133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T+64 4 496 2000

23 May 2022

Harold

By email: fyi-request-17035-e25f68c1@requests.fyi.org.nz
Ref: H202204655

Tēnā koe Harold

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 28 March 2022 for:

> *"For the two advisory groups:*
> *1) COVID-19 Testing Technical Advisory Group*
> *2) COVID-19 Therapeutics Technical Advisory Group*
> *I would like to request copies of*
> *1) All meeting minutes*
> *2) All reports or advice they have produced and submitted to any minister dated since 25 Jan 2022."*

Regarding the first part of your request, the minutes for the COVID-19 Testing Technical Advisory Group and the COVID-19 Therapeutics Technical Advisory Group from 25 January 2022 to the date of your request are attached and are outlined in the table in Appendix 1. Where information has been withheld in part, this is noted in the documents themselves. Where information has been withheld under section 9, I have considered the public interest but do not consider it outweighs the need to withhold the information at this time.

Regarding the second part of your request, neither advisory group produces or submits reports or advice to any Minister, therefore this part of your request is refused under section 18(e) on the grounds that the information requested does not exist.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

Gill Hall
Group Manager, Science, Surveillance & Insights
COVID-19 Health System Response

Appendix 1: Documents for release

#	Date	Title	Decision on release
1	11 March 2022	COVID-19 Testing Technical Advisory Group Minutes	Withheld in full under section 9(2)(f)(iv) to maintain the constitutional conventions that protect the confidentiality of advice tendered by officials.
2	23 March 2022	COVID-19 Testing Technical Advisory Group Minutes	Some information withheld under the following sections of the Act: • section 9(2)(f)(iv); and • section 9(2)(k) to prevent the disclosure or use of official information for improper gain or advantage.
3	28 January 2022	COVID-19 Therapeutics Technical Advisory Group Minutes	Some information withheld under section 9(2)(k).
4	11 February 2022	COVID-19 Therapeutics Technical Advisory Group Minutes	
5	25 February 2022	COVID-19 Therapeutics Technical Advisory Group Minutes	
6	11 March 2022	COVID-19 Therapeutics Technical Advisory Group Minutes	Some information withheld under the following sections of the Act: • section 9(2)(b)(ii) to protect information where the making available of the information would unreasonably prejudice the commercial position of the person who supplied the information; and • section 9(2)(k).
7	25 March 2022	COVID-19 Therapeutics Technical Advisory Group Minutes	

Document 2

MINUTES: COVID-19 Testing Technical Advisory Group

Date:	23 March 2022
Time:	12:30pm to 1:30pm
Location:	s9(2)(k) [redacted]
Chair:	Kirsten Beynon
Members:	Maia Brewerton, Patricia Priest, Susan Morpeth, Tim Blackmore, David Murdoch
Ministry of Health Attendees:	Ian Town, Mark Ayson, Christian Marchello
Guests:	
Apologies:	Pisila Fanolua

1.0	**Welcome and Previous Minutes** Kirsten Beynon welcomed all Members and Attendees in her capacity as Chair of the COVID-19 Testing Technical Advisory Group (CT TAG). Minutes of the last meeting (11 March 2022) were accepted.
2.0	**Update on Open Actions** Actions 4 and 6 are currently in progress.
3.0	**Testing Strategy Update** This is in progress. Surveillance papers have been sent to members. Feedback from COVID-19 Technical Advisory Group to be shared with members for oversight.
4.0	**Antibody and Immunity testing** In response to the announcement of a serology test becoming available at pharmacies the Ministry has requested CT TAG to advise on when and why serology antibody testing should be used. Members are to develop key messages to feedback to the Ministry and Ministers. The Chair apologises for the lateness of the document re: Serology Testing for COVID and appreciates members weren't given time for detailed observations. The Chair asks for all members input into this document and welcomes any comments via email by Friday 25 March 2022. • The document will formulate advice for the appropriate use of serology testing for SARS-CoV-2 and brings together information from international guidance for antibody and immunity testing.

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	• A member noted the importance of including information and need for wider methods of immunity testing i.e. pseudo neutralisation assays. The Chair supports this information being included in the document. • A high-level executive summary will be created from the information gathered in the document. This summary is intended for the DG and will also be used to feedback to other Technical Advisory Groups. **ACTIONS:** • The Chair asks for all members input into this document and welcomes any comments by Friday 25 March 2022. • Document to be shared with NZNM and Immunology groups via Dr Brewerton for comment.
5.0	**CV TAG Statement on Utility of Antibody Testing** A member commented on a point raised in COVID-19 Vaccine Technical Advisory Group noting concern in members around public access to testing without clinical oversight. This was noted. .
6.0	**Testing Strategy and Plan** The final testing strategy and plan is due early April for the Director-General and Ministers and will be used for guidance into the future Chair will send out the document re: Director-General memo on a revised testing strategy. Noting this is a work in progress. • Chair welcomes all members feedback and comments either via email or in next meeting. • Chair stresses the approach of 'form follows function': identifying gaps, what sits under public health, health NZ, and business guidance including considerations for different phases. To also consider how we would deliver the information. • The Ministry of Health noted CT TAG's specific input will be commissioned on seroprevalence in particular sampling frame considerations.
7.0	**OIA Requested** The following OIA request was included in the agenda for noting. Copies of meeting minutes from the 'COVID-19 Technical Advisory Group' and 'COVID-19 Testing Technical Advisory Group (CT TAG)' groups between 28 October and now
8.0	**Next Steps/Decisions Pending** Two placeholder meetings to be set up for following two weeks to discuss feedback on draft strategy
9.0	**Any Other Business**
10.0	**Agenda Items for Next Meeting** Members comments and input on strategic plan
11.0	**New Action Items Raised During Meeting**

#	Agenda item	Actions	Action Owner
7	**Antibody and Immunity Testing**	The Chair asks for all members input into this document and welcomes any comments via email by Friday 25 March 2022.	Chair

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	8	**Antibody and Immunity Testing**	Document to be shared with NZNM for comment.	Susan Morpeth
	9	**Testing Strategy**	Updated documents to be circulated to CT TAG for further input	Chair
Meeting closed at **1:13pm** Next meeting: **TBD**				

Open Actions:

#	Agenda item	Actions	Action Owner	Updates
4	s 9(2)(f)(iv) [redacted]			
6				
7	**Serology Antibody Testing**	The Chair asks for all members input into this document and welcomes any comments via email by Friday 25 March 2022.	Chair	23/03 – Action raised
8	**Serology Antibody Testing**	Document to be shared with NZNM for comment.	Susan Morpeth	23/03 – Action raised
9	**Testing Strategy**	Updated documents to be circulated to CT TAG for further input	Chair	23/03 – Action raised

Closed Actions:

#	Agenda item	Actions	Action Owner	Updates
5		To send the COVID-19 Testing Strategy and Surveillance Strategy documents to CT TAG members for discussion in following meeting.	Chair	11/03 – Action raised 12/03 – Action closed

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MINISTRY OF HEALTH
MANATŪ HAUORA

MINUTES: COVID-19 Therapeutics Technical Advisory Group
Te Rōpū Haumanu Kowheori-19

Date:	Friday 28 January 2022
Time:	1:30pm to 2:30pm
Location:	s9(2)(k) [redacted]
Chair:	Nigel Raymond
Members:	Colin McArthur, Eamon Duffy, Jessica Keepa, Saleimoa Sami, Susan Morpeth, Tim Cutfield
Attendees:	Andi Shirtcliffe, Andrew Oliver, Anne Buckley, Derek Fitzgerald, Josh Wiles, Ian Town, Phoebe Currie
Guests:	Pauline Horrill
Apologies:	Chris Hopkins, Elaine Yap, Michael Maze, Daniel Bernal, Justine Lancaster, Mark Ayson, Therese Egan, Adrienne Martin, Rachel Webb

1.0	**Welcome and Accept Previous Minutes** Dr Nigel Raymond welcomed all members and attendees in his capacity as Chair of the COVID-19 Therapeutics Technical Advisory Group. Minutes of the last meeting (14 January 2022) were accepted.
2.0	**Therapeutics** **Pharmac Update** • The December meeting record of Pharmac's COVID-19 Treatments Advisory Group is still being finalised. • Pharmac was aware of some rheumatology patients being transferred to the stock of subcutaneous tocilizumab that is available, in order to preserve the IV tocilizumab for COVID-19 patients. Further supply of IV tocilizumab has been secured. • Pharmac approached Roche and Baxter regarding the request for information on the stability of tocilizumab after conversion from subcutaneous to IV, however the information isn't currently available. • Pharmac is currently processing the feedback provided to the notification about eligibility criteria for baricitinib, and casirivimab and imdevimab (branded as Ronapreve). • Pharmac is planning to open consultation on the eligibility criteria for molnupiravir and Paxlovid shortly.

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- Pharmac's COVID-19 Treatments Advisory Group will discuss remdesivir at the next meeting, with a focus on possible use earlier in the disease course. Remdesivir is a Section 29 (s29) product – this adds to the potential complexity of community use.
- Pharmac is in discussion with Gilead and is planning for further supplies of remdesivir in increased volumes considering the anticipated increase in cases.
- Pharmac is in active discussions with GSK regarding sotrovimab.
- Pharmac noted there are regular meetings between Pharmac and the Ministry COVID Care in the Community team to keep them informed.

Discussion

- A member asked about budesonide and Pharmac noted that there are ongoing supply discussions.
- An attendee asked about Evusheld and Pharmac noted they are progressing discussions with AstraZeneca.

Medsafe Update

- Medsafe noted that there is no indication of when an application for Evusheld may be expected.
- Medsafe have noted the known reduction in effectiveness of Ronapreve against Omicron and the potential need for communication with the sector about this.
- Medsafe is progressing the Paxlovid application and expecting to take this forward to the Medicines Assessment Advisory Committee (MAAC) shortly. It was noted that Paxlovid has provisional approval in Australia.
- Medsafe has completed the evaluation of the remdesivir application and has issued a request for further information.
- Medsafe is expecting an application for approval for molnupiravir in February. It was noted that molnupiravir has provisional approval in Australia.

Discussion

- Discussion about the s29 process in the context of COVID-19 was raised by Pharmac. This related to practical aspects of medicine delivery once prescribed. Medsafe will provide further clarification to Pharmac.
- A member raised a question about selective serotonin reuptake inhibitors (SSRIs), in particular fluvoxamine. It was noted that these may be considered by Pharmac's COVID-19 Treatments Advisory Group in a future meeting, but that there is currently limited evidence available. Athough fluvoxamine was previously approved for non-COVID-19 indications, Medsafe has been informed by the company that it is not available. If it is required for use, the company should be contacted regarding its current status.

Paxlovid in the context of Omicron

- The Chair raised a question about the timeline of the Paxlovid application and supply, noting the potential benefits of Paxlovid as an oral treatment rather than infusion and the increasing clinical concern given the projected surge in Omicron cases. The question was raised as to whether there was any further action that could be taken to expedite timely arrival/distribution of Paxlovid.

  Pharmac noted that discussions with Pfizer are moving quickly and that the Medsafe approval is one of the triggers for delivery. It was noted that the application is progressing.

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	• A member queried if there are any operational needs to consider if Paxlovid is approved. It was suggested that it would be helpful to have concise, straightforward guidance on interactions, their significance and what to do if a patient is on the medicines involved. It was noted that there may be international guidance/resources that could support development of guidance. • A query was raised to Pharmac by a Ministry attendee about resourcing available to produce information for pharmacists and primary care. Pharmac suggested liaison with the relevant team member within Pharmac. **Action**: Clinical Chief Advisor (Pharmacy) to liaise with Pharmac team member advised on preparation of guidance for pharmacists and primary care practices on the use of Paxlovid, focusing on interactions, their significance, and the appropriate management. **Remdesivir use in immunocompromised** • A member raised a question about the use of remdesivir earlier in the disease course for this group, noting some countries have incorporated this into their approach to Omicron. It was noted that the access criteria for remdesivir are to be discussed next week by the Pharmac COVID-19 Treatments Advisory Group. **Airfinity/STA Update** • '*Highlights from Airfinity Therapeutics Report 21st Jan 2022*' was circulated with the agenda for noting. • The STA-produced excerpt from the latest Variant of Concern – Omicron Update on therapeutics was circulated with the agenda for noting.
3.0	**Covid Care in the Community/Ministry update** • It was noted that the Ministry responded to the Pharmac consultation for patient access criteria for baricitinib and casirivimab/imdevimab (branded as Ronapreve). The submission was circulated with the agenda. • An update was given on the ongoing work in the COVID Care in the Community team, requesting the groups' feedback on how therapeutics can be incorporated. • Development of the 'Population level risk stratification tool' was outlined, noting that the system would provide an initial estimation of risk of severe disease or hospitalisation (based on Delta data) for each person based on age, deprivation, ethnicity, vaccination status and enrolment status, linked to NHI number. It was noted there are still many aspects to be worked through including ethical constraints and data validity. • Different levels of care are being considered based on risk and dynamic symptom monitoring. The pre-diagnosis algorithm is still being finalised. Different pathways (self-management or active management) would be provided based on the initial assessment; however, people would be able to 'change lanes' as needed at any time. It was emphasised that resource distribution and equity are a key focus of this tool. High levels of patient self-management are expected given the anticipated increase in case numbers. Discussion/feedback • A member raised a question about the dataset and extrapolation of the data to Omicron cases. The COVID Care in the Community representative noted that the tool is designed to be updated over time and that a wide group of data experts are working to ensure the tool can be adapted quickly.

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	• A member noted that while pragmatic for community management, rough grouping can be difficult from a therapeutics perspective. Depending on the agent, groupings may be too crude to accurately identify people who appropriately meet criteria for a specific therapeutic intervention.
	• The group noted that including comprehensive details of vaccination status is important - especially differentiating between a third primary dose and a booster dose, as this could serve as a signal of patients with known risk factors or immunocompromised status.
	• The group raised several equity aspects as an important part of the feedback and noted concerns about whether those who most need monitoring in the community would receive it, given they may not be enrolled with primary care, for example. The COVID Care in the Community representative noted that equity is a key focus, many of these points are being considered and the idea of the tool is that people who need more support are identified and appropriately triaged to receive it. All feedback was welcomed.
	  ○ Members had concerns about relying on patients entering data, as a large number of people aren't digitally enabled. Access to a phone (with credit, reception, and data) is not something everyone has and is particularly important for remote communities.
	  ○ A member raised the importance of language and wording in the information sent to people about symptoms. Health literacy differs and it is important that information is accessible.
	  ○ A member suggested that geographical location (rurality) be included as a parameter of risk.

4.0	**Equity Considerations** • A member discussed a recent hui with Te Rōpū Whakakaupapa Urutā (National Māori Pandemic Group). Hospital and primary care doctors who are preparing for Omicron are keen to know more about the timelines for antivirals. • It was suggested that some preliminary information on antivirals would be helpful, so that health professionals can prepare and educate themselves on their use before they are having to use them. This was also a concern raised in the Pacific health community. • There are concerns around potential logistical issues of distribution of therapeutics that could exacerbate geographical inequities, particularly on the East Cape. • There are concerns around the access criteria for antivirals and how that will affect those in Level 1 hospitals/rural settings. Pharmac noted that therapeutics will be made available via DHBs for their distribution as appropriate including to primary care and Level 1 hospitals.
5.0	**Guideline Update** • The guideline was last updated on 21 January 2022. The next planned update is 04 March 2022 – this is expected to be brought forward (as Pharmac access criteria for Ronapreve taking effect from 1 February 2022). **Next Guideline Update** • There was discussion about preparing guidance on Ronapreve, specifically for use for confirmed Delta cases given its known limitations in treating Omicron. While important as there are still Delta infections in New Zealand, it was noted that criteria for use based on Whole Genome Sequencing (WGS) was unsuitable as it is not set up as part of a clinical diagnostics pathway. Of note, WGS is done at PH direction, results not visible to clinicians, anticipated increased use of Rapid Antigen Tests (RATs) etc all make use of WGS criteria impractical. Noted that infections are increasingly likely to be Omicron and this needs to be reflected in recommendation wording.

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	• Remdesivir – recommendations will reflect any change in Pharmac access criteria following forthcoming meeting of Pharmac COVID-19 Treatments Advisory Group. No change anticipated in the next update.
6.0	**Next Steps/Decisions Pending** • Planned Guideline Update 4 March 2022 – an earlier update including Ronapreve recommendation/s now planned – by 1 February if possible.
7.0	**Any Other Business** **Sector/ID physician update re therapeutics planned for use** It was suggested that a general therapeutics update be sent out to the sector, including community (primary care and their teams, and pharmacies), in order to provide clarification and direction. It was stated as important at this time to provide information to health professionals, as there is some concern and confusion around what medicines are available, information regarding approvals and criteria and what approximate timelines might be. • These communications to the sector need to have Pharmac and Medsafe approval in terms of releasing information about timelines etc. • The Comms team in the Ministry can support this work. Sector communications can be sent out through several channels - DHB, NGO, pharmacy. **Action**: STA and Clinical Chief Advisor (Pharmacy) to organise sector communication update on therapeutics. • It was also suggested that a 'one pager' summary for hospital clinicians could be helpful. It was noted that a member was intending on drafting an infographic, drawing on an Australian example.
8.0	**Agenda Items for Next Meeting** • Ronapreve Practical Guidance document – Mike Maze • Paediatric Update – Rachel Webb
9.0	**New Action Items Raised During Meeting** **Action**: Clinical Chief Advisor (Pharmacy) to liaise with Pharmac team member on preparation of guidance for the use of Paxlovid, focusing on interactions, their significance, and the appropriate management. **Action**: STA and Clinical Chief Advisor (Pharmacy) to organise sector communication update on therapeutics.
Meeting closed at **2:35pm** Next meeting **11 February 2022 – 1:30pm to 2:30pm**	

Open Actions:

#	Agenda item	Action	Action Owner	Updates
5	Guideline update	Review update and publish revised guideline 12/11/21 Guideline update to be brought forward and	Tim Cutfield/STA	17/09 – Action raised Guideline update published 5/11/21

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		prepared within 2 weeks if possible to provide guidance on baricitinib use - aligning with arrival of baricitinib supply. 26/11/21 Next guideline update planned for 3 December 2021. 10/12/21 Next planned update 21 January 2021		Guideline update published 22/11/21- including guidance on baricitinb Guideline update published 3/12/21 Guideline update published 21/01/22 Next update 04/02/22
18	Ronapreve – 'Position Statement'	10/12/21 Document to support use of Ronapreve in the community - to be developed in early 2022. 28/2/22 In development.	Mike Maze/Guideline Development subgroup	10/12 Action raised
20	Paxlovid – in the context of Omicron	Preparation of guidance for primary care and pharmacists on use of Paxlovid, including interactions and appropriate patient management.	Clinical Chief Advisor (Pharmacy)	28/2/22 Action raised.
21	Sector communications – therapeutics update	STA and Clinical Chief Advisor (Pharmacy) to organise sector communication update on therapeutics.	STA	28/2/22 Action raised.

Closed Actions:

#	Agenda item	Action	Action Owner	Updates
19	Airfinity Update	STA to provide clarification on Airfinity slide data with respect to source of definitions of severity.	STA	14/01/2022 - Action raised 27/01 – Clarification provided. Action closed.

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MINISTRY OF HEALTH
MANATŪ HAUORA

MINUTES: COVID-19 Therapeutics Technical Advisory Group
Te Rōpū Haumanu Kowheori-19

Date:	Friday 11 February 2022
Time:	1:30pm to 2:30pm
Location:	s9(2)(k) [redacted]
Chair:	Nigel Raymond
Members:	Chris Hopkins, Eamon Duffy, Elaine Yap, Michael Maze, Susan Morpeth
Attendees:	Andrew Oliver, Anne Buckley, Daniel Bernal, Derek Fitzgerald, Josh Wiles, Ian Town, Phoebe Currie
Guests:	Therese Egan, Rachel Webb
Apologies:	Colin McArthur, Jessica Keepa, Saleimoa Sami, Tim Cutfield, Andi Shirtcliffe, Justine Lancaster, Mark Ayson

1.0	**Welcome and Accept Previous Minutes** Dr Nigel Raymond welcomed all members and attendees in his capacity as Chair of the COVID-19 Therapeutics Technical Advisory Group. Minutes of the last meeting (28 January 2022) were accepted.
2.0	**Therapeutics** **Pharmac Update** • Pharmac is still finalising the record for the December meeting of the Pharmac COVID-19 Treatments Advisory Group. • The Pharmac COVID-19 Treatments Advisory Group met to discuss updated data on the use of remdesivir earlier in the disease course. The meeting record is being finalised and consultation on eligibility criteria will follow. • Remdesivir is not currently listed in the Pharmaceutical Schedule but is to be added. • Pharmac is working with Gilead in planning for ongoing supply of remdesivir and has secured another shipment. • Pharmac is continuing to engage with GSK regarding sotrovimab. • Pharmac has received further advice from the Pharmac COVID-19 Treatments Advisory Group regarding oral antivirals (Paxlovid and molnupiravir). Pharmac consultation on Paxlovid and

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molnupiravir eligibility criteria is due out next week and feedback from the Therapeutics TAG is welcomed.

- Pharmac is in regular communication with the Ministry COVID Care in the Community team about therapeutics for potential community use.

Discussion

- A member raised a question regarding the timeline for oral antivirals and Pharmac noted it is working at pace to finalise agreements and it is understood there is progression through Medsafe.
- An attendee raised a question regarding availability and timelines for sotrovimab. Pharmac noted this will be a key product once available. At this stage, it is not anticipated to be available until Q3 at the earliest.
- An attendee raised a question regarding the draft sector communications and the drafted availability timeline for the oral antivirals of April. Pharmac noted that the delivery dates are not finalised, and that molnupiravir may not be available as early as Paxlovid.

Medsafe Update

- Medsafe has received all quality, manufacturing and clinical information for Paxlovid and the request for information to Pfizer has been assessed. A final request for information has been issued and is currently with Pfizer. It was noted that Paxlovid now has conditional approval in Europe.
- Medsafe is continuing discussions with MSD regarding an application for molnupiravir and anticipates an application.

Discussion

- A member raised a question regarding the status of remdesivir. Medsafe noted that the company has the initial evaluation request for information and Medsafe are waiting on a response.
- Pharmac asked about the progression of the 'Dear Healthcare Professional Letter' updating on Ronapreve. Medsafe noted this should be available on the Medsafe website shortly.

Airfinity/STA Update

- '*Highlights from Airfinity Therapeutics Report 7th Feb 2022*' was circulated with the agenda for noting. Key points included recent information on remdesivir and fluvoxamine and the WHO recommendations for baricitinib and sotrovimab.

Therapeutics Update for the health sector

- STA reported progress on the therapeutics update for the health sector - open action #21 'Sector communications – therapeutics update'.
- A draft has been developed and discussion with the Ministry communications team regarding distribution channels is progressing.
- The draft was shared within the meeting and specific feedback was provided.
- Members noted that having an update, especially regarding potential timelines of treatment availability, released as soon as possible would be beneficial and assist in answering queries, particularly from medical colleagues.

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	• Members suggested a key inclusion would be the indication of differences in Aotearoa New Zealand, compared to the Australian context, as that is often the comparison due to information coming from specialist colleges etc.
	• Pharmac noted it would be helpful to include a hyperlink through to eligibility criteria on Pharmac website for Ronapreve.
	• Members suggested it was key to include the Aotearoa New Zealand context about:
	  ○ What treatments are currently available
	  ○ What treatments are expected
	  ○ What treatments are not expected
	  ○ What treatments are advised against
	• Once approved by Pharmac and Medsafe, this communique will be published on the Ministry health professionals page and distributed in discussion with the Ministry Communications team.
	• It was agreed that the intention of this communique is to provide clarity around current and possible COVID-19 treatments in Aotearoa New Zealand, not providing details of administration – that is the purpose of the guideline.
	• Feedback from the meeting will be addressed and STA will circulate the revised draft for review by members.

3.0	**Equity Considerations** • No issues were raised for discussion and due to apologies for this meeting, the Chair requested that this item be addressed at the next meeting.
4.0	**Paediatric Update** • It was noted that the communique for the health sector would be helpful to share with paediatric sub-specialist colleagues who have queries about timelines for delivery of oral antivirals and monoclonal antibodies. • A member raised a question regarding remdesivir use in children and it was noted that this is already in the current Starship paediatric guideline *Covid-19 Disease in Children* here and that remdesivir has been used in Melbourne and Sydney in response to recent outbreaks.
5.0	**Ronapreve Practical Guidance document** Feedback, sign off & distribution strategy • The Ronapreve Practical Guidance document is now in the final draft stage and members feedback has been incorporated and circulated back to the group for final sign off. • The distribution of the 'Ronapreve Practical Guidance document' will occur next week through the same process as the Guideline. The Ronapreve Practical Guidance document will be published on the Ministry's Health Professional web page once finalised. Members will circulate to their networks as appropriate eg. ID pharmacy group, TSANZ. • Members noted that the timeline for the use of Ronapreve was limited due to its reduced efficacy against Omicron. • There was a discussion on the value of developing advice around the potential locations where Ronapreve use may still be appropriate. It was noted that there is geographical data for Whole Genome Sequencing (WGS) that could possibly be accessed to support guidance provided by the Therapeutics TAG.

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	• Members noted that it had been agreed that using WGS as a clinical diagnostic wasn't appropriate to set up in a reasonable time frame, given that it would lose relevance in an Omicron dominant outbreak. • It was noted that Public Health teams have greater awareness of the clusters and could support and provide further information. Geographic information around clusters would be helpful for clinicians to support treatment decisions in the absence of WGS. • In some instances, requesting a microbiology lab to send a sample to ESR for WGS could be possible and valuable, but it cannot be guaranteed that it will be available for treatment decisions. • Members discussed that some remaining Delta dominant areas could still be utilising Ronapreve. It was suggested that connection with Primary Care in these areas is required to support implementation. **Action**: Chair and STA to prepare a Memo to the COVID Care in the Community team, advising that Ronapreve remains appropriate for patients with a Delta infection and highlighting the ESR WGS geographical reporting which could be used to support implementation.
6.0	**Guideline Updates** Previous updates - 1&4 February • The 'Clinical management of COVID-19 in hospitalised adults' guideline was updated on 1 & 4 February 2022. The next planned update is 4 March 2022. Next update • Members continued the discussion regarding the limited timeline for use of Ronapreve and the limited access to WGS outside hospital. Members discussed the possibility of utilising ESR WGS geographical reporting to gain insight into the variants by region and support treatment decision making. • A member shared a report from ESR and showed the group an example of the type of data that could be accessed. It was suggested that the Chair request wider distribution of the ESR WGS geographical reporting for supporting treatment decisions on Ronapreve. **Action**: Chair to email ESR and request a wider distribution of the ESR WGS geographical reporting for supporting treatment decisions on Ronapreve.
6.0	**Any Other Business** There was no other business discussed.
8.0	**Agenda Items for Next Meeting** • Equity considerations
9.0	**New Action Items Raised During Meeting** **Action**: Chair and STA to prepare a Memo to the COVID Care in the Community team, advising that Ronapreve remains appropriate for patients with a Delta infection in specific geographical areas. **Action**: Chair to email ESR and request a wider distribution of the ESR WGS geographical reporting for supporting treatment decisions on Ronapreve.
Meeting closed at **2:29pm** Next meeting 25 **February 2022 – 1:30pm to 2:30pm**	

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Open Actions:

#	Agenda item	Action	Action Owner	Updates
5	Guideline update	Review update and publish revised guideline 12/11/21 Guideline update to be brought forward and prepared within 2 weeks if possible to provide guidance on baricitinib use - aligning with arrival of baricitinib supply. 26/11/21 Next guideline update planned for 3 December 2021. 10/12/21 Next planned update 21 January 2021 1& 4/2 22 Guideline updated with Ronapreve content	Tim Cutfield/STA	17/09 – Action raised Guideline update published 5/11/21 Guideline update published 22/11/21- including guidance on baricitinb Guideline update published 3/12/21 Guideline update published 21/01/22 Next update 04/03/22
20	Paxlovid – in the context of Omicron	Preparation of guidance for primary care and pharmacists on use of Paxlovid, including interactions and appropriate patient management.	Clinical Chief Advisor (Pharmacy)	28/1/22 Action raised.
21	Sector communications – therapeutics update	STA and Clinical Chief Advisor (Pharmacy) to organise sector communication update on therapeutics. 11/2/22 Draft has been developed and is to be circulated to Members for further review.	STA	28/1/22 Action raised.
22	Memo on potential for Ronapreve use in community	Chair and STA to prepare a Memo to COVID Care in the Community team about potential Ronapreve use	Chair/STA	11/2/22 Action raised
23	ESR request for WGS reporting	Request for wider distribution of ESR WGS geographical reporting to support	Chair	11/2/22 Action raised

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		treatment decisions about Ronapreve		

Closed Actions:

#	Agenda item	Action	Action Owner	Updates
18	Ronapreve – Practical Guidance Document	Document to support use of Ronapreve in the community - to be developed in early 2022.	Development subgroup	10/12 Action raised 28/1/22 In development. 11/2/22 Draft being finalised prior to publishing online. 18/2/22 Published on the Ministry health professional page and distributed to Therapeutics TAG members. Action closed

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MINISTRY OF HEALTH
MANATŪ HAUORA

MINUTES: COVID-19 Therapeutics Technical Advisory Group
Te Rōpū Haumanu Kowheori-19

Date:	Friday 25 February 2022
Time:	1:30pm to 2:30pm
Location:	s9(2)(k) [redacted]
Chair:	Nigel Raymond
Members:	Chris Hopkins, Colin McArthur, Eamon Duffy, Elaine Yap, Jessica Keepa, Saleimoa Sami, Susan Morpeth, Tim Cutfield
Attendees:	Andrew Oliver, Anne Buckley, Daniel Bernal, Derek Fitzgerald, Justine Lancaster, Josh Wiles, Ian Town, Mark Ayson, Phoebe Currie
Guests:	Therese Egan
Apologies:	Michael Maze, Andi Shirtcliffe

1.0	**Welcome and Accept Previous Minutes** Dr Nigel Raymond welcomed all members and attendees in his capacity as Chair of the COVID-19 Therapeutics Technical Advisory Group. Minutes of the last meeting (11 February 2022) were accepted. Matters Arising – The Therapeutics Update for Health Professionals document was circulated with the agenda. This final version included input from Pharmac and Medsafe.
2.0	**Therapeutics** **Pharmac Update** • Pharmac have opened the consultation on access criteria for molnupiravir (Lagevrio) and nirmatrelvir with ritonavir (Paxlovid). Pharmac noted the consultation is an agenda item for this meeting and welcomed feedback from the group or individuals. The consultation closes on 2 March 2022. • Pharmac is continuing to progress negotiations on details of supply agreements for molnupiravir and Paxlovid. • Remdesivir – 5000 vials have arrived in Aotearoa New Zealand. Pharmac expects these to be receipted by the wholesaler today. After the recent results of the PINETREE study, global supply of remdesivir is constrained and Pharmac is working with Gilead to secure more stock as a measure before other agents such as oral antivirals become available. • Tocilizumab - additional stock was delivered in January this year. Global stocks of IV and subcutaneous tocilizumab remain constrained and this is expected to continue.

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	• Baricitinib is now listed on the Pharmaceutical Schedule with the same criteria as tocilizumab. DHBs can order. Small regular orders as required will assist in managing stock levels. • Pharmac noted no change for Ronapreve since the last update - stock remains available. • The next Pharmac COVID-19 Treatments Advisory Group meeting is on 28 February 2022 and will focus on fluvoxamine and ivermectin. Pharmac is aware of the international consensus that ivermectin is not recommended for use as a COVID-19 treatment and aims to publish advice in order to formalise the group's recommendations, inform the public and assist in responding to ongoing queries about ivermectin for COVID-19. • Sotrovimab and Evusheld - Pharmac expects to be able to provide further updates in the coming weeks. Discussion • A member raised a question regarding the incoming remdesivir stock. Pharmac confirmed the new stock is the same product as available currently, which is the powder rather than the solution. • A member commented that there are ongoing queries from clinicians regarding remdesivir access criteria. Pharmac noted that additional information regarding access criteria is expected to be released on 28 February. It was noted that this timing will align with preparation of the next guideline due to be published 4 March 2022. **Medsafe Update** • The Paxlovid application has been through the Medsafe process and was considered by the Medicines Assessment Advisory Committee (MAAC) on 24 February 2022. A decision may be made on whether to grant approval next week. • Medsafe received an application from MSD for molnupiravir last week and an evaluation is now underway. It is an abbreviated application, based on an application to an overseas regulator and Medsafe have already received all the data needed for evaluation. • Remdesivir evaluation - Medsafe have made a further request for information to Gilead and are awaiting a response. **Airfinity/STA Update** • '*Highlights of Airfinity report 18 February 2022'* was circulated with the agenda for noting. A selection of key updates was included, such as recent information on oral antivirals. • *'Trends and Insights Report – 24 February 2022'* was circulated on the day of the meeting as an addition to the agenda for noting. Particularly of interest was the latest Whole Genome Sequencing (WGS) data, which included the identified number of Delta cases.

3.0	**Equity Considerations**
	• Equity concerns were raised regarding the timeline of access for antivirals. It was suggested that there are a series of potentially challenging factors that need to align in order for treatment to be provided to those that need it most.
	• Factors to be considered in the timeline for access include:
	  ○ Early testing of individuals – some individuals may not seek tests for varying reasons e.g. distrust in the system.
	  ○ Accurate reporting of the test results – some individuals may not report their RATs results due to the consequences e.g. loss of income from isolating.
	  ○ Practitioners need to familiarise themselves with the eligibility criteria for new therapeutics. It was noted that this is an increased workload on primary care.

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	○ Prompt delivery of prescriptions is required to ensure therapeutics can be given within the recommended treatment window. A member suggested allowing practitioners to prescribe early for high risk patients to ensure timely access. ○ Potential supply chain disruption is a concern, especially for rural situations. Stock distribution is important. ○ Providing the appropriate information on therapeutics to patients. • It was noted that it would be beneficial to have oral antivirals included in COVID Health Pathways. Considering initiatives like audits/query builders to identify and flag eligible patients in advance would be helpful. • As the COVID response shifts to 'self-management', there are concerns that individuals could be overlooked. It was noted that ideally high risk individuals will be triaged into active management. • A member raised a query regarding pharmacies not being able to buy or hold stock. Pharmac noted that currently oral antivirals can't be purchased directly by pharmacies, but they will be able to be ordered to fill prescriptions. This approach is intended to prevent potential stockpiling by some pharmacies but Pharmac is open to revising the distribution approach if needed. • Ideas for addressing the equity concerns raised included: further support provided to primary care; providing clear practical information about who needs to do what and when; incentivising prospective planning in primary care to identify eligible patients; and increasing patient awareness of treatments they may be eligible for through patient information sheets.
4.0	**Pharmac Consultation on access criteria for oral antivirals** • Feedback on the access criteria from members by linked email discussion was provided to STA after a request from the Chair and this was collated and circulated as a paper with the agenda for further discussion. • Members agreed that 'tightening' the criteria (increasing the number of co-morbidities) would be beneficial overall to make the criteria more restrictive. Members supported specifying Maori and Pacific ethnicity in the criteria to help identify those at high risk. The feedback on specific co-morbidities provided by members by email was noted. • Members discussed whether there was a need for the criteria to specify aspects such as drug interactions (for Paxlovid) and need for concomitant contraceptive use (molnupiravir). It was agreed that these aspects are not commonly included in access criteria and while important, are more relevant to prescriber safety. It was noted that if there are broader access criteria, drug interaction becomes increasingly relevant as the broader clinical benefit possibly reduces. • It was noted that the COVID Care in the Community team have recently established a Therapeutics Implementation Group. Equity is a key pillar in the framework and the implementation plan for the roll out of therapeutics is in development. Further information is required in order to develop the implementation plan, such as Medsafe approval status, Pharmac access criteria, stock levels and timelines of deliveries. Further work on the plan will be done as information becomes available. • Members raised equity concerns about the access criteria, suggesting that they may not capture some individuals who may benefit from oral antivirals, such as 'mobile communities' (individuals not enrolled with a general practice) or those who may have a later diagnosis of risk factors such as diabetes and hypertension due to limited contact with primary care. Members supported allowing for risk factors to be identified through clinical suspicion. • A member commented that under the current criteria, some practices would have a large number of people who may be eligible. Members discussed concerns that this could increase pressure on the health system, while the benefit of the treatment overall is reduced due to lower hospitalisation rates with Omicron (compared to Delta). • A member suggested that there were potential medicolegal implications of having wide access criteria which could not be reflected in the delivery of treatment.

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	• It was suggested that having a single set of access criteria for all antivirals for potential use in the community would be helpful and this view was supported by the group. It was noted that prescriber and safety information could be communicated separately to professionals to assist with management. **Action:** A Therapeutics TAG submission on two oral antivirals is to be finalised by the Chair and STA for submission to Pharmac by March 2, taking in the feedback provided by members and the meeting discussion.
5.0	**Implications for Ronapreve** • The number of likely cases of Delta circulating in the community was discussed, informed by two ESR reports of whole genome sequencing (WGS) and the *Trends and Insights Report – 24 February 2022.* The reports suggest there is very little Delta in the community. Members noted that the relevance of Ronapreve is now limited due to reduced efficacy against Omicron and limited ability to complete WGS in the community. • It was noted that Delta may be persistent for longer in hospital admissions - the Australian experience was of a 'long tail of Delta' in the hospital setting, given greater severity of illness with Delta. Members noted that Ronapreve use in hospital may still be relevant. • Overall members noted that without WGS, distinguishing between Delta and Omicron at disease onset is very difficult and dependent on knowledge of specific outbreak clusters. • The Therapeutics TAG decided to recommend that Ronapreve should not be used in the community in general - except for use on expert recommendation or in extenuating circumstances. **Actions**: Information on Ronapreve in the Therapeutics Update for Health Professionals is to be updated to align with recommendation that not for general use in community. Ronapreve content in the *Clinical management of COVID-19 in hospitalised adults* guideline will be reviewed as part of the next guideline update.
6.0	**Guideline Updates** • The next update of the guideline is planned for March 4 and is underway. The group discussed changes being considered for this update including updating the discharge and disposition sections with input from the Public Health team in the Ministry as needed. STA acknowledged a role in facilitating this. • Members discussed budesonide and the varying use around Aotearoa New Zealand. Some areas have removed budesonide from use due to logistics with prescribing and other factors. The group generally agreed that therapeutic recommendations should be the same for the whole of Aotearoa New Zealand. The subgroup will consider how to reflect this in the guideline. • Members discussed the length of the guideline document and if there could be changes to the current format facilitated by the Ministry to make it easier to read. STA reported preliminary discussions with the Ministry communications team about this and that design support was available but limited. Further suggestions of required improvements could assist with progression. Ease of rapid updating needs to also be considered given timeframe from final preparation of a guideline update to publication online. • A member suggested that the full guideline was helpful in its current format and adding summary flowcharts grouped by severity could be an alternative approach to improving accessibility of information.
7.0	**Any Other Business** There was no other business.
8.0	**Agenda Items for Next Meeting**

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	• Paediatric update
Meeting closed at **2:38pm** Next meeting **11 March 2022 – 1:30pm to 2:30pm**	

Open Actions:

#	Agenda item	Action	Action Owner	Updates
5	Guideline update	Review update and publish revised guideline 12/11/21 Guideline update to be brought forward and prepared within 2 weeks if possible to provide guidance on baricitinib use - aligning with arrival of baricitinib supply. 26/11/21 Next guideline update planned for 3 December 2021. 10/12/21 Next planned update 21 January 2021 1& 4/2 22 Guideline updated with Ronapreve content	Tim Cutfield/STA	17/09 – Action raised Guideline update published 5/11/21 Guideline update published 22/11/21- including guidance on baricitinb Guideline update published 3/12/21 Guideline update published 21/01/22 Next update 04/03/22
20	Paxlovid – in the context of Omicron	Preparation of guidance for primary care and pharmacists on use of Paxlovid, including interactions and appropriate patient management. 8/3/22 Liaising with Pharmac about potential third party production of appropriate prescriber/patient information.	Clinical Chief Advisor (Pharmacy)	28/1/22 Action raised.

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Closed Actions:

#	Agenda item	Action	Action Owner	Updates
21	Sector communications – therapeutics update	STA and Clinical Chief Advisor (Pharmacy) to organise sector communication update on therapeutics. 11/2/22 Draft has been developed and is to be circulated to Members for further review. 25/02/22 – Final document circulated with agenda. Updated Ronapreve content added with Chair sign off. 28/2/22 Published on the Ministry health professional website with comms notifications to sector.	STA	28/1/22 Action raised. 28/2/22 Action closed.
22	Memo on potential for Ronapreve use in community	Chair and STA to prepare a Memo to COVID Care in the Community team about potential Ronapreve use 25/02/22 Confirmed at the meeting that this memo not needed due to Omicron predominating.	Chair/STA	11/2/22 Action raised 25/02/22 Action closed
23	ESR request for WGS reporting	Request for wider distribution of ESR WGS geographical reporting to support treatment decisions about Ronapreve 25/02/22 ESR was contacted and regular circulation of reports has begun.	Chair	11/2/22 Action raised 25/02/22 Action closed

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Guests:	Therese Egan, Rachel Webb, James Entwisle
Apologies:	Saleimoa Sami, Andi Shirtcliffe, Daniel Bernal, Ian Town, Mark Ayson

1.0	**Welcome and Accept Previous Minutes** Dr Nigel Raymond welcomed all members and attendees in his capacity as Chair of the COVID-19 Therapeutics Technical Advisory Group. The meeting was opened with a karakia. Minutes of the last meeting (25 February 2022) were accepted.
2.0	**Therapeutics** **Pharmac Update** • Consultation on the proposed access criteria for molnupiravir and Paxlovid closed on 2 March 2022. Pharmac had good engagement, including a submission from the Therapeutics TAG. Pharmac is working through a number of detailed responses and considering possible effects on the criteria. Outcomes of this process are expected in the coming weeks. • s 9(2)(b)(ii) [redacted] Molnupiravir is undergoing evaluation by Medsafe. • Paxlovid - Pharmac are expecting information on shipping arrangements for Paxlovid in the next few weeks. • Remdesivir - In response to significant feedback, Pharmac made changes to the remdesivir access criteria on 4 March 2022. Pharmac increased the number of comorbidities required to access the treatment, a temporary change until oral antivirals become available. There has been interest from DHBs regarding community access to remdesivir. Pharmac noted that while stock is available, supplies are limited, and insufficient to support wide community use at this time.

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- Tocilizumab - The most recent delivery was in January; supply remains constrained and Pharmac continues to work with Roche to manage stock.
- Baricitinib stock is available from Onelink. Pharmac is monitoring usage and considering when stock may need to be reordered.
- Discussions regarding sotrovimab and Evusheld are progressing, and updates are expected in the coming weeks.
- Ronapreve stock remains available and evidence about Ronapreve and Omicron is being monitored.

Discussion

- A member noted that the recently published RECOVERY trial results for baricitinib were likely to lead to increased use and asked if that was accounted for in supply discussions. Pharmac acknowledged the possible constraint in the future due to increased demand, which would be discussed with Eli Lily; currently supply is satisfactory.
- A member raised a recent publication in the NEJM regarding monoclonal antibodies and BA.2 The study showed a reduction in activity for sotrovimab against BA.2 and that imdevimab retained some activity against BA.2. There was discussion around the two components of Ronapreve, including whether further evidence may suggest dosage changes in the future and STA noted awareness of this study. It was suggested that STA investigate further, given the current outbreak in Aotearoa New Zealand is dominated by BA.2 and Ronapreve is not being used in NZ for Omicron on the basis of existing evidence.

Action: STA to report on emerging evidence on casirivimab and imdevimab and BA.2 and any developments arising from the NEJM paper.

Medsafe Update

- Paxlovid has been approved under section 23 of the Medicines Act with conditions on 2 March 2022.
- Remdesivir - Medsafe is waiting on a response to a request for information regarding remdesivir, sent to the company in January.
- Molnupiravir - Medsafe has sent a request for information to Merck regarding molnupiravir and are expecting a response next week.
- Medsafe will be having pre-submission meetings with GSK (sotrovimab) and Novartis (ensovibep) to discuss information required and facilitating the approval process.

Airfinity/STA Update

'*Highlights of Airfinity report 04 March 2022'* was circulated with the agenda for noting. A selection of key updates was provided, including the FDA recommendation for doubling of Evusheld dose to 300mg, the baricitinib RECOVERY trial results and emerging studies regarding Paxlovid and molnupiravir retaining efficacy against BA.2.

3.0

Equity Considerations

- A member provided feedback from Primary Care that the 'Clinical management of COVID-19 in hospitalised adults' guideline is useful and the recent formatting updates are helpful, particularly regarding decisions around remdesivir.

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	• A member noted that their DHB was trialling remdesivir IV in the community in a patient who has comorbidities. Members discussed the challenges of identifying people at high risk for treatment in the community, especially people who are not currently engaged with the health system. • Members also discussed the information circulated about the upcoming workshop, 'Te Tiriti-based futures + anti-racism'. It was noted that there were several different speakers and topics across different days that may be of interest to the group.
4.0	**Operational considerations for Paxlovid use in primary care – update** • A representative from the COVID Care in the Community team provided an update. • Paxlovid has been approved by Medsafe and 60,000 doses are expected to arrive in the country with first shipment in early April. The Therapeutics Implementation Group is in the final stages of developing an implementation plan to operationalise this, focusing on equitable distribution. • One of the key recommendations will be having one wholesaler for oversight. Stock will be distributed through nominated community pharmacies. • Nominated community pharmacies will be determined locally by DHBs and hubs, as it is acknowledged that local regions have greater awareness of community needs and populations at high risk. Usual pharmacy purchasing and claiming of medicines processes will not apply so there is greater control of distribution. • Prescribing guidance will be supported by Matui (He Ako Hiringa) – as noted in the section below. Guidance will have clear prescribing and dispensing information to advise people how to safely take the medication. • Guidance will also be distributed via the Health Pathways website for GPs, so there is point of care information and nationally consistent pathways. • The COVID Care in the Community team is in discussion with Digital teams within the Ministry to ensure that systems provide a collaborative platform for Care in the Community management. • It is understood that Pharmac is utilising xPharm to allow for flexible stock management. • The Therapeutics Implementation Group is exploring options for auditing and monitoring distribution and are focusing on timely access to medications for those who are at greatest need. Discussion • A member raised a question about the xPharm process and how that will connect with Māori and Pacific providers. It was noted that the nominated community pharmacies in each area will be working closely with iwi and Māori providers. Providers will assist with options such as pick up or delivery of treatments when needed due to isolation requirements. • A member raised a question regarding Paxlovid drug interactions and how these will be addressed when operating in this new model, diverging from the 'usual' process of prescribing and dispensing. The Therapeutics Implementation Group is discussing this and would prefer that where possible, the person's normal pharmacist is able to be engaged in a medication review. However, it is noted that this could be difficult when someone is engaging at a different pharmacy than usual. It was noted that prescribers will have access to clinical information to assist with providing advice around taking the treatment and any required adjustments to other medications. There are challenges in ensuring both a simple process for timely distribution and a trusted process to provide equitable outcomes. Further discussion is needed. • A member raised a question regarding the process from a person testing positive on a rapid antigen test (RAT) to receiving a treatment in a timely manner, given the limited treatment window. It was outlined that the Care in the Community model was designed with this in mind. The positive result is uploaded, triggering a notification to GP and the contact tracing system. Local

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	coordination hubs have visibility of this, and the risk stratification process occurs simultaneously to triage people into the active management stream. High risk people are proactively identified and prioritised in the calling schedule. The risk stratification tool is not a clinical assessment but assists in prioritising who is likely to need support and so should be contacted first. There is continuous improvement to ensure the most at risk are being picked up by the system. When the treatments are available, the GP will become aware of the need for a prescription through the above process. • While covering the COVID Care in the Community model, members discussed the current situation with remdesivir, in that eligibility is significantly greater than available supply which creates challenges for Primary Care. Members discussed that further advice on determining who to prescribe to would be appreciated by the sector to support navigation of this challenge. Further data on who is at the highest risk is required; members discussed the possibility of gaining insights from data from the current outbreak but agreed that action was needed before that would be available. **Action:** Therapeutics TAG to develop clinical advice on remdesivir use to help guide patient selection for treatment.in the community. This is considered by the group as an urgent priority. • Members discussed the need for providing advance notice to people about their eligibility for and benefits of accessing a treatment, targeted to those who are likely to need it most. • Members discussed whether the remdesivir access criteria could include people who have a negative RAT but are symptomatic in a household with positive COVID-19 cases. It was noted that 'probable' is listed in the criteria, however such cases would not be picked up by the electronic system at this stage, so it is challenging to provide them with rapid access to the treatment. **Resource development update** • A brief document 'Update from Pharmac Implementation team 9.3.22 – Guidance on Paxlovid resource' which outlines an approach to develop Paxlovid guidance to support prescribers in the community was circulated to members on 10 March 2022 to inform discussion. • The document outlines the current approach of focusing on awareness and management of the drug-drug interaction potential of Paxlovid and will be adapted from an international resource for a New Zealand context and audience. Publication of this resource is anticipated by 1 April 2022, with the support of Matui (He Ako Hiringa). Updates on the timeframe for final delivery will be provided.
5.0	**Guideline Updates** • The most recent 'Clinical management of COVID-19 in hospitalised adults' guideline was published on 4 March 2022. Many changes were made in the recent update, including the removal of Ronapreve due to the displacement of Delta by Omicron and updated remdesivir access criteria. Members discussed the need for further data to support advice around determining high risk individuals and it was noted that finding people who require early treatment needs to be strongly linked to testing. • Members discussed a draft infographic that collated information from the tables and put together criteria for the severity categories alongside the therapeutic options. The infographic is a simplified approach, intended as a reference figure in the document. It does not contain dosing or contraindications, which will remain in the main body of the document. • There is an ongoing conversation with the Ministry communications team regarding capacity for design and updates of an infographic of this nature. It was noted that the graphic would require an expert reviewer before it was published to ensure clinical accuracy if it were to be updated by other

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	than the guideline development team. Members discussed that a one-off design review of the graphic would be helpful and then clinical updates could be completed by the subgroup going forward. The infographic as prepared will be included in the next update. • Members discussed the RECOVERY trial results regarding baricitinib and tocilizumab, noting that these agents cannot currently be used together in Aotearoa New Zealand. Pharmac noted that this topic was scheduled to be discussed by the Pharmac COVID-19 Treatments Advisory Group.
6.0	**Paediatric Update** • Clinical guidance was recently updated with respect to: COVID-19 Disease in Children, COVID-19 associated multisystem inflammatory conditions (PIMS-TS, MIS-C) and neonatal management. This guidance can be accessed through the Starship clinical guidelines website. • Remdesivir - The high number of eligible patients for remdesivir alongside limited supply was noted and the challenge of determining those who are high risk for poor COVID-19 outcomes. It was acknowledged that some children who are at high risk may not be engaged in clinical services.
7.0	**Any Other Business** A member raised the issue of the impact of border opening on other respiratory illnesses and whether the group might pivot to support work on other important infections in the community. Members noted this was beyond the current scope of the group.
A karakia concluded the meeting. Meeting closed at **2:40pm** Next meeting **25 March 2022 – 1:30pm to 2:30pm**	

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		1& 4/2 22 Guideline updated with Ronapreve content		Guideline update published 04/03/22 Next update planned 01/04/22
24	Evidence review on BA.2 and casirivimab/imdevimab	11/3/22 Report on emerging evidence	STA	11/03 – Action raised
25	Clinical guidance on use of remdesivir in community	11/3/22 Preparation of clinical guidance	Chair/Guideline development subgroup	11/03 – Action raised

Closed Actions:

#	Agenda item	Action	Action Owner	Updates
20	Paxlovid – in the context of Omicron	Preparation of guidance for primary care and pharmacists on use of Paxlovid, including interactions and appropriate patient management. 8/3/22 Liaising with Pharmac about potential third party production of appropriate prescriber/patient information.	Clinical Chief Advisor (Pharmacy)	28/1/22 Action raised. 11/3/22 Pharmac overseeing prescriber resource in development. Due for completion 1/4/22. 11/3/22 Action closed.

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1.0	**Welcome and Accept Previous Minutes** Dr Nigel Raymond welcomed all members and attendees in his capacity as Chair of the COVID-19 Therapeutics Technical Advisory Group. Minutes of the last meeting (11 March 2022) were accepted.
2.0	**Therapeutics** **PHARMAC Update:** • Pharmac has updated its website for the portfolio on COVID treatments including availability, access criteria, clinical advice, and published guidance. • s 9(2)(b)(ii) [redacted] • Antivirals access criteria are being drafted based on feedback received in response to the consultation which closed on 2 May 2022. Pharmac is aiming to have this finalised in the week commencing 28 March 2022. • Paxlovid and molnupiravir will be listed on the Pharmaceutical Schedule from 1 April 2022. Stock won't be available from that date but, the treatments are being listed it in anticipation of one or both treatments being available at some point during April. • s 9(2)(b)(ii) [redacted]

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	• s 9(2)(b)(ii) [redacted] • Remdesivir: stock remains available. Additional stock is expected to arrive in New Zealand in the week commencing 28 March 2022. • Pharmac is working with Roche to manage supply and stock of Tocilizumab in NZ • s 9(2)(b)(ii) [redacted] Discussion: A member noted there are shortages of supply of Paxlovid in the United States currently. PHARMAC acknowledged this but noted this is not expected to affect NZ's supply. There is the ability to order more stock as needed and Pfizer has not communicated any issues with stock availability. **Medsafe Update:** • Have met with GSK (sotrovimab) and Novartis (ensovibep) • Sotrovimab: expecting an abbreviated application by end April • s 9(2)(b)(ii) [redacted] • Evusheld: Medsafe is expecting an application from AstraZeneca late March/early April. Company has indicated it will be an abbreviated application. • Molnupiravir (Lagevrio): Medsafe received additional information from sponsor on 18 March however there are still unresolved issues. Discussion: A Member noted the actions of Therapeutics TAG will be scrutinised. People are dying of COVID; there is need to put emphasis on the urgency of supply for NZ. Both PHARMAC and Medsafe agree with comment and are acutely aware of time sensitivity. Reassured the group that they are working to get supply into the country as soon as possible. **Airfinity/STA Update** • Key slides for drugs of interest have circulated around members – the key thing to note from this is the global supply shortage with Paxlovid however supply looks OK for NZ. • *Excerpt taken from 'Science and Technical Advisory Variants Update, 15 March 2022:* This document brings in data from neutralisation studies on casirivimab and imdevimab (Ronapreve) suggesting possible future use for BA.2. This is from the New England Journal of Medicine (NEJM). Discussion: A member noted the group needs to be mindful of the NEJM article. There is no evidence to suggest neutralising activity for BA.2. The article appears vague, conclusions drawn from this require more careful consideration before sharing.
3.0	**Equity Considerations** • Some technology issues with people learning how to log a RAT test result. Issues arising with patients not knowing how to log their test results. • Some RAT tests are returning false negative tests early in the illness meaning some patients who are eligible for Oral medication are missing out due to the 5-day window. • Budesonide stock is available locally however breakdown in communication has occurred; GPs being told not to prescribe this due to low stock. • It was noted Māori now have the highest COVID case rates, overtaking Pacific Peoples. This needs to be front of mind with guidelines, prioritising Māori and Pacific peoples when there is a limited supply.

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	• Rural communities that are prone to geographical isolation (from flooding etc.) need thought into how supply is maintained and managed. Action: Feedback to digital team re usability and availability of different instructions for logging RAT results specifically around having an instructional video available.
4.0	**Remdesivir Community Guidance** • Community advice became available yesterday. • Group sees the need for external guidance prioritising risk. • Information for this is largely sourced from overseas, data from NZ is only becoming available now. This will be used to prioritise medications coming into the country as well as learning who is high risk. Becoming progressively important to look at different subgroups with Māori being recognised as falling behind in health outcomes.
5.0	**Budesonide – Possible Update** • This has been brought up for discussion due to concern for supply. It was noted that the issue was more likely an issue with distribution and not supply. • Issues were noted with time constraints teaching patients to use a new inhaler device. Not always practical for non-English speakers or those who don't have internet access. With a limited workforce there are large time constraints, therefore there needs to be consideration of the practical benefit of use for those who are low risk. • It was noted by a member there was a lack of evidence for use of inhaled budesonide against Omicron in the general population. It was recommended to reduce the access criteria and target those at high risk of hospitalisation and/or partially/not vaccinated individuals. • A member noted that remdesivir and antivirals should be prioritised before budesonide for practicality and budesonide would be better suited to prescribe if a patient was to miss the window for antivirals/intravenous medications. • Noted it would be helpful for clinicians to have a clear set of criteria for prioritisation. Medications need a clear priority order. A risk table and guidelines for clinicians would be useful especially when oral medications arrive. It was mentioned a heat map would be useful and include ethnicity, vaccination status and age. • It was noted that once the access criteria are updated, the position statement should be updated from the original guidance to reflect the changes and their rationale. Actions: Elaine to revise the Position Statement on Budesonide Use and send to members.
6.0	**Nirmatrelvir/Ritonavir (Paxlovid)** • **Approach for Therapeutics TAG advice** A member noted Therapeutics TAG was not only for hospital guidance. Suggested the sub-group for more community focussed guidelines and include community guidelines into physical statements. There will be further work between the Ministry and PHARMAC for clinical access and guidelines. Need national subject expertise to guide content for the national health pathways. Therapeutics TAG is a good place for this. Therapeutic TAG is interested to move towards integrated community guidance. In the short-term Therapeutics TAG is to support resources being developed elsewhere for Paxlovid. Making sure the information being produced is consistent and reflects consensus of health pathways. • **Update - Information for public (eg. Health Navigator)** Health navigator currently creating information for consumers around Paxlovid. Health Navigator is asking for expert advice on content.

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	It was noted advice around pregnancy and contraception from Health Navigator was quite complex and could possibly be over messaging. A member asked if the Ministry was able to produce the infographic for Paxlovid start of April. It was noted by the Ministry that there may be capacity issues to meet the deadline. Ministry to look into using external contractors that use Visio to develop infographics. Pharmac has commissioned He Ako Hiringa to produce information on Paxlovid to supply to general practitioners. There is currently no simple tool for managing ritonavir drug interactions. The Ontario brief will be circulated to members. This document includes advice from 20 pharmacists although not all medications available in NZ are represented. This will be the advice that will go out pending approval from the Ministry and Pharmac. Action: Justine to send around Health Navigator advice on pregnancy and contraception to members for comment. Action: Ministry to look into using external contractors that use Visio to develop infographics.
7.0	**Guideline Updates** Guideline updates are being prepared and are due 1 April. Expecting changes will need to be made to the document after publication to include antivirals. The Ministry has had further communication surrounding the infographic for the update. It is possible for this to be done as a one off and could look to external contractors for use of Visio. A Member has created an infographic with the support of the members will be published in the next update on 1 April. Risk stratification for timing from second vaccination needs to be asked in COVID-19 Vaccine TAG. Need to know someone's risk depending on time from second vaccine dose. Member asked group if there are other members wanting to lead guideline discussion to please get in touch in the following month. Sharing this workload would be beneficial for capacity constraints of members. Action: Update due 1 April Action: Bring question on risk and timing from second vaccination to COVID-19 Vaccine TAG for input.
8.0	**Any Other Business**
9.0	**Agenda Items for Next Meeting**
Meeting closed at **2:38pm** Next meeting **08 April 2022 – 1:30pm to 2:30pm**	

Open Actions:

#	Agenda item	Action	Action Owner	Updates
5	Guideline update	Review update and publish revised guideline	Tim Cutfield/STA	17/09 – Action raised Guideline update published 5/11/21

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		12/11/21 Guideline update to be brought forward and prepared within 2 weeks if possible to provide guidance on baricitinib use - aligning with arrival of baricitinib supply. 26/11/21 Next guideline update planned for 3 December 2021. 10/12/21 Next planned update 21 January 2021 1& 4/2 22 Guideline updated with Ronapreve content Next update due 01/04/22		Guideline update published 22/11/21- including guidance on baricitinb Guideline update published 3/12/21 Guideline update published 21/01/22 Next update 01/04/22
26	Equity Considerations	Feedback to digital team re usability and availability of different instructions for logging RAT results specifically around having an instructional video available	Justine	25/03/22 Action raised
27	Nirmatrelvir/Ritonavir (Paxlovid)	Send Health Navigator advice on pregnancy and contraception to members for comment.	Justine	25/03/22 Action raised
28	Nirmatrelvir/Ritonavir (Paxlovid) & Guideline Updates	Ministry to look into using external contractors that use Visio to develop infographics.	STA	25/03/22 Action raised
29	Guideline update	Bring question on risk and timing from second vaccination to COVID-19 Vaccine TAG for input.	STA	25/03/22 Action raised STA progressing with Vaccine TAG

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Closed Actions:

#	Agenda item	Action	Action Owner	Updates

21	Sector communications – therapeutics update	STA and Clinical Chief Advisor (Pharmacy) to organise sector communication update on therapeutics. 11/2/22 Draft has been developed and is to be circulated to Members for further review. 25/02/22 – Final document circulated with agenda. Updated Ronapreve content added with Chair sign off. 28/2/22 Published on the Ministry health professional website with comms notifications to sector.	STA	28/1/22 Action raised. 28/2/22 Action closed.
22	Memo on potential for Ronapreve use in community	Chair and STA to prepare a Memo to COVID Care in the Community team about potential Ronapreve use 25/02/22 Confirmed at the meeting that this memo not needed due to Omicron predominating.	Chair/STA	11/2/22 Action raised 25/02/22 Action closed
23	ESR request for WGS reporting	Request for wider distribution of ESR WGS geographical reporting to support treatment decisions about Ronapreve 25/02/22 ESR was contacted, and regular circulation of reports has begun.	Chair	11/2/22 Action raised 25/02/22 Action closed
20	Paxlovid – in the context of Omicron	Preparation of guidance for primary care and pharmacists on use of Paxlovid, including interactions and appropriate patient management. 8/3/22 Liaising with Pharmac about potential third party production of appropriate prescriber/patient information.	Clinical Chief Advisor (Pharmacy)	28/1/22 Action raised. 11/3/22 Pharmac overseeing prescriber resource in development. Due for completion 1/4/22. 11/3/22 Action closed.

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30	Budesonide – Possible Update	Update the Position Statement on Budesonide Use and send to members.	Elaine	25/03/22 Action raised 01/04 Posted. Action closed

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