

# Briefing

## COVID-19 Therapeutics supply management

<b>Date due to MO:</b>	3 September 2021	<b>Action required by:</b>	N/A
<b>Security level:</b>	IN CONFIDENCE	<b>Health Report number:</b>	20211968
<b>To:</b>	Hon Chris Hipkins, Minister for COVID-19 Response Hon Andrew Little, Minister of Health		
<b>Copy to:</b>	Hon Ayesha Verrall, Associate Minister of Health Hon Peeni Henare, Associate Minister of Health Hon Aupito William Sio, Associate Minister of Health		

### Contact for telephone discussion

Name	Position	Telephone
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### Minister's office to complete:

- |   |                                    |  |
|---|------------------------------------|--|
| <input type="checkbox"/> Approved             | <input type="checkbox"/> Decline   | <input type="checkbox"/> Noted               |
| <input type="checkbox"/> Needs change         | <input type="checkbox"/> Seen      | <input type="checkbox"/> Overtaken by events |
| <input type="checkbox"/> See Minister's Notes | <input type="checkbox"/> Withdrawn |  |

Comment:

# COVID-19 therapeutics supply management

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**Security level:** IN CONFIDENCE      **Date:** 2 September 2021

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**To:** Hon Chris Hipkins, Minister for COVID-19 Response  
Hon Andrew Little, Minister of Health

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## Purpose of report

1. This report describes management of medicines supply for treatment of COVID-19 in light of heightened risks and pressures, and additional measures being developed to proactively manage access to therapeutics now in development.
2. This report discloses all relevant information and implications.

## Summary

3. Continuity of supply for medicines used to treat COVID-19 is at heightened risk globally, with one of the few treatments for moderate to severe COVID-19, tocilizumab, in limited supply from now until January 2022.
4. Though the path of the current Auckland outbreak is uncertain, modelling suggests that the number of people hospitalised with COVID-19 over the course of the outbreak is likely grow to between 120 and 280. The majority of these people are likely to meet clinical guidelines for use of tocilizumab, and potentially other therapeutics.
5. Based on these projections, it is uncertain whether supplies of tocilizumab will be sufficient for treatment of all hospitalised people with moderate to severe COVID-19 over the current outbreak as well as for continued treatment of people with severe autoimmune conditions who would not tolerate changing treatments. People who have options other than tocilizumab for autoimmune conditions will likely have changes to treatment until additional supplies are available.
6. Pharmac is working with:
  - Roche Pharmaceuticals and wholesalers to identify any possible avenues to secure further tocilizumab supplies
  - suppliers of COVID-19 treatments to identify available alternatives to tocilizumab
  - suppliers to source alternative treatments for those with autoimmune conditions
  - clinical groups to determine criteria for allocation of existing stock
  - the sector to redirect stockholdings to where needed for COVID-19 treatment.
7. The Ministry is working with the sector, a therapeutics technical advisory group, Te Pūnaha Matatini and Pharmac to understand likely treatment needs as the outbreak continues and to ensure treatment guidance adapts for optimal use of therapeutic

products and available supply. Advice on emerging therapeutics is also being considered on a weekly basis by the therapeutics technical advisory group.

8. Supply issues with COVID-19 therapeutics will be inevitable with the greater impacts of the Delta variant across the world. Active anticipatory and responsive approaches have been put in place to manage COVID-19 supplies including supplies for treating and managing COVID-19. Nevertheless, additional measures may be needed in view of the challenges and equity concerns, especially for Pacific people, becoming evident in the current outbreak.
9. The Ministry is examining additional measures to bolster future supplies, both in the near term for this current outbreak and in the longer term with Reconnecting New Zealanders and ongoing response to changes through the pandemic.

## Recommendations

We recommend you:

- a) **Note** that supplies of tocilizumab are being reserved mainly for COVID-19 patients and are likely to be exhausted over the course of the current outbreak ☒ Yes / No
- b) **Note** that officials are working rapidly to ensure optimal use of current supplies and to investigate any sources of further supplies, including supplies of alternative treatments, during 2021 ☒ Yes / No
- c) **Note** that Pharmac will update you on progress with supply management and use of tocilizumab and alternative treatments during the Auckland outbreak, by mid-September ☒ Yes / No
- d) **Note** that the Ministry will provide advice on additional measures to proactively manage supply of future COVID-19 therapeutics by the end of September. ☒ Yes / No



Ashley Bloomfield

**Te Tumu Whakarae mō te Hauora**  
**Director-General of Health**

Date:

2/9/21



Hon Chris Hipkins

**Minister for COVID-19 Response**

Date: 7/9/2021

NZ needs to be a "fast mover" in this space as evidence of the effectiveness of new therapeutics starts to emerge. If we need to adopt a portfolio based APA process as we did with vaccines we could consider that? CH

Hon Andrew Little

**Minister of Health**

Date:



# COVID-19 therapeutic products supply management

## Background / context

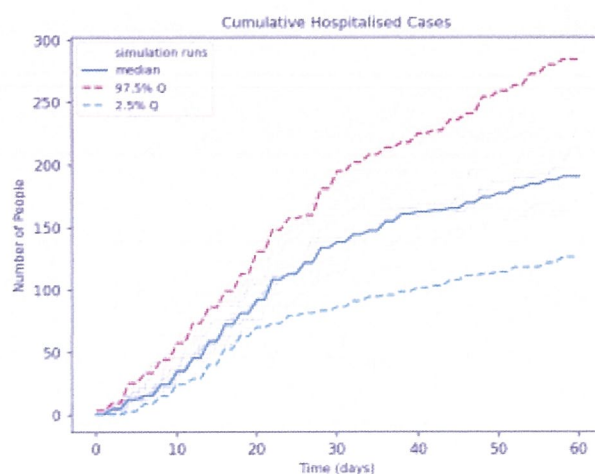
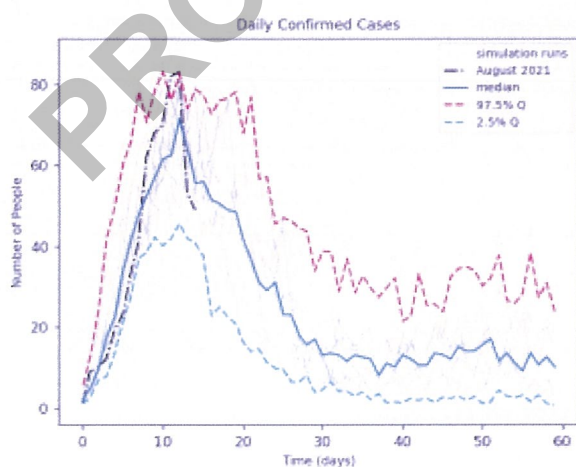
1. Supply constraints have been a feature of the pandemic with massive global demand for therapeutic products, medicines and medical devices including PPE equipment.
2. With the Delta variant now dominant across the world, rising hospitalisations, even in countries that have achieved reasonably high vaccination, have massively increased demand. This is particularly so for products recommended by the World Health Organization (WHO), who publish regularly updated guidance <https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2021.2>
3. Good supplies are available in New Zealand for most therapeutic products and equipment for the COVID-19 health system response (including PPE, ventilation equipment and devices, consumables, testing kits). However, supplies of some medicines, particularly those recommended for treatment of COVID-19 disease in hospital care, are vulnerable.
4. An overview of COVID-19 therapeutic agents is attached.

## Current Auckland outbreak and likely hospitalisation and treatment needs

5. As predicted for the Delta variant, the current COVID-19 outbreak in Auckland is much faster growing than the previous Auckland outbreak of August 2020.

## Te Pūnaha Matatini modelling

6. Modelling by Te Pūnaha Matatini has suggested the current outbreak is likely to result in somewhere between 120 and 280 hospitalisations over the coming six weeks or so. This high range is partially driven by the high numbers of Pacific people affected by the outbreak. Pacific communities include higher numbers of people at heightened risk of more severe COVID-19, with up to three times the likelihood of needing hospital care.
7. Preliminary modelling charts below show rough ballpark estimates for COVID-19 case incidence and projected hospitalisations. If case numbers fall more slowly than projected, hospitalisations could exceed these projections. Note these are early estimates and will be updated as input data and modelling assumptions are refined.



## **Treatment and care**

8. Clinical guidance for COVID-19 treatment in New Zealand is based on international best practice and draws on "living guidance" regularly updated by WHO and health authorities in Australia, the UK, US and others.
9. Treatment of milder COVID-19 is supportive with close monitoring, as no prevention or early intervention treatments are yet established. Care for hospitalised patients in New Zealand is informed by the Counties Manukau Health treatment guideline which is being used as a basis to develop nationwide guidance.
10. All guidance will continue to require frequent updates as evidence on effective clinical management emerges.

## **Medicines currently used for treatment**

11. Treatment options already available and being used in New Zealand include dexamethasone, tocilizumab, remdesivir and budesonide.
12. Dexamethasone and budesonide are readily available, as they are funded for other conditions. Stocks of remdesivir are available, and Pharmac is working with the supplier to secure further stock in case it is needed for the current outbreak.

## **Equity**

13. People living in New Zealand who are at highest risk of more severe COVID-19 disease and poor outcomes include those who are older and/or have multiple or serious health conditions, especially where they are also living in crowded conditions, have a high number of close contacts with others and/or have contacts with people at heightened risk of COVID-19 through their work.
14. Pacific communities are at especially high risk – 18% of cases to date have been of Pacific ethnicity, and this unadjusted incidence does not take into account prior travel, age structure in the population or severity. It appears likely that, of people living in New Zealand, Pacific communities are at highest risk of poor outcomes from COVID-19 disease. Māori are also at risk.
15. Prevention of COVID-19 through continued public health measures and vaccination, along with community engagement and the provision of financial, housing, business, employment and social support that enable adherence to these, remain the most important promoters of equitable health outcomes through the pandemic.

## **Supply management**

16. Pharmac is actively managing supplies of COVID-19 therapeutics to promote best practice management of patients needing COVID-19 treatment and assure access.

## **Current supply shortage - Tocilizumab**

17. The Minister of Health received an urgent no surprises update from Pharmac on Friday 27 August, for an upcoming shortage of tocilizumab (Actemra®, Roche Pharmaceuticals). Roche NZ had previously assured Pharmac of continuity of supply (for arthritis patients) up until 19 August when Roche suspended global supply to New



Zealand. Roche predicted that New Zealand would be out of stock for three months beginning in October, based on prior usage patterns.

18. Tocilizumab is an immune modulator used to treat certain forms of arthritis and other autoimmune conditions, and also now a widely used COVID-19 treatment since it received Emergency Use Authorisation from the United States FDA in June 2021 and a strong recommendation for use by WHO in July 2021. Prior to the current outbreak, it had been used for treatment of three COVID-19 patients in New Zealand; since the outbreak more than 18 patients had received it by earlier this week.
19. Given that the Roche decision was made just as the Auckland outbreak was starting, Pharmac has been discussing supply for COVID-19 treatment with Roche NZ, without success so far. Roche advised its decision was made in response to high global demand despite doubled production.

### **Action to manage tocilizumab supplies**

20. Pharmac is working closely with Roche and DHB hospitals to manage supply allocation of tocilizumab to enable use for the treatment of COVID-19. This week, Pharmac has sought advice from relevant experts about possible alternative treatments for current patients on tocilizumab and measures to preserve the remaining stock. Following that, Pharmac will advise clinicians prescribing tocilizumab to their patients of the shortage and share the advice from their experts
21. Pharmac is working with Roche Pharmaceuticals and wholesalers to identify any possible avenues to bolster New Zealand's tocilizumab supply for use in COVID-19 treatment in the current outbreak.
22. Pharmac is also working with suppliers of alternative COVID-19 treatment products to identify and assess suitability of treatments and access supplies, and with the sector to redirect stockholdings to where needed for COVID-19 treatment.
23. Pharmac is working with clinicians to consider alternative treatments for patients using tocilizumab for arthritis and other autoimmune conditions, to free up tocilizumab for Covid patients.
24. The Ministry is working with the sector and Te Pūnaha Matatini to understand likely treatment needs during the current Auckland outbreak. Modelling early in the outbreak suggested that more than 80 people were likely to be hospitalised, this has now been revised upwards. As most will be in quarantine as symptoms emerge, early recognition of worsening symptoms will enable prompt treatment to be used.
25. The Ministry and Pharmac are working to:
  - regularly update emerging evidence and guidance in light of supply constraints
  - ensure treatment guidance adapts to reflect optimal use of therapeutic products as demand and supply shifts in the pandemic.

### **Longer term management of COVID-19 therapeutics supply**

26. Globally, development efforts for COVID-19 treatments have been significant with firm clinical use recommendations now emerging. Though attracting perhaps one 20<sup>th</sup> of the international investment seen in vaccine development, much research is underway into preventive, early interventive and especially severe COVID-19 treatment.

27. A range of pharmaceuticals have been trialled with some popularised substances found to be ineffective or actually harmful (eg, hydroxychloroquine, certain antivirals, ivermectin). Increasing numbers of products are in or have completed phase 3 clinical trials and are now being conditionally approved by medicines regulators.
28. As new products become established and recommended by authorities, demand can be predicted to grow rapidly and supply shortages to occur as is being seen with tocilizumab. The Ministry is working with Pharmac, the sector and other governments to proactively consider and manage options for ongoing COVID-19 therapeutics supply.
29. Of particular interest will be preventive and early interventive treatments to slow or halt progression of COVID-19 symptoms, lowering severity and hospitalisation needs. One example is an oral antiviral medicine being developed by Pfizer to prevent progression of COVID-19 – phase 2 trials on lower risk patients started this week.
30. See the attachment for more detailed information on COVID-19 therapeutics that are further through clinical trials and for which evidence is becoming firmer.

### **Current management approach for emerging therapeutics**

31. The current management approach involves:
- horizon scanning and initial product assessment by the Ministry's COVID-19 Science and Technical Advisory team on a rolling basis, to synthesize emerging evidence on therapeutic products in development
  - review of emerging evidence and potential for clinical use in New Zealand by the Ministry's therapeutics technical advisory group
  - review of evidence on the risks, benefits, efficacy and safety of therapeutic products with potential use in New Zealand by Pharmac, with Medsafe input as required, to clinically evaluate treatments, make funding decisions and determine access criteria
  - supply chain facilitation and contract management by Pharmac, using COVID-19 funds to acquire supplies for clinical use in New Zealand, keeping Medsafe informed and involved and working with suppliers to ensure regulatory obligations are met
  - providing up-to-date clinical guidance on use of therapeutics informed by the Ministry's therapeutics technical advisory group.

### **Expert advice**

32. The Ministry has established a COVID-19 Therapeutics Technical Advisory Group (COVID-19 Therapeutics TAG) to provide expert technical advice on therapeutics for use for patients with COVID-19 including:
- identifying therapeutics which may be beneficial in the management of COVID-19 through horizon scanning activities
  - providing advice to Pharmac on what therapeutics to consider
  - developing appropriate guidelines for clinical use.
33. Pharmac is also establishing an expert advisory group to evaluate clinical evidence and provide evidence-based recommendations on COVID-19 therapeutics and how their use can be optimised for New Zealand. Pharmac's role is to clinically evaluate treatments,



make funding decisions, and determine access criteria for COVID-19 therapeutics, as well as procure supply.

### International approaches

34. The WHO Access to COVID-19 Tools Accelerator (ACT-A) supports global access to treatments for COVID-19 through research (including research in developing countries), analysis, assessment and guidance as development progresses, and a global fund which has provided oxygen and dexamethasone across the developing world.
35. Several countries have established taskforces to promote development, production and supply of therapeutics, similar to their vaccine taskforces. For example, the UK assembled a COVID-19 therapeutics taskforce early in the pandemic to co-ordinate research on the use of safe and effective therapeutics as well as the end-to-end production and provision of treatments for COVID-19 across the UK.
36. Australia has established a 'National COVID-19 Clinical Taskforce' made up of clinical experts who regularly evaluate evidence and provide up-to-date evidence-based recommendations to guide care of people with COVID-19. Australia is now negotiating advance purchase arrangements with suppliers of promising therapeutics.

### Potential additional approaches for New Zealand

37. Early in the pandemic it was hoped that a full elimination strategy would minimise the direct impacts of COVID-19 until immunity could be achieved through vaccination. A rapid response adaptation of Pharmac's standard processes, with additional COVID-19 response funds and partnerships, was put in place to source the needed supplies of therapeutic products. Pharmac is part of the cross-sector critical supply monitoring group and has worked with specific suppliers of critical care medicines to build additional stock in New Zealand and develop processes to rapidly deal with emerging supply issues.
38. Now, with the emerging information about the delta variant and vaccine efficacy, it appears that numbers of people requiring treatment for COVID-19 will be higher than previously thought. A more active interventionist approach is now being taken to ensure supplies of therapeutics will be available, especially once further changes to QFT and isolation requirements occur with Reconnecting New Zealanders.
39. The Ministry is working with Pharmac and MFAT to identify options for more actively accessing therapeutics supplies for treating COVID-19 in New Zealand.
40. Options being explored include:
  - Enhancing sponsorship of the engagement of New Zealand clinicians and researchers in treatment **clinical trials** – while patient recruitment limited by low numbers of patients in New Zealand through much of the pandemic, New Zealand clinical and research leads have been actively engaged and their contributions could be a platform for increasing attention and engagement, including at earlier stages in product development
  - Intensifying the current approach to actively **facilitate entry** to New Zealand of products newly evidenced and approved internationally that have clinical support for use (within or outside clinical trials)



- Increasing active interest **signals for suppliers** with products in development – how best this could proceed would require careful judgment about the strength of signals, a focus on development and clinical goals rather than commercial, and positioning the lead so as to protect the benefits of Pharmac's established relationships and/or MFAT's global head office connections and preserve attention to meeting current supply chain challenges during the pandemic
- Building **closer international liaison** with other countries' Health ministries, therapeutics taskforces, regulators and purchasers, and clinical guidelines groups
- Building on these more active international links, including research, clinical, regulator and supplier links to promote **collaborative approaches to managing supply** of therapeutics
- Examining the potential for **pooled advance purchase opportunities**, both multilateral (similar to what the COVAX Facility is providing for vaccines) and potentially bilateral (such as negotiating arrangements with a larger advance purchase partner).

### Next steps

41. Pharmac will update you on progress with supply management and use of tocilizumab and alternative treatments during the Auckland outbreak, by
42. The Ministry will provide advice on additional measures to proactively manage supply of future COVID-19 therapeutics by the end of September.

ENDS.