annex One of the agreement
- Gilead has agreed to submit an application for Ministry of Health market approval as soon as reasonably practicable
- Remdesivir will be available subject to access criteria set by Pharmac.
- Stock is to be supplied to and held by Onelink for use by DHB Hospitals. Pharmac staff intend to investigate positioning some stock in the South Island, likely held at either CDHB or ProPharma.
- Pharmac and Gilead may agree in writing to extend this agreement to include additional orders as required.

The 31 August 2020 agreement includes a price for remdesivir of \$578.72 per vial. Recent communications from Gilead have noted that the price per vial of remdesivir is now \$390 USD and that Gilead has a fixed NZD/USD 2021 budget rate of \$0.665. This means that the price per vial of remdesivir will now be \$586.78 NZD. Acknowledgement and agreement of this updated price would be included in the exchange of emails to extend the agreement.

Remdesivir would not be listed on the Pharmaceutical Schedule and would continue to be held as emergency stock for use by DHB Hospitals as required.

Remdesivir is not Medsafe approved and would continue be supplied under Section 29 of the Medicines Act 198; however, Gilead has noted that is continuing to progress regulatory approval for remdesivir with Medsafe.

The **Withhel** vials of remdesivir stock would be dispatched from Ireland and supplied in English language packaging. Timeframes for delivery of the stock would be confirmed once a purchase order has been submitted. Gilead expects the full volume of stock would be available in New Zealand in less than three weeks.

Gilead is unable to confirm the expiry of the remdesivir stock until a purchase order is submitted and accepted; however, Gilead anticipates the stock will have an expiry of September 2023.

In accordance with clause 8 of the 31 August 2020 Agreement, Gilead has noted it is amenable for the agreement extension for **Withh** additional vials of remdesivir stock to be completed via email.

The [Australian Government's Criteria](#) for access to remdesivir from the National Medical Stockpile (31 July 2020) would continue to be used as inclusion and exclusion criteria for access to remdesivir the New Zealand, in line with recommendations from the Ad Hoc Remdesivir COVID-19 Advisory Group. Pharmac staff note that the evidence for the use of

remdesivir is still emerging and Pharmac staff intend to seek further clinical advice to determine if the access criteria should be updated to reflect any recent changes in the evidence. Remdesivir is currently included in the Middlemore Hospital guidelines for the treatment of COVID-19, which are being adapted for national use.

It is estimated that this proposal would have a one-off cost of [Withheld] to the Combined Pharmaceuticals Budget in the year ending 30 June 2022.

## Background

Remdesivir is a novel antiviral agent that is used in the treatment of patients hospitalised with COVID-19

On 31 August 2020, as a result of New Zealand's 2020 outbreak of COVID-19 Pharmac entered into an agreement with Gilead for the supply of [With] vials of remdesivir as it had recently been identified as a possible treatment for patients hospitalised with COVID-19.

Remdesivir continues to be used for the treatment of COVID-19 and has recently received provisional approval from the Therapeutic Goods Administration (TGA) in Australia for this indication.

As a result of the current outbreak of COVID-19 in New Zealand and the possibility of future outbreaks, Pharmac staff recommend that additional stock of remdesivir should be secured. As a result of the considerable uncertainty regarding the length and spread of the current COVID-19 outbreak and the possibility of future outbreaks, it is considered that [With] vials would be an appropriate volume of remdesivir to secure initially. It is important to have stock on hand to initiate treatment promptly. The current agreement allows for further supplies to be secured by mutual agreement.

In reaching this figure, Pharmac staff have considered the possibility the current outbreak continues for longer than anticipated. In addition, the supplier has noted increasing global demand for remdesivir as countries increasingly lessen COVID-19 restrictions and open their international borders. Securing remdesivir stock in anticipation of demand will help to mitigate the risk of future stock shortages or unavailability for the New Zealand market.

[With] vials of remdesivir would allow for the treatment of approximately [With] patients. It is anticipated that a portion of this stock would be used to treat patients as a result of the current outbreak, with the remaining stock being retained for future COVID-19. The current outbreak has demonstrated that the increased transmissibility of the delta variant can result in a large number of active cases. A higher hospitalisation rate has also been observed, although it is not known if this is due the delta variant causing more severe disease or that the communities affected have high rates of comorbidities which can lead to more severe COVID-19 cases.

Pharmac staff note that the 31 August 2020 agreement would remain in place and further remdesivir stock could be secured in future if required.

### *Clinical Advice*

Following the signing of the 31 August 2020 agreement Pharmac staff sought clinical advice from a number of groups:

In September 2020 advice was sought from PTAC members via email regarding the priority of different groups for access to remdesivir. The members considered that the quality of the available evidence for the use of remdesivir for the treatment of COVID-19 appeared to be low and did not consider they were well placed to provide the required advice to Pharmac as it appeared the decision to fund remdesivir had already been made.

In September 2020 advice was also sought from members of the Anti-Infectives Subcommittee of PTAC via email regarding the priority of different groups for access to remdesivir. The members were generally supportive of the process being followed in Australia for the treatment of patients with remdesivir and considered that remdesivir is likely to be most effective in patients requiring supplemental oxygen prior to ventilation being required.

Advice was also sought from members of the Critical Care Advisory Group in September 2020 via email regarding the priority of different groups for access to remdesivir. The members noted the concerns about the quality of the evidence available for the effectiveness of remdesivir; However, they were generally supportive of the process being followed in Australia for the treatment of patients with remdesivir and considered that remdesivir is likely to be most effective in patients requiring supplemental oxygen prior to ventilation being required.

To gain further advice on the priority of different groups for access to remdesivir an Ad Hoc Remdesivir COVID-19 Advisory Group was established by Pharmac. On 24 September 2020 Advice was sought from the Ad Hoc Remdesivir COVID-19 Advisory Group. The Group recommended the [Australian Government's Criteria](#) for access to remdesivir from the National Medical Stockpile (31 July 2020) be used as inclusion and exclusion criteria for the New Zealand stock of remdesivir, with an added criterion that treating physicians consider that such escalation of care is appropriate. The Group stressed that this recommendation was made in the context of prioritising the supply of remdesivir that had already been secured and reiterated the current evidence for benefits of remdesivir was limited.

The Group noted that Māori and Pacific populations are potentially more vulnerable to the impacts of COVID-19, especially due to higher rates of comorbidities in these populations compared with the non-Māori/non-Pacific population. Members considered that this would be a case for case for assigning higher priority for availability for the Māori and Pacific populations.

## Implementation

We intend to communicate this directly to the following people within each DHB:

- DHB Chief Pharmacists
- Pharmac's Expert Clinical advisors
- MoH COVID-19 Therapeutics TAG

It is proposed to make the eligibility criteria visible on the Pharmac website, along with details to advise DHBs how to obtain stock. Feedback from some DHBs has indicated this would be helpful to guide staff. We intend to add these details to the website after a letter has been sent to the key stakeholders listed above.

## Factors for Consideration

This paper sets out PHARMAC staff's assessment of the proposal using the Factors for Consideration in the [Operating Policies and Procedures](#). Some Factors may be more or less relevant (or may not be relevant at all) depending on the type and nature of the decision being made and, therefore, judgement is always required. The decision maker is not bound to accept PHARMAC staff's assessment of the proposal under the Factors for Consideration and may attribute different significance to each of the Factors from that attributed by PHARMAC staff.



### Footnotes

<sup>1</sup> The person receiving the medicine or medical device must be an eligible person, as set out in the [Health and Disability Services Eligibility Direction 2011](#) under Section 32 of the [New Zealand Public Health and Disability Services Act 2000](#).

<sup>2</sup> The current Māori health areas of focus are set out in PHARMAC's [Te Whaioranga Strategy](#).

<sup>3</sup> Government health priorities are currently communicated to PHARMAC by the Minister of Health's [Letter of Expectations](#).

<sup>4</sup> Pharmaceutical expenditure includes the impact on the Combined Pharmaceutical Budget (CPB) and / or DHB hospital budgets (as appropriate).

<sup>5</sup> Please note PHARMAC's Factors for Consideration schematic currently does not explicitly refer to the health needs of family, whānau and wider society, but this factor should be considered alongside those depicted in the schematic.



## Factors for Consideration



### Health need

#### *Disease/illness*

Coronavirus disease 2019 (COVID-19) is an infectious acute respiratory disease caused by a novel coronavirus. The clinical presentation is generally that of a respiratory infection with a symptom severity ranging from a mild common cold-like illness to a severe viral pneumonia leading to acute respiratory distress syndrome that is potentially fatal. Severe viral pneumonia patients are treated in intensive care setting and can be considered for oxygenation and ventilation.

#### *Availability and suitability of existing treatments*

A number of other existing pharmaceuticals are used as treatments for severe COVID-19 patients; however, there is limited or no evidence to support their use. Remdesivir has recently received provisional approval from the TGA for the treatment of COVID-19. In addition tocilizumab, which can be used in the treatment of COVID-19 is currently experiencing supply issues.

The availability of other treatments of COVID-19 would be unaffected by this proposal.

#### *Impact on Māori health areas of focus and health outcomes*

COVID-19 was not identified as a Māori health areas of focus as a result of the Hauora Arotahi community consultation; however; Māori are more likely than other ethnic groups in New Zealand to be hospitalised as a result of COVID-19

#### *Any other populations experiencing health disparities*

Of all the ethnic groups in New Zealand Pacific Peoples are the most likely to be hospitalised as a result of COVID-19.

#### *Is the disease/illness a Government health priority*

COVID-19 is not one of the Government health priorities; however, the Government has allocated significant funds and resources to manage the consequences and to respond to the COVID-19 pandemic in New Zealand.



### Health Benefit

#### *Health benefit to others*

Health benefit to others would be unchanged by this proposal as remdesivir would remain available for patients who need it.

#### *Consequences for the health system*

Consequences for the health system would remain unchanged by this proposal as remdesivir would remain available for patients who need it.



## Suitability

The [Withheld] vials of remdesivir would be provided in the following form and strength:

- 100 mg powder for injection. A vial contains 100 mg of remdesivir. After reconstitution, each vial contains 5 mg/ml of remdesivir solution.

The recommended dosage of remdesivir in patients 12 years of age and older and weighing at least 40 kg is:

Day 1 - a single loading dose of remdesivir 200 mg given by intravenous infusion

Day 2 onwards - 100 mg given once-daily by intravenous infusion

The total duration of treatment should be at least 5 days and not more than 10 days. This would equate to between 6 and 12 vials per patient – such that [Withheld] vials would be sufficient to treat approximately [Withheld] patients in New Zealand.

Remdesivir does not have Medsafe approval in New Zealand. It has been approved under emergency authorisations or provisional consent in other jurisdictions. Remdesivir has been granted emergency authorisation in Australia.

Although granting provisional consent would be the preferred regulatory pathway for the emergency supply of remdesivir, Gilead has advised that it is continuing to consider its approach to regulatory approval in New Zealand internally and is working with Medsafe.

Medsafe has previously advised that supply under Section 29 would be acceptable in this circumstance. The existing stock guarantee agreement with Gilead requires that Gilead makes the necessary regulatory submission as soon as practicable, and Gilead has advised that it is discussing this with Medsafe.



## Costs and Savings

### *Cost and savings to Pharmaceutical expenditure*

The 31 August 2020 agreement for the supply of remdesivir included a price of \$586.78 per vial this would result in a total cost of [Withheld] for the supply of [Withheld] vials of remdesivir. These costs for remdesivir would be met from the COVID-19 funds.



## Cost-Effectiveness

The cost-effectiveness of remdesivir has not been formally assessed.

## MINUTE OF THE DIRECTOR OF OPERATIONS DECISION UNDER DELEGATED AUTHORITY

September 2021

The Director of Operations, exercising the authority delegated by the Chief Executive under the Financial Delegations Policy has made the following decision to:

**resolve** to direct Pharmac staff to extend the current agreement dated 31 August 2020 between Pharmac and Gilead Sciences, Australia & New Zealand via exchange of emails to include an additional **Withh** vials of remdesivir;

**resolve** to approve the Purchase Order ([15106](#)) provided in Appendix One for the supply of **Withh** vials of remdesivir;

**note** that the price for remdesivir has increased to \$586.78 NZD per vial from \$578.72 paid previously;

**note** that remdesivir is used in the treatment of patients hospitalised with COVID-19, it is anticipated that a portion of this stock would be used to treat patients from the current outbreak and the remaining stock would be held to treat eligible patients who may be hospitalised with COVID-19 in the future.;

**note** that the number of vials secured and the total impact to the CPB are confidential and they cannot be disclosed to the public;

**note** that the costs would be recovered from COVID-19 funds.