

3 November 2021

M.R.M.

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Ref: H202114662

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) on 19 October 2021. Your requests have been consolidated under section 18(A) of the Act.

- 1. Has Medsafe approved the safety and efficacy of Novovax vaccines? If not, what progress has been made in this area, and, when is this likely to happen?*
- 2. What are the delivery timeframes of Novovax vaccines currently?*
- 3. Has consideration been given to the use of Novovax vaccines in New Zealand, and if so what decision has been reached and the reasons for that.*
- 4. Has a decision been reached not to use Novovax vaccines in New Zealand, and if so what are the reasons for that.*
- 5. Has a decision been reached not to use Novovax vaccines in New Zealand, and what are the consequences of agreeing to purchase 10.72 million doses ... in particular will there be penalties payable for breaching the agreement by withdrawing from or cancelling the agreement?*

This vaccine is not currently approved for use in New Zealand. Medsafe is New Zealand's medicines safety authority and it robustly assess all vaccines 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 here: <https://www.medsafe.govt.nz/COVID-19/status-of-applications.asp>.

As noted on the website, Medsafe is currently assessing the application for the Novavax vaccine with some data under evaluation and further data to be provided by the sponsor. We recommend that you continue checking the link above for further updates.

Once approved, Cabinet then considers advice and makes decisions on when and for who a particular vaccine will be used as part of the COVID-19 immunisation programme. If or when Cabinet approves a 'decision for use', this would determine how the Novavax vaccine would be used in New Zealand. If the Novavax vaccine is regulated for use by Medsafe, and Government decides to use this vaccine in New Zealand, we expect Novavax delivery in early 2022.

- 6. Noting that it was also disclosed that New Zealand has bought enough vaccines for the Cook Islands, Niue, Tokelau, Sāmoa, Tonga, and Tuvalu, and if a decision has been*

reached not to use Novovax vaccines in New Zealand, will the abovementioned agreement be honoured by the New Zealand government through providing one or more of the aforementioned countries with Novovax vaccines, and, if so what are the reasons for that?

New Zealand has purchased a portfolio of COVID-19 vaccines from four suppliers: Pfizer, AstraZeneca, Janssen, and Novavax. New Zealand has offered access to our vaccine portfolio for the Realm nations and territories (Cook Islands, Niue and Tokelau) and Sāmoa, Tonga and Tuvalu. The Realm nations and territories and Samoa and Tonga have requested Pfizer vaccines. While a request for the Novavax vaccine has not been received, there is still the option for countries to request alternative vaccines from other donors to complement their existing roll out plan. New Zealand officials are working closely with their counterparts in these nations to understand the support they need from New Zealand and will respond accordingly. As noted above, Novavax has started to submit an application to Medsafe for its COVID-19 vaccine. Medsafe is reviewing the data and is waiting for further information from the company. For further updates you can refer to this page: <https://www.medsafe.govt.nz/COVID-19/status-of-applications.asp>.

7. What is the cost to New Zealand of buying enough vaccines for the Cook Islands, Niue, Tokelau, Sāmoa, Tonga, and Tuvalu? Please provide the fullest possible answer with cost breakdowns and giving me complete disclosure of financial estimates, actual costings, etc.

New Zealand has earmarked \$65 million in Official Development Assistance in vaccine access and rollout, ensuring enough vaccines and support can be provided to cover the Realm and Polynesia and; and ensuring support to other countries in the Pacific with access to vaccines along with Australia and other partners in the region. Your request for cost breakdowns is refused under section 9(2)(j) of the Act, to enable a Minister or any public service agency to carry on negotiations without prejudice or disadvantage (including commercial and industrial negotiations).

8. Why is New Zealand responsible for buying vaccines for the Cook Islands, Niue, Tokelau, Sāmoa, Tonga, and Tuvalu when our health workers have had a 3 year moratorium placed on salary increases, the cost of living in New Zealand is robbing people of their hard-earned income and leaving many families hungry, and, - in my opinion - we need to take care of our own before we take care of anyone else? Again, please provide the fullest possible answer with cost breakdowns and giving me complete disclosure of financial estimates, actual costings, etc.

New Zealand is best placed to support these countries directly because of our constitutional relationships and the especially strong links between our health systems, our close people-to-people ties and builds on the technical support New Zealand has provided throughout the pandemic.

The Cook Islands, Niue and Tokelau are constituent parts of the Realm of New Zealand, with the Cook Islands and Niue being self-governing in free association with New Zealand. All residents of the Realm are New Zealand citizens. New Zealand has a Treaty of Friendship with Samoa which requires the New Zealand Government to “consider sympathetically requests from the Government of ... Samoa for technical, administrative and other assistance.” The Treaty is publicly available at: www.treaties.mfat.govt.nz/search/details/t/609.

if Novovax will not be made available as aforementioned, then will it be possible for those who want it as a first and second dose Covid-19 vaccination to self-fund this treatment? If not, why not,, and, what would the likely cost of it be per vial if this is to be an option?

As advised above, a decision regarding Novavax is still being assessed. Medsafe approval is one step in the process for accessing a COVID-19 vaccine. Once approved, Cabinet then considers advice and makes decisions on when and for who a particular vaccine will be used as part of the COVID-19 immunisation programme. If or when Cabinet approves a 'decision for use', this would determine how the Novavax vaccine would be used in New Zealand.

I want to know what caused such a radical change as to bring the Government to recently decide it is now mandatory that teachers and workers in the health and disability sectors be fully vaccinated as a condition of their employment (when most if not all of the Individual and Collective Employment Agreements in New Zealand do not require this as an health and safety related employment term and condition).

can you please advise me which law or laws in New Zealand compel people to undergo Covid-19 treatment to address a public health issue but which recognizes and upholds the right to consent or not to such treatment?

what is the Government's position in relation to the punitive measure for non-compliance which has and will continue to see workers being fired from their jobs for simply exercising their Bill of Rights Act endorsed right not to receive medical treatment by declining to have a Covid-19 vaccination?

The Health Act 1956 provides for situations where persons may be directed to undertake health treatment or otherwise be subject to restrictions when they have, or are believed to have, a notifiable disease such as COVID-19. In addition, Orders made under the COVID-19 Public Health Response Act 2020, such as the COVID-19 Public Health Response (Vaccinations) Order 2021, may require persons to undergo vaccination or other medical treatment relating to COVID-19.

All Orders made, including the COVID-19 Public Health Response (Vaccinations) Order 2021, are made with regard to the New Zealand Bill of Rights Act 1990 (NZBORA). Under NZBORA, rights may be subject to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society, such as supporting requirements for vaccination where this is necessary for public health.

- 1. On what date did the Pfizer Covid-19 and the BioNTech vaccine clinical trials end?*
- 2. If the Pfizer Covid-19 and the BioNTech vaccine clinical trials have not yet ended, on what date will they end, or, on what date will they likely end?*
- 3. If the Pfizer Covid-19 and the BioNTech vaccine clinical trials have not yet ended, did Pharmac nonetheless approve their use in New Zealand, and if so under what conditions did this happen?*

Pfizer clinical trial data can be found on their website here:

<https://www.pfizerclinicaltrials.com/find-a-trial?search=Coronavirus,COVID-19&distance=1000&age=7>.

- 4. If the Pfizer Covid-19 and the BioNTech vaccine clinical trials have not yet ended, this would mean that they are still in the experimental phase of development. In such circumstances, and with the Government having taken on the liability of claims that may*

arise from use of the Pfizer and BioNTech vaccines, what laws, regulations, rules, guidelines etc. make it the responsibility of the Accident Compensation Corporation to accept cover of injuries that are in all probability caused by vaccines that have a) not been fully and properly trialed and b) are still in the experimental phase of development?

The vaccine is not experimental. It has been granted provisional consent under section 23 of the Medicines Act 1981. Please refer to the approval process page on the Medsafe website above.

Please note that on 28 October 2021 Medsafe renewed the provisional consent for the Pfizer Comirnaty COVID-19 vaccine. All conditions that have been met to date have been removed from the renewed consent. For more information see www.medsafe.govt.nz/COVID-19/status-of-applications.asp. Medsafe also issued a media release on this: www.health.govt.nz/news-media/news-items/medsafe-renews-covid-19-vaccine-provisional-approval.

It is not unusual for companies to run clinical trials for approved vaccines. There are lots of approved medicines that have ongoing trials for new indications.

In any case, any treatment harm caused by COVID-19 vaccination is covered by Accident Compensation Corporation if the criteria are met. There is more information at: www.acc.co.nz/covid-19/providers/general-covid-19-provider-information.

New Zealand operates a no-fault accident compensation system, there is no requirement to indemnify employers and/or healthcare providers. ACC provides assistance and cover in these situations: www.covid.immune.org.nz/faq/will-acc-provide-cover-covid-19-vaccination-injuries.

I trust this fulfils your request. 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.

Nāku noa, nā



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