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

s 9(2)(a)

By email: s 9(2)(a)
Ref: H202202872

Tēnā koe s 9(2)(a)

Response to your request for official information

Thank you for your requests under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 22 February 2022. As advised, your requests have been consolidated under section 18(A)(2) of the Act. You requested the following:

> *What is the MoH's definition for the term: 'suitably qualified specialist'?*
>
> *As noted in communications from the Covid-19 Temporary Medical Exemptions Team on the 22nd of February: "[You must supply clinical evidence from a suitably qualified specialist as to why a vaccine cannot be given or a suitable alternative cannot be used]*
>
> *The FINAL version of the 'Vaccine Temporary Medical Exemption Clinical Criteria, Clinical Guidance and Resources' document was replaced and the most recent one appears to be the 'Vaccine Temporary Medical Exemption Clinical Criteria, Clinical Guidance and Resources' Version 4.*
>
> *The information I request please is the evidence and information used as the basis to remove ME/CFS from this document.*

The Ministry established a temporary medical exemption panel (the Panel) to receive and consider applications for a temporary medical exemption (TME) from being vaccinated against COVID-19. The most up to date information regarding the TME process, including the most recent version of the Vaccine Temporary Medical Exemption Clinical Criteria can be found here: https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-response-planning/covid-19-mandatory-vaccinations/covid-19-exemptions-mandatory-vaccination#temp-exempt

A TME is granted if the application is deemed to meet the exemption category criteria. Each application is considered carefully according to the supporting medical evidence. A recommendation is presented to the Director-General of Health, who then notifies the applicant of the outcome of his decision.

Under certain categories, evidence is required in the form of support from a medical specialist within the relevant scope of practice. For example, under category 2 where a *'letter of support from the medical specialist within the relevant scope of practice.'* is required, the term '*suitably qualified specialist*' requires that information be provided by an Immunologist.

The TME criteria are prepared on the basis of advice from the COVID-19 Vaccine Technical Advisory Group (CV TAG), a body which provides science and decision to use advice to the National Immunisation Programme. The Ministry has identified one memorandum within scope of this part of your request. This document is attached to this letter as document one and includes CV TAG advice on medical exemptions for the COVID-19 vaccine. This document has been released to you in full.

I note your question about the decision to remove a reference to Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) in the updated Vaccine Temporary Medical Exemption Clinical Criteria. The Temporary Medical Exemption Clinical Criteria is regularly reviewed, with input from both the Panel and CV TAG. It is important to note that when the eligibility criteria for section 1B *Serious Adverse Event to previous dose*, changed to section 2b *Significant Adverse Reaction to previous dose,* the eligibility criteria itself did not change, the document was updated to remove examples of the type of conditions that may make someone eligible for this category of exemption.

As the clinical criteria did not change, the eligibility for someone suffering from ME/CFS to receive a TME also did not change.

I trust this information 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 of Health website at: www.health.govt.nz/about-ministry/information-releases.

Nāku noa, nā

Astrid Koornneef
Director
National Immunisation Programme

Memo

Temporary Medical Exemptions for the COVID-19 Vaccine: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations

Date:	3 November 2021
To:	Dr Juliet Rumball-Smith, General Manager Clinical Quality & Safety, COVID-19 Vaccine Immunisation Programme (CVIP) Joanne Gibbs, Director of National Operations, CVIP
From:	Dr Ian Town, Chief Science Advisor, Ministry of Health
For your:	Consideration

Purpose of report

1. To outline the COVID-19 Vaccine Technical Advisory Group's (CV TAG) recommendations on the clinical criteria for medical exemptions to the first or second dose of the Pfizer COVID-19 vaccine.

Background and context

2. COVID-19 Vaccine Certificates (CVCs) are an important potential tool to help support the broader public health response to COVID-19, being particularly important in settings where there is greater risk of community transmission. In this context, CVCs, either in paper form or the digital equivalent, will allow people to demonstrate that they have been fully vaccinated or are medically exempt from vaccination for a defined period.

3. Evidence of medical exemption for vaccination is also important for people who are mandated to be vaccinated in certain roles due to their employment, such as border workers, teachers, healthcare workers, and employees of businesses where CVCs are mandatory.

4. To date, the Pfizer COVID-19 vaccine has shown an excellent safety and efficacy profile[1] and is recommended for all New Zealanders 12 years of age and over.[2]

5. The only contraindication to the Pfizer vaccine is hypersensitivity to the active substance or to any of the excipients, for example anaphylaxis to a vaccine component, such as polyethylene glycol (PEG).[3] Such reactions are rare and, even people with this history can usually receive the Pfizer vaccine after specialist assessment under supervision.[3]

6. Well-defined clinical criteria for a temporary medical exemption from full vaccination are needed for both the health professionals who will be asked to provide the exemption and for the people applying for an exemption, especially where CVCs are mandatory.

Medical Exemptions

7. Overall, the number of people in New Zealand estimated to be eligible for a medical exemption is expected to be small, and includes those who may be waiting for an alternative vaccine for their second dose, for example due to an adverse reaction following the first dose of the Pfizer vaccine.

8. The Australian Technical Advisory Group on Immunisation (ATAGI) have released guidance on medical exemptions.[4] ATAGI states that "*Vaccinations may reasonably be temporarily deferred for individuals with some acute major medical conditions (e.g. undergoing major surgery or hospital admission for a serious illness). Typically, these are time-limited conditions (or the medical treatment for them is time limited) and therefore temporary exemptions are considered appropriate. These exemptions are only to be given where a suitable alternative COVID-19 vaccine is not readily available for the individual.*" Furthermore, the ATAGI guidance recommends a maximum duration of 6 months, with review as the individual recovers from their acute major medical illness.

First dose

9. The Pfizer data sheet provided to Medsafe documents the following contraindications only: *'Hypersensitivity to the active substance or to any of the excipients* .[5] PEG is an excipient in the vaccine that is potentially associated with hypersensitivity reactions, but these are rare.[3, 6] It is possible for the Pfizer vaccine to be successfully administered despite a history of PEG allergy.[7]

10. It is difficult to estimate the number of people affected by these contraindications, due in part to the rarity of the events. However, the incidence of anaphylaxis following administration of the Pfizer vaccine is estimated at 8 cases per million doses administered in the US.[3] The current reporting rate for anaphylaxis (reports meeting levels 1-3 of the Brighton Collaboration case definition) in New Zealand is approximately 11 per million doses administered.[8]

11. Fewer people should request a medical exemption to the first dose of the Pfizer vaccine when a second class of vaccine becomes available, such as a vector-based vaccine (Janssen or AstraZeneca) for the population aged 18 and over.

Second dose

12. Myocarditis and/or pericarditis is a known rare side effect of the Pfizer vaccine and such events occurring after the first Pfizer dose may provide the basis for an exemption to the second dose.

13. Other adverse events that have been reported to the Centre for Adverse Reactions Monitoring (CARM), the Immunisation Advisory Centre (IMAC), or have been observed internationally[9] include: shingles, appendicitis, lymphadenopathy with or without fever, exacerbation of myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), regional pain syndrome, and neurological events with localised arm pain. These events may or may not be related to the vaccine and it is generally advised to defer the second dose until the symptoms have fully resolved.

14. The number of people with medical exemptions to the second dose of the Pfizer vaccine should also decrease in size when a second class of vaccine becomes available, such as a vector-based vaccine (Janssen or AstraZeneca) for the population aged 18 and over.

Proposed principles of medical exemption

15. There are very few situations where a vaccine is contraindicated and, as such, a medical exemption is expected to be rarely required.

16. Vaccinations may reasonably be temporarily deferred for individuals with some acute major medical conditions, such undergoing major surgery or hospital admission for a serious illness. Typically, these conditions are considered time-limited, and therefore a temporary exemption is considered appropriate.

17. Exemptions are only to be given where a suitable alternative COVID-19 vaccine is not readily available for the individual.

18. Exemptions should be for a specified time, reflecting, for example, recovery from clinical conditions or the availability of alternate vaccines.

19. It is likely that most people who are not medically exempt can be safely vaccinated with extra precautions.

Recommendations

20. CV TAG recommends that the clinical criteria given in Table 1 below be used as the basis for temporary exemptions:

Table 1 Criteria for temporary COVID-19 vaccine exemption

	Type of vaccine	**Criteria for temporary exemption**
1.	Pfizer	1. Anaphylaxis to the first dose of the vaccine or known severe allergy to the excipients of the vaccine as per the datasheet provided to Medsafe.[a, b] 2. Myocarditis/pericarditis following the first dose of the vaccine.
2.	mRNA COVID-19 vaccine e.g. Pfizer, Moderna	1. Inflammatory cardiac illness within the past 6 months including: myocarditis, pericarditis, endocarditis, acute rheumatic fever or acute rheumatic heart disease (i.e., with active myocardial inflammation). 2. Acute decompensated heart failure. Although myocarditis and/or pericarditis is very rare following vaccination, if such an event were to occur, then it may exacerbate a patient's pre-existing heart failure.
3.	All COVID-19 vaccines	1. PCR-confirmed SARS-CoV-2 infection until complete recovery from the acute illness. Chronic symptoms following COVID-19 ("Long COVID") is

		not a contraindication to COVID-19 vaccine but does warrant a clinical discussion with the patient regarding the benefits and risks. 2. Serious adverse event[c] attributed to a previous dose of the same COVID-19 vaccine with no other cause identified. 3. Unable to tolerate vaccine administration with resulting risk to themselves or others (e.g., due to severe neurodevelopmental condition such as autistic spectrum disorder). This may warrant a temporary exemption while additional resources and support to facilitate a safe administration of a second dose are arranged.

Notes for table above:

a. This criterion will be removed as an exemption when there is an alternative vaccine available in New Zealand.

b. Many of these individuals will be able to be safely vaccinated in a controlled environment, and we recommend clinical immunologist/specialist assessment.

c. An adverse event is considered serious for the purposes of these criteria[1] if it:
i) requires in-patient hospitalisation or prolongation of existing hospitalisation OR results in persistent or significant disability/ incapacity.

AND
ii) has been reported to CARM.

AND

iii) has been determined following review by, and/or on the opinion of, a relevant medical specialist to be associated with a risk of recurrence of the serious adverse event if another dose of the same vaccine is given.

Note that if a serious adverse event to a previous dose of a COVID-19 vaccine is used as a reason for the exemption, then this may require discussion with a suitably qualified health professional, such as a Medical Doctor or Nurse Practitioner, who is registered with the relevant responsible authority, and holds a current Annual Practising Certificate (APC) issued by that authority.

21. The CV TAG also recommends:

a. Those who are confirmed as having a non-placebo vaccine in any COVID-19 vaccine trial in New Zealand (for example, the Valneva COVID-19 vaccine trial NCT04956224) should be offered a temporary exemption. Note that this exemption does not equate

[1] Examples of serious AEFIs may include but are not limited to: a medically significant illness (e.g., immune thrombocytopenia purpura (ITP), myocarditis, potentially life-threatening events (e.g., anaphylaxis), severe ME/CFS, or persistent or significant disability (e.g., Guillain-Barré Syndrome). These reactions do not include common expected local or systemic reactions known to occur within the first few days after vaccination.

to determining them to be adequately vaccinated for the purposes of a CVC or fulfilment of the Vaccination Order.

b. A maximum duration of 6 months for the exemption, with the ability to apply for a new exemption if required. This time limitation will allow individuals who can safely be vaccinated, with either the same vaccine or an alternative vaccine, as appropriate, to be protected against COVID-19 in a timely way.

c. Those who are not medically exempt include the following:

   i. People who had an otherwise negative experience that is not mentioned above, with other vaccines in the past.

   ii. People with disabilities, once adequate resources are available to support safe delivery. People with disabilities are generally at higher risk from COVID-19, and therefore are a priority for vaccination.

   iii. Pregnant people. Pregnancy is not a valid reason for exempt on in the absence of any of the criteria listed in the above table. Pregnancy is associated with higher risk from COVID-19 compared to the general population and therefore this group are a priority for vaccination.

22. CV TAG will continue to monitor all relevant information and will update their recommendations as further evidence becomes available

Dr Ian Town

Chief Science Advisor and Chair of the COVID-19 Vaccine Technical Advisory Group

References

1. Polack, F.P., et al., *Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine*. New England Journal of Medicine, 2020. **383**(27): p. 2603-2615.
2. Medsafe. *Approval status of COVID vaccines applications received by Medsafe*. 2021 25 August 2021 [cited 2021 18 October]; Available from: https://www.medsafe.govt.nz/COVID-19/status-of-applications.asp.
3. Greenhawt, M., et al., *The Risk of Allergic Reaction to SARS-CoV-2 Vaccines and Recommended Evaluation and Management: A Systematic Review, Meta-Analysis, GRADE Assessment, and International Consensus Approach*. The Journal of Allergy and Clinical Immunology: In Practice, 2021. **9**(10): p. 3546-3567.
4. ATAGI. *ATAGI expanded guidance on acute major medical conditions that warrant a temporary medical exemption relevant for COVID-19 vaccines*. 2021; Available from: https://www.health.gov.au/sites/default/files/documents/2021/10/atagi-expanded-guidance-on-temporary-medical-exemptions-for-covid-19-vaccines.pdf.
5. Medsafe - New Zealand Medicines and Medical Devices Safety Authority. *New Zealand Data Sheet, Comirnaty Covid-19 Vaccine*. 2021; Available from: https://www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf.
6. Sellaturay, P., et al., *Polyethylene glycol (PEG) is a cause of anaphylaxis to the Pfizer/BioNTech mRNA COVID-19 vaccine*. Clinical & Experimental Allergy, 2021. **51**(6): p. 861-863.
7. Krantz, M.S., et al., *Safety Evaluation of the Second Dose of Messenger RNA COVID-19 Vaccines in Patients With Immediate Reactions to the First Dose*. JAMA Internal Medicine, 2021.
8. Medsafe. *Adverse events following immunisation with COVID-19 vaccines: Safety Report #31 – 2 October 2021*. Available from: https://medsafe.govt.nz/COVID-19/safety-report-31.asp.
9. Barda, N., et al., *Safety of the BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting*. New England Journal of Medicine, 2021. **385**(12): p. 1078-1090.