From:Michael JohnsonSent:Wednesday, 2 February 2022 1:10 pmTo:Melody WillisSubject:FW: COVID treatmentsAttachments:4583444_14104 - Therapeutics.DOC

Michael Johnson | Director of Strategic Initiatives

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From: Hannah Lobb [TSY] <<u>Withheld under section 9(2)(a)</u> > Sent: Friday, 12 November 2021 12:46 pm To: Michael Johnson <<u>Withheld under section 9(2)(a)</u> > Subject: RE: COVID treatments

Hi Michael

Thank you for your email and for the chat just now. Here are the financial recs that we are expecting to go through the CRRF Cabinet paper next week. It hasn't yet been lodged and could potentially still change, please treat sensitively for now until the decisions are confirmed.

As mentioned, we went with the 140/160 split and have included the rec about Pharmac's existing funding. Let me know if you have any thoughts or concerns.

Thanks for your help! Hannah

From: Michael Johnson <Withheld under section 9(2)(a) Sent: Friday, 12 November 2021 12:17 pm To: Hannah Lobb [TSY] <Withheld under section 9(2)(a) > Subject: FW: COVID treatments

Hi Hannah

Any update on progress?

Cheers

Michael.

From: Michael Johnson Sent: Thursday, 11 November 2021 7:45 am To: Hannah Lobb [TSY] <<u>Withheld under section 9(2)(a)</u> >; Jess Hewat [TSY] <<u>Withheld under section 9(2)</u> Subject: COVID treatments

Hi Hannah

Further to our discussion on Monday our team have been working through what the split over the two years needs to be for COVID-19 treatment costs. It remains difficult to predict given current information available. However we could work with proposed split of \$100 million additional in 2021/22 and \$200 million in 2022/23. Noting we would have total of Withheld for this current year (if Ministers approve the use of existing \$25 from CRF for COVID treatments). So far we have already signed up for expected costs of around Withheld.

We may however need to bring some funding forward to 2021/22 if we need to pay upfront for some products. This is all a bit unknown at this point. Do you think that would be an option? Alternatively would it be better to get more funding in 2021/22 and then carry over to 2022/23 if not fully utilised?

Draw down timing is tricky, we expect some products to be pay on invoice following delivery (the ones we have agreed to date), others may require upfront payment. We will likely need funding this side of Christmas in case we need to pay for Ronapreve before end of year. Next invoices would likely be February. We would likely draw down the funding across several draw down windows but given uncertainty likely better that we front load. We estimate we would need Withheld to get us through from December to end of Feb 2022. We met with Ferg and Kevin last week and mentioned CRF funds and need to sort mechanics of funding. Did not land but they know got to sort. Also mechanics of funding depending on distribution arrangements etc and we are working with MoH on implementation.

In terms of assurance for Ministers, as you are aware we have established a COVID expert advisory group who are assessing each treatment and considering the evidence available. We are taking a risk based approach similar to vaccine arrangements and may procure treatments that possibly don't work or have wastage. Also much of this is dependent on Medsafe approval of the treatment. Happy to provide more context if needed.

Is it possible to see a draft of the paper and we can add any comment you may require.

Happy to discuss further.

Thanks

Michael.

Michael Johnson | Director of Strategic Initiatives

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From:	Michael Johnson < Withheld under section 9(2)(a) >		
Sent:	Tuesday, 2 November 2021 4:45 pm		
To:	Hannah Lobb [TSY]; Kevin Davies		
Cc:	Withheld under section 9(2)(a) ; Jess Hewat [TSY]; Rachel Read		
Subject:	RE: COVID therapeutics funding		
Attachments:	2021-11 Estimated COVID-19 treatment costs for budget request.docx		

Hi Hannah

Please find attached information as requested.

Happy to discuss or answer any further questions or provide further detail as required

Kind regards

Michael

Michael Johnson | Director of Strategic Initiatives

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From: Hannah Lobb [TSY] < Withheld under section 9(2)(a) >
Sent: Monday, 1 November 2021 1:37 pm
To: Michael Johnson < Withheld under section 9(2)(a) >; Kevin Davies < Withheld under section 9(2) >
Cc: Withheld under section 9(2)(a) ; Jess Hewat [TSY] < Withheld under section 9(2) >; Rachel Read < Withheld under section 9(2)
Subject: RE: COVID therapeutics funding

Hi Michael

Thanks for setting up those meetings. I just got some revised timeframes for the omnibus process and we need to have our advice finalised on Friday, so at a bare minimum will need to know the **amount** of funding being sought for therapeutics and a description for what it will cover by <u>COP tomorrow</u>.

Do you think this will be possible? **Kevin**, if this request is going ahead, could someone in your team also enter an initiative on CFISnet so that we have something to respond to? I don't think you need to fill out a whole template but we will definitely need the funding sought and initiative description.

Relatedly, if the funding is going into contingency the appropriation could be set up later in a drawdown paper, but it's probably worth getting a view on what is needed at your meeting on Thursday.

Happy to discuss given the tight timeframes.

Best Hannah

Pharmac funding request for securing new COVID-19 treatments for 2021 and out years

Note: confidential pricing informed the estimated costs discussed in this memo

Pharmac is engaging with suppliers about emerging COVID-19 treatments and products repurposed for COVID-19, as well as some investigational products still in clinical trials. We are assessing treatments and supply as soon as information is available, prior to Medsafe approval

We aim to secure a portfolio of COVID-19 treatments (currently working on eight products in total) that would cover prevention of disease and treat all severities of illness in hospitalised and non-hospitalised patient. Preventative treatments would most likely be targeted to those unable to be vaccinated or with low vaccination response who have been exposed, and those who have comorbidities that put them at high risk from COVID-19.

Funding mechanism

The CPB is not a suitable mechanism for rapidly purchasing COVID-19 treatments, nor is there headroom in the budget for this purpose.

The Government has allocated \$175 million since 2019/20 in separate funds for medicines costs related to COVID-19, including supply chain costs, assuring supply and purchasing of alternative products Unspent COVID-19 funds have been reallocated or carried forward to future years, in discussion with Treasury and the Ministry of Health. For 2021/22 about Withheld of these funds remain available.¹ At the time of the initial Cabinet decision establishing this funding source, it was not foreseen that that these funds would be used to purchase new treatments for COVID-19.

Cabinet's approval is sought to repurpose some of the remaining funds to purchase new COVID-19 treatments. We also seek additional funding for new COVID-19 treatments to secure advance purchase arrangements for a range of treatments required in 2021/22 and 2022/23.

Estimated expenditure

There is significant uncertainty with the estimated costs for securing COVID 19 treatments. For most treatments secured to date, pricing is highly confidential and Pharmac has signed confidentiality agreements. Costs are not to be shared outside of this request

2021/22

We estimate that Pharmac would need up to \$141 million in addition to our current COVID-19 funding in the current financial year if we were successful in securing the eight COVID-19 treatments currently being assessed. This is likely an overestimate as it assumes that all eight treatments are available over the next 6 months and gain Medsafe regulatory approval We expect to use up to \$25 million of the available Withheld we from the already allocated COVID-19 supply chain funding to support this work, subject to agreement by Cabinet that we can use funding already allocated for medicines costs related to COVID-19 for COVID-19 treatments



¹ It is unknown at this point how much funding from this allocation will be needed for supply chain management purposes for the remainder of 2021/22. We do expect these costs to continue and predict some new investments for managing COVID-related impacts may be required (for example treatments of other infections that may increase post the border opening).

2022/23

To secure ongoing supply of these eight treatments for 2022/23, we estimate Pharmac would need up to \$341 million. We have not included costs for other COVID-19 treatments that may also be developed and become available in the future.

Breakdown of estimated costs for COVID-19 treatments (contains confidential pricing)

Estimated expenditure for securing COVID-19 treatments for 2021 and 2022/23				
Financial year	2021/2022	2022/2023		
Total estimated cost	\$ 166,800,000	\$ 341,000,000		
Confirmed treatments (4 products) at 1 Nov 2021	Withheld under	Withheld under		
All treatments being considered (including confi	rmed)			
Funded treatments (plus baricitinib as alternative)	Withheld under	Withheld under		
Oral antiviral treatments	Withheld under	Withheld under		
Monoclonal antibody treatments	Withheld under	Withheld under		
Use of already allocated COVID-19 funding	(\$ 25,000,000)			
Funding required ²	\$ 141,000,000	\$ 341,000,000		

A more detailed breakdown of these costs is available if required. Estimated costs are based on the known price for four products secured to date (about with of costs) and these have informed an estimate cost for other products that are being pursued with a likely similar place in therapy. The quantity of each product we may be able to secure is also unknown Global manufacturing capacity is under strain and most countries that have contracted for supply have typically secured relatively small quantities of product over the coming quarters. We are unlikely to secure the quantity we would prefer for each individual product and therefore aim to secure a range of treatments.

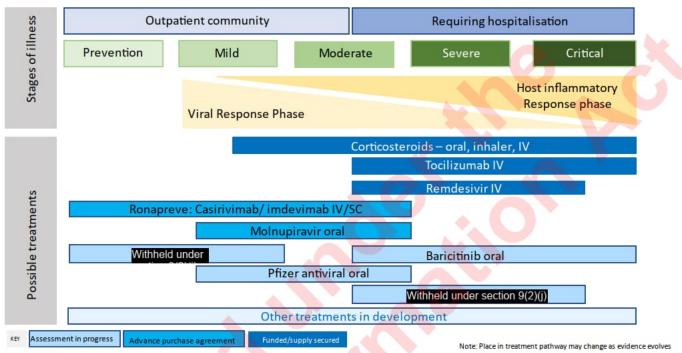
Progress to date

Discussion and negotiations are underway with suppliers of eight different potential products.

Two pharmaceuticals have already been funded explicitly for the treatment of COVID-19 in New Zealand, tocilizumab for the treatment of moderate-severe COVID-19 in hospitalised patients and remdesivir for the treatment of moderate to severe COVID-19. The cost of these treatments is about With for 2021/22 and has already been attributed to the COVID-19 supply chain funding.

² The funding required excludes the \$25 million we propose to use from existing COVID-19 funds for the purpose of funding new COVID-19 treatments and excludes the costs of already funded treatments tocilizumab and remdesivir

Figure 1: An overview of COVID 19 treatments being considered and their potential place in treatment pathway for patients with COVID-19.



Overview of COVID-19 treatments and place in treatment pathway

We have recently announced publicly that we have secured advanced purchased agreements (APA) for two of the eight treatments under assessment

- In October 2021 Pharmac committed to the purchase of 60,000 treatment courses of molnupiravir conditional on Medsafe approval. Molnupiravir is an oral antiviral treatment and is the first treatment option that has been secured by Pharmac for mild to moderate COVID-19 in the community. The earliest molnupiravir could be expected to be available in New Zealand is Withheld under section. Payment would be required within 30 days of invoice following delivery so expenditure in 2021/22 is only of portion of the confirmed purchase.
- Also in October 2021 Pharmac committed to the purchase of 5300 treatment courses of <u>casirivimab and imdevimab</u> (brand name Ronapreve). We expect this treatment would be complementary to treatments already funded for COVID-19 in New Zealand and could provide an additional treatment option for patients hospitalised with COVID 19 It may also provide an additional option for patients with mild COVID 19 requiring treatment in the community.

The table below provides more detail:

		Pharmaceutical	Supplier	Medsafe approval status	Use in COVID-19	Current funding status and availability in NZ (at 1 November 2021)
Already funded	1.	Tocilizumab (intravenous infusion)	Roche	Approved in NZ for rheumatoid arthritis. COVID-19 indication to be submitted to Medsafe	Moderate to severe cases	Available and funded for COVID-19
	2.	Remdesivir (intravenous)	Gilead	Not approved in NZ	Moderate to severe cases	Available and funded for COVID-19
APAs secured	1.	Casirivimab/ imdevimab (Regen-COV/ Ronapreve) (subcutaneous injection and IV infusion)	Roche	Application submitted to Medsafe TGA has provisionally approved in Australia	Prevention and treatment of mild, exposed, or at-risk patients	APA signed. Stock ordered and expect supply before end of 2021 – as above
APA	2.	Molnupiravir (oral)	MSD	Supplier has not yet submitted an application to Medsafe	Likely to be useful for mild to moderate cases	APA signed. Stock ordered and expect supply Withheld – as above
In negotiation	3.	Baricitinib (oral tablets)	Eli Lilly	Not approved in NZ Registered in Australia for rheumatoid arthritis	Moderate to severe cases (alternative to tocilizumab)	Pharmac negotiations well advanced Stock could be available in November 2021
	4.	Antiviral (investigational product) (oral)	Pfizer	Not approved in NZ	To be confirmed	Pharmac discussing with supplier
	5.	Withheld Withheld	With	Withheld under Withheld Withheld under section	Withheld under Withheld under Withhe	Withheld under Withheld
	6.	Withheld under Withheld	Withheld	Withheld under section Withheld under Withheld under Withheld under	Withheld under Withheld under Withheld under Withheld under Withheld under Withheld under	Withheld under Withheld
	7.	Withheld Withheld	Withheld	Withheld under V Withheld under section Withheld under section Withheld under section Withheld under section	Withheld under Withheld Withheld	Withheld under Withheld
	8.	Withheld Withheld Withheld	Withheld	Withheld under V Withheld under Withheld under section Withheld	Withheld under Withheld under Withheld under Withheld under Withheld under Withheld under Withheld under Withheld under	Withheld under Withheld

From:	Michael Johnson < Withheld under section 9(2)(a) >
Sent:	Monday, 1 November 2021 3:49 pm
To:	Hannah Lobb [TSY]; Kevin Davies
Cc:	Withheld under section 9(2)(a) ; Jess Hewat [TSY]; Rachel Read
Subject:	RE: COVID therapeutics funding

Hi Hannah

Yes we will have funding numbers with you by close of play tomorrow.

In terms of detail for the Cabinet papers, the two weekly briefings that we provided Vaccine Ministers on 21 and 28 October provide the context or detail for the Cabinet paper. Jess gets these papers and so you should be able to get from her. Otherwise I can send thru

Cheers

Michael.

Michael Johnson | Director of Strategic Initiatives

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From: Hannah Lobb [TSY] < Withheld under section 9(2)(a) >

Sent: Monday, 1 November 2021 1:37 pm

To: Michael Johnson < Withheld under section 9(2)(a) >; Kevin Davies < Withheld under section 9(2)

Cc: Withheld under section 9(2)(a) ; Jess Hewat [TSY] < Withheld under section 9(2) >; Rachel Read < Withheld under section 9(2)

Subject: RE: COVID therapeutics funding

Hi Michael

Thanks for setting up those meetings. I just got some revised timeframes for the omnibus process and we need to have our advice finalised on Friday, so at a bare minimum will need to know the **amount** of funding being sought for therapeutics and a description for what it will cover by COP tomorrow.

Do you think this will be possible? **Kevin**, if this request is going ahead, could someone in your team also enter an initiative on CFISnet so that we have something to respond to? I don't think you need to fill out a whole template but we will definitely need the funding sought and initiative description.

Relatedly, if the funding is going into contingency the appropriation could be set up later in a drawdown paper, but it's probably worth getting a view on what is needed at your meeting on Thursday.

Happy to discuss given the tight timeframes.

Best Hannah

From: Michael Johnson < Withheld under section 9(2)(a)

Sent: Wednesday, 27 October 2021 2:45 pm

To: Hannah Lobb [TSY] <<u>Withheld under section 9(2)(a)</u> >; Kevin Davies <<u>Withheld under section 9(2)</u> >; Rachel Read <<u>Withheld under section 9(2)</u> >; Allison Bennett <<u>Withheld under section 9(2)(a)</u> >; C: Jess Hewat [TSY] <<u>Withheld under section 9(2)</u> >; KARRAN, Glenys (CPCD) <<u>Withheld under section 9(2)</u> >; Sarah Fitt <<u>Withheld under section 9(2)</u> >; Subject: RE: COVID therapeutics funding

Subject: RE: COVID therapeutics in

Thanks Hannah.

From our end we should have info hopefully early next week.

We have set up a meet with Kevin and Ferg for next Thursday to discuss mechanics of funding.

We shall set up meet with MOH/MFAT to discuss Pacific

Cheers

Michael.

Michael Johnson | Director of Strategic Initiatives

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From: Hannah Lobb [TSY] < Withheld under section 9(2)(a) >

Sent: Wednesday, 27 October 2021 12:26 pm

To: Michael Johnson < Withheld under section 9(2)(a) >; Kevin Davies < Withheld under section 9(2) >; Rachel Read < Withheld under section 9(2) >; Allison Bennett < Withheld under section 9(2)(a) > Cc: Jess Hewat [TSY] < Withheld under section 9(2) >; KARRAN, Glenys (CPCD) < Withheld under section 9(2) > Subject: COVID therapeutics funding

Kia ora koutou

To return to the issue of covid therapeutics funding, which seems to have got a bit lost recently, I think we need to sort out an alternative approach to make sure that there is funding available when it is needed.

We think that the following approach would make the most sense but very keen for thoughts from MoH and Pharmac as to whether this would work:

- 1. MoH to submit an initiative for therapeutics through DPMC/Tsy's omnibus covid funding process. This initiative would seek Cabinet's agreement to add additional funding for covid therapeutics to the vaccine contingency and to expand the scope of Pharmac's current covid funding to cover therapeutics.
- 2. Use the existing health report that Therese has drafted as a vehicle to seek Vaccine Minister's agreement to draw down from the vaccine contingency to Pharmac. This report would need to go to Vaccine Ministers after the omnibus paper is considered on 15 Nov.

If this sounds sensible to MoH and Pharmac, I think the next steps are:

Michael is working on the following questions that will need to be answered ahead of seeking funding through the omnibus process (ideally we would have this information ready by the end of this week or early next week).

What is the appropriate amount of funding for therapeutics over the next 18 months (rest of 21/22 and 22/23)?

Why is this the case and how can Ministers be sure that the funding is providing value for money?

Following this funding being provided, at what point should covid therapeutics be purchased from within the CPB?

How will the funding work for Pharmac? I.e. will you need all of the funding appropriated/drawn down in one go, or will the funding be drawn down at different times as was the case with vaccines.

Pharmac/MoH/MFAT need to discuss whether therapeutics should also cover the Pacific and what the implications of this might be. E.g. if there is limited supply and outbreaks in various countries, what would happen? Will also be important to know whether this will have an impact on the amount of funding required.

Kevin is finding out whether Pharmac will need a new appropriation if purchasing for the Pacific.

MoH, the health report will need to go to Vaccine Ministers following the omnibus paper being considered by Cabinet on 15 November. This report will need new drawdown recommendations which I am happy to help with and will also need to include information about the proposed approach for the Pacific.

Give me a call if it would be useful to discuss any of this.

Ngā mihi, Hannah



Hannah Lobb (she/her) | Analyst, Health & ACC | Te Tai Ōhanga - The Treasury

Tel: Wit With With | Email/IM: Withheld under section 9(2)(a) Visit us online at https://treasury.govt.nz/ and follow us on Twitter, LinkedIn and Instagram

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From:	Michael Johnson < Withheld under section 9(2)(a) >
Sent:	Tuesday, 26 October 2021 3:51 pm
To:	Hannah Lobb [TSY]
Cc:	Jess Hewat [TSY]; Niki Lomax [TSY]
Subject:	RE: COVID Relief Fund

Thanks Hannah. Very helpful and yes contacts for folks at MFAT and MoH Global Health would be great so that we can engage with them. We shall get cracking on pulling together info.

Hear from you in due course.

Cheers

Michael.

Michael Johnson | Director of Strategic Initiatives

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 From: Hannah Lobb [TSY]
 Withheld under section 9(2)(a)

 Sent: Tuesday, 26 October 2021 2:51 pm

 To: Michael Johnson
 Withheld under section 9(2)(a)

 Cc: Jess Hewat [TSY]
 Withheld under section 9(2)

 Subject: RE: COVID Relief Fund
 >; Niki Lomax [TSY]

Kia ora Michael

I followed up with our Office on the therapeutics paper this morning and there are two options:

Combine the therapeutics paper with the immunisation paper planned for November. This paper is seeking agreement to a combined immunisation approach for 2022 (flu, covid booster, MMR, HPV etc) so is already quite big, but it may be possible to seek agreement for new funding for therapeutics through this paper.

There is an omnibus paper for new funding from the CRRF also going to Cabinet in November. It may be possible to either seek the funding for therapeutics through this process, or to seek agreement to top-up the contingency through this process subject to joint Ministers agreeing a therapeutics strategy before drawing any funding down.

In my mind, the outstanding questions/issues that need to be covered off in one of these processes are:

- 1. What is the appropriate amount of funding for therapeutics over the next 18 months (rest of 21/22 and 22/23)? Why is this the case and how can Ministers be sure that the funding is providing value for money? Following this funding being provided, at what point should covid therapeutics be purchased from within the CPB?
- 2. How will the funding work for Pharmac? I.e. will you need all of the funding appropriated/drawn down in one go, or will there be different stages in the purchasing approach and funding drawn down at different times (as was the case with vaccines).
- 3. Is it appropriate for Pharmac to be purchasing therapeutics to cover the Pacific as well as New Zealand? Who is responsible for making allocation decisions if there is limited supply? Do we need to establish a new appropriation if purchasing to cover the Pacific as well? (note that these questions will need to be considered by MoH, Pharmac and MFAT together)
- 4. We also need to seek Cabinet's agreement to use Pharmac's existing funding for new therapeutics, but there's nothing else to do on this right now.

Do you think you could start preparing some information to support points 1-3 (i.e. the narrative we discussed at the meeting last week) and then I will get back to you on the best avenue to seek the new funding through? I can also connect you with MFAT and Global Health at MOH on point 3 if that would be helpful?

Happy to discuss.

Thanks Hannah

From: Niki Lomax [TSY] < Withheld under section 9(2) > Sent: Tuesday, 26 October 2021 12:21 pm To: Hannah Lobb [TSY] < Withheld under section 9(2)(a) > Subject: FW: COVID Relief Fund

Kia ora Hannah, could you update Michael on this? Niki

Niki Lomax | Health & ACC | Te Tai Öhanga – The Treasury Waea tõtika: Wit With With | Waea pükoro: Wit W With With

From: Michael Johnson < Withheld under section 9(2)(a) Sent: Tuesday, 26 October 2021 12:19 pm To: Niki Lomax [TSY] < Withheld under section 9(2) Subject: FW: COVID Relief Fund

Can you help?

MJ

From: Michael Johnson Sent: Tuesday, 26 October 2021 12:16 pm To: Jess Hewat [TSY] < Withheld under section 9(2) Subject: COVID Relief Fund

Hi Jess

Sarah informs me that a paper went to COVID Imms meeting on Friday about next proposed drawdown for the COVID contingency fund for vaccines that directed officials to develop a Cabinet paper for November. As previously discussed can we weave in the funding for COVID therapeutics to that same paper?

Cheers

Michael.

Michael Johnson | Director of Strategic Initiatives

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