

5 November 2021

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M.R.M

By email: fyi-request-17220-42e2cd75@requests.fyi.org.nz

Ref: H202114645

Tēnā koe M.R.M

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 17 October 2021 for information relating to COVID-19.

On 26 October 2021, the Ministry contacted you to clarify what you referred to when you mentioned "government" in your request. You replied saying that it is in relation to what Professor Kurt Krause meant when he said he wrote to the "government", assuming he tried to obtain information from Director-General of Health, Dr Ashley Bloomfield.

Each part of your request is responded to below:

1) Why RNZ's requests to the Ministry of Health - over a period of two weeks - in early August 2021 about monoclonal antibodies did not receive a response?

The Ministry endeavours to provide information to reporters through direct responses and interviews to reporters in response to their questions. To help ensure a good flow of information to reporters during times of intense public interest relating to the pandemic response, the Ministry participates in daily media briefings. During the two-week period referred to by the requestor, Dr Bloomfield, or the Director of Public Health, Dr Caroline McElnay, attended 12 media conferences where they were able to respond to queries from any media. This included Radio New Zealand, on any COVID-19 or health related topics, including access to new treatments for COVID-19. Dr Bloomfield provided the following information at the stand-up on 15 September 2021:

'And so, on to an update about treatments for COVID-19 in New Zealand. Yesterday, I noted my warning about potential misuse of ivermectin, which hasn't been shown to be safe or effective for the treatment of COVID-19. However, even though there have been relatively few cases in New Zealand, we are up to date in terms of our knowledge and use of appropriate treatments. We have good processes in place to assess emerging and new treatments, and a fast and proven approval process when we decide on which ones we want to use here.

Just a note on how the main medications and treatments for COVID-19 work. COVID-19 infections cause two major issues in people. First of all is the viral attack on the body, and the harm that causes in and of itself, and the second is that in some cases, the virus can trigger an immune reaction, which can cause further problems.

So new treatments are now being investigated and, indeed, used to cover both these areas, and they concentrate on three domains. First of all, antiviral drugs that limit the ability of the

virus to replicate and thrive in the body—an example here is remdesivir, which has been used for quite a while internationally and is being used in New Zealand.

There are then, secondly, medicines that calm the immune system overreaction that is prompted in some patients, particularly those who end up very unwell and in ICU—an example here is dexamethasone, which is a standard and widely used steroid and it's been part of our routine treatment protocols here for some time, for people who are very unwell in ICU.

And then, third, there are antibody treatments that help the body fight the virus. Studies have shown that one of these, a monoclonal antibody called tocilizumab may help hospitalised patients by reducing the severity of their infection and the length of time they require in hospital. Pharmac recently completed consulting with clinicians on funding tocilizumab for the treatment of moderate to severe COVID-19 in New Zealand; they will make a decision soon about its ongoing funding, but, in the meantime, it has already been used and funded by Pharmac for treatment in more than 30 patients through an exceptions-based process. There are several other monoclonal antibodies in trials, or approved overseas under emergency authorisation, and Pharmac is actively discussing those with the manufacturers and suppliers. Two new treatments are showing the most promise. The first is Ronapreve. which is showing benefit in the early treatment of COVID-19 and can help cases from developing. It complements rather than replaces vaccination, as all these treatments do. An application has been made to Medsafe in the last couple of weeks, and the UK counterpart of Medsafe has actually approved that treatment in the UK. Medsafe is looking at all the evidence to see if this is a medication we will want to use in New Zealand, and then Pharmac will move on the funding on it.

A second promising monoclonal antibody treatment is sotrovimab. This is another one that is similar to Ronapreve, and it complements rather than replaces vaccination. Some good data coming through from evidence in trials, and Medsafe has not yet received an application. However, the ministry is engaging with Pharmac to already explore potential supply options and encourage an application for approval through to Medsafe.

In the meantime, any of these medications can be prescribed by a doctor if they are indicated and if available here. Even if there's not an approval through Medsafe, they can be prescribed off-label. We have a technical advisory group of clinicians who meet weekly, since late August, and it's providing updated advice to us all the time on emerging treatments.'

2) Why University of Otago professor Kurt Krause, an infectious diseases doctor who wrote to the government to try and find out where we are in the process with monoclonal antibodies, also did not receive a response?

The Ministry has searched through the Director-General's inbox and found no emails from Professor Krause within scope of your request.

3) Why the government has not moved, and fast, on making available to Covid-19 infected patients with risk factors for disease progression at least one monoclonal antibody for use in NZ when Kurt Krause described this treatment as "a game changer" and "extremely important that we acquire this as soon as possible"?

Medsafe has received an application for Roache's monoclonal antibody product *Ronapreve*. This is currently under evaluation.

Medsafe is New Zealand's medicines safety authority and while a business unit of the Ministry, undertakes its evaluation of applications for new medicines independently. It robustly assesses all medicines to ensure they meet international standards and local requirements for quality and safety. If you would like to check the approval of any COVID-19 vaccines in New Zealand, you can do so on Medsafe's website at:

<u>www.medsafe.govt.nz/COVID-19/status-of-applications.asp</u>. Information about the medicine evaluation process can also be found at:

www.medsafe.govt.nz/consumers/safety-of-medicines/medsafe-evaluation-process.asp.

4) When is the government and/or Pharmac going to announce that at least one monoclonal antibody will be available, fully funded, for the benefit of all New Zealanders who need this potentially life-saving treatment?

This part of your request is refused under section 9(2)(f)(iv) of the Act, to maintain the constitutional conventions for the time being which protect the confidentiality of advice tendered by Ministers of the Crown and officials. Information about monoclonal antibodies can be found at:

https://www.health.govt.nz/system/files/documents/pages/csu 09 july 2021 covid-19 pharmaceutical treatments.pdf.

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

Nick Allan

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