
IN THE HIGH COURT OF NEW ZEALAND
WELLINGTON REGISTRY

I TE KŌTI MATUA O AOTEAROA
TE WHANGANUI-Ā-TARA ROHE

CIV-2021-485-595

UNDER THE

Judicial Review Procedure Act 2016 and the
Declaratory Judgments Act 1908

IN THE MATTER OF

the making and amendment of the
COVID-19 Public Health Response
(Vaccinations) Order 2021 under section 11
of the COVID-19 Public Health Response Act
2020

BETWEEN

NZDSOS INC AND NZTSOS INC

Applicants

AND THE

MINISTER FOR COVID-19 RESPONSE,
DIRECTOR-GENERAL OF HEALTH and
ATTORNEY-GENERAL

Respondents

AFFIDAVIT OF RACHEL MACKAY ON BEHALF OF THE RESPONDENTS

11 February 2022

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I, Rachel Margaret Mackay, of the Ministry of Health, 133 Molesworth St, Wellington, Group Manager, Operations, National Immunisation Programme (formerly Director, National Contracts & Sector Engagement Workforce and Welfare, COVID-19 Vaccine and Immunisation Programme), solemnly and sincerely affirm:

Role and responsibilities

1. I am responsible for implementing the COVID-19 Public Health Response (Vaccinations) (No 3) Order (**the Order**) as part of implementing the COVID-19 Vaccination and Immunisation Programme (**CVIP**).
2. I have pharmaceutical industry qualifications in clinical pharmacology, pharmaco-dynamics and pharmaco-economics, and a range of senior leadership and management qualifications, including the Mt Eliza School of Business. I was seconded into CVIP in March 2021, having had 30+ years experience in the health sector across a range of areas including the pharmaceutical industry, Health Benefits (now Sector Operations, Ministry of Health) PHARMAC and TAS (Central Region Technical Advisory Services Ltd, a shared services agency owned by District Health Boards (**DHBs**)). My roles have largely focused on implementation, operationalisation and response, contract management and relationship management. I led the Demand Side and Schedule & Contracts teams at PHARMAC, PHARMAC's response to the Christchurch earthquake and was on PHARMAC's Senior Leadership team for a decade. Prior to my current secondment I am the Director, Integrated Community Services at TAS leading the implementation of the DHB contracts with primary care, community pharmacy, ambulance, public health and oral health.

The No 3 Order as enacted

3. The COVID-19 Public Health Response (Vaccinations) (No 3) Order (**the Order**) including the health and disability sector and affected education services took effect on 25 October 2021.
4. The Order provided a broad medical exemption process in clause 7A from the clause 7 duty on the affected person not to carry out certain work

unless vaccinated: an affected person may carry out certain work without being vaccinated if that person has particular physical or other needs that a “suitably qualified health practitioner” determines, in the course of examining the person, that the needs make it inappropriate for the person to be vaccinated (and the affected person provides written confirmation of that to the relevant PCBU).

5. Before the No 3 Order, the Order had applied to a narrower workforce: managed quarantine facilities, managed isolation facilities, affected airports, affected ports, and groups in relation to aircraft. Upon the broadening of the scale of workers affected and the affected sectors in the No 3 Order:

5.1 officials were receiving feedback from PCBUs (person conducting a business or undertaking) about medical exemptions they had received and wanted clarity about the legitimacy of, for health and safety at work purposes; and

5.2 it was brought to officials’ attention that the trust-based medical exemption model was being abused by the selling of medical exemptions from medical practitioners to patients unknown to them.

6. The Order provided an exemption process in clause 12A for exemptions to be granted by the Minister for COVID-19 response where the Order would significantly disrupt supply chains and the exemption is necessary or desirable to promote the purposes of the COVID-19 Public Health Response Act 2020 (**the Act**). That process requires the Minister to take into account the potential for supply chain disruption if the particular unvaccinated person cannot carry out the work (and the risk to the public interest if the work does not occur), the extent to which the work is necessary or could reasonably be delayed or performed by someone else, and the public health risk associated with the work.

Key amendments to the exemption processes

7. On 5 November 2021 the COVID-19 Public Health Response (Required

Testing and Vaccinations) Amendment Order 2021 (SL 202/358) amended the Order in respect of exemptions in the following ways:

- 7.1 revoked clause 7A:
 - 7.2 amended clause 7 so as to provide that “an affected person must not carry out certain work unless they are vaccinated or; an exempt person”; and
 - 7.3 introduced a new clause 9B for COVID-19 vaccination exemptions and corresponding definitions, which provided a centralised process under which only the Director-General may grant COVID-19 vaccination exemptions for medical purposes.
 - 7.4 amended clause 12A to extend significant service delivery to health services, and the operation of registered schools and essential operations of hostels in the education sector, with the education services clauses to be revoked on 1 January 2022.
8. Two expert Panels were established by the Ministry of Health to facilitate each of the exemption processes in respect of affected healthcare and disability workers. The Terms of Reference of the Temporary Medical Exemptions Panel for the COVID-19 Vaccine was approved by the Director-General of Health on 5 November and is annexed to this affidavit at **RM-1**. The Terms of Reference for the Significant Service Disruption Panel for the COVID-19 Vaccine Health Order was approved by the Director-General of Health on 12 November 2021 is annexed to this affidavit at **RM-2**. Both Terms of Reference are publicly available on the Ministry of Health website.
- [305.1189]
- [305.1194]
9. The Temporary Medical Exemptions Panel is appointed by the Director-General and comprised of an independent chair, a Māori health leader, and a number of registered health practitioners, whose expertise reflects the specialty areas required for consideration of applications.
 10. The Significant Service Disruption Panel is appointed by the Director-General and comprised of a chair (a DHB chief executive), a primary care

specialist, secondary/tertiary care specialists (including a Chief Operating Officer and DHB General Manager of Human Resources), and a specific relevant sector representative based on the original of the exemption raised (for example, Education, Corrections, Health).

11. Both Panels are constituted of subject matter experts, have reporting obligations to the Director-General of Health, have minimum periods of review of the Terms of Reference establishing each Panel (initially two months – in January 2022, then at a minimum every six months), and have a requirement that members of the Panels have a commitment to work for the public of New Zealand. The function of each of the Panels is to maintain consumer safety, ensure consistency and integrity in the exemption process, and ensure the effectiveness in achieving the goals and outcomes of the COVID-19 Protection Framework. Both Panels have at least one member having a recognised awareness of te reo Māori and understanding of tikanga: a Māori expert sits on the Temporary Medical Exemption Panel; and the Significant Service Disruption Panel calls on a Māori expert as and when required.
12. Further amendments to the Order in respect of the exemption processes reflect that the need for amendment and operationalisation of the amendment happened over a matter of days.

Temporary medical exemptions

13. If health and disability and education workers were granted a medical exemption under the Order that came into force on 25 October 2021, this became void from 11.59pm on 7 November 2021 when the amendments came into effect. Affected persons seeking a medical exemption had to do so under the new centralised process.
14. The centralised process created clarity and consistency for workforces affected by the Order.

The centralised process

15. Under clause 9B, an application may be made by a suitably qualified medical practitioner or nurse practitioner on behalf of an affected person

if the person meets the specified COVID-19 vaccination exemption criteria. The affected person must certify the information they provided to the practitioner is accurate. The practitioner must certify that they reviewed the affected person's medical history and assessed the person's state of health and have and state reasonable grounds for believing that the person meets the specified COVID-19 vaccination exemption criteria.

16. The Temporary Medical Exemptions Panel receives and considers applications for temporary medical exemptions, and recommends to the Director-General of Health (or delegate) they are satisfied the application is in order to grant or decline a temporary medical application for a period of up to six months. The Panel seeks advice as appropriate to recommend a temporary medical exemption.
17. The Director-General may grant the application if the Director-General is satisfied, on the basis of the evidence or other information provided, that the person meets the specified COVID-19 vaccination exemption criteria.
18. A temporary medical exemption applies the individual's life as a whole (as opposed to only their work) as it feeds into the vaccination pass required for entry to daily services in the COVID-19 Protection Framework.

Clinical criteria

19. On the 9 November 2021 the Ministry of Health published the Vaccine Temporary Medical Exemption Criteria, Clinical Guidance and Resources. This document, which is published on the Ministry of Health website, sets out the criteria for a medical exemption and guidance to medical practitioners in applying them.

Amendments

20. The Criteria, Clinical Guidance and Resources has been amended a number of times and have been published as the following versions, exhibited to this affidavit:

Version 1	9 November 2021	RM-3	[305.1199]
Version 1.1	10 November 2021	RM-4	[305.1210]

Version 1.2	11 November 2021	RM-5	[305.1221]
Version 2	19 November 2021	RM-6	[305.1232]
Version 3	30 November 2021	RM-7	[305.1244]
Version 4	13 January 2022	RM-8	[305.1256]

21. The November amendments were minor and reflect that the Criteria, Clinical Guidance and Resources were brought in at speed to transition to the centralised model.
22. The amendments made by the 13 January 2022 revision are detailed below and were Gazetted on 17 January 2022 (notice 2022-go169).

Principles

23. The principles of temporary medical exemption set out in the Criteria, Clinical Guidance and Resources remained the same in the November 2021 versions but have changed in the January 2022 version. The principles are reflected in the below table, with amendments in italics:

November 2021 versions	January 2022 version
	<i>We recommend that all eligible people get vaccinated against COVID-19.</i>
	<i>Those with known medical conditions or poor health the risk of adverse outcomes from COVID-19 disease are substantially greater than the risk of adverse outcomes from COVID-19 vaccination.</i>
There are very few situations where a vaccine is contraindicated and, as such, a medical exemption is expected to be rarely required.	There are very few situations where a COVID-19 vaccine is contraindicated and, as such, a <i>longer</i> medical exemption is expected to be rarely required.
Exemptions should be limited to situations where a suitable alternative COVID-19 vaccine is not readily available for the individual.	<i>Temporary</i> exemptions should be limited to situations where a suitable alternative COVID-19 vaccine is not readily available for the individual.

Exemptions should be for a specified time, reflecting, for example, recovery from clinical conditions or the availability of alternate vaccines.	Temporary exemptions are time specific, reflecting, for example, recovery from clinical conditions or the availability of alternate vaccines and <i>specialised supportive care arrangements to be vaccinated.</i>
Vaccination should be completed as soon as clinically safe within the exemption timeframe. This is particularly relevant for criteria 1C where it is unlikely that a full six months is required.	Vaccination should be completed as soon as clinically safe within the exemption timeframe.
It is likely that most people who are not medically exempt can be safely vaccinated, with some requiring extra precautions.	It is likely that most people who are not medically exempt can be safely vaccinated, with some requiring extra precautions <i>and/or support.</i>
The practitioner completing the application form should have an existing clinical relationship with the consumer and will support them for completing their vaccinations going forward.	The practitioner completing the application form should have an existing clinical relationship with the consumer and will support them for completing their vaccinations going forward.

24. The following people are not medically exempt:
- 24.1 People who had a negative experience with other vaccines in the past.
 - 24.2 Disabled people once adequate resources are available to support safe delivery. People with disabilities are generally at higher risk from COVID-19 and are therefore a priority for vaccination.
 - 24.3 Pregnant people. Pregnancy is associated with a higher risk from COVID-19 compared to the general population and therefore this group are a priority for vaccination. They are advised to seek advice from their Lead Maternity Carer.
 - 24.4 In the pre-January 2022 versions, vaccination could be reasonably deferred for individuals with some acute major

medical conditions, such as undergoing major surgery or hospital admission for a serious illness.

Clinical criteria for exemptions

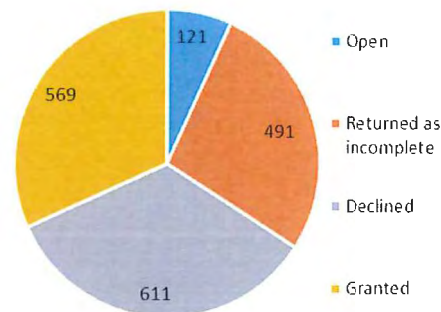
25. The criteria initially in use were based on recommendations from the COVID-19 Vaccine Technical Advisory Group (CV-TAG) and approved by the Director-General of Health. Since establishment of the criteria and the Panel, the Astra Zeneca COVID-19 vaccine has become available, and further vaccines are expected to become available. The Panel reviewed the criteria and proposed revisions based on vaccine availability and the applications received to date.
26. The differences brought about by the January 2022 amendments are:

November 2021 versions	January 2022 version
<p><u>Category 1A – COVID-19 Infection</u></p> <p>PCR-confirmed SARS-CoV-2 infection until complete recovery from the acute illness.</p>	<p><u>Category 1A – COVID-19 Infection</u></p> <p>PCR-confirmed SARS-CoV-2 infection (within the last 3 months).</p>
<p><u>Category 3A – Non-Placebo participant in a vaccine trial</u></p> <p>Those who are confirmed as having the vaccine (i.e., non-placebo) in any COVID-19 vaccine trial in Aotearoa New Zealand (for example, the Valneva COVID-19 vaccine trial NCT04956224).</p>	<p><u>Category 4A – Non-Placebo participant in a vaccine trial</u></p> <p>Those who are verified as having two doses of the trial vaccine (i.e., non-placebo) in any approved COVID-19 vaccine trial in Aotearoa New Zealand.</p>

How the process for medical exemptions have operated

27. As at 27 January 2022, 1792 applications for a temporary medical exemption had been processed. Approximately a third of applications had been granted, and the other statistics are seen in the figure below:

Total applications



28. The largest majority of applications have been from people on clinical trials. Many of the other applications are highly technical, where people have a variety of complex health conditions. Other trends in applications are people who have had adverse reactions to prior vaccination, and people who are at risk of causing harm to themselves or to others (for example, people with autism) and need a temporary exemption to get access to a sensory sedation site. There was a large spike in the number of applications process when the COVID-19 Protection Framework came into effect and vaccination passes were required for entry to various premises according to the CPF.

Significant service disruption exemptions

The process

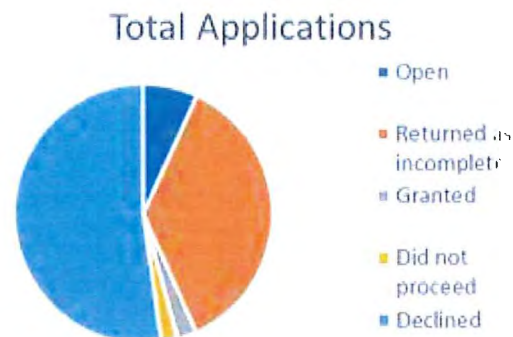
29. Under clause 12A, a PCBU can apply to the Minister in writing for a person specified in the application for an exemption from any provision of the Order. The organisation applies on behalf of the affected worker, and must specify the affected worker and their role. But the exemption is for the specific worker, rather than the PCBU.
30. The Significant Service Disruption Panel considers the application who makes a recommendation to the Director-General, who in turn makes a recommendation to the Minister. The Minister determines whether the exemption is necessary or desirable to promote the purposes of the Act, prevent significant disruption, and that the extent of the exemption is not broader than is necessary to reasonably address the matters that gave

rise to the exemption (clause 12A(4)).

31. Significant service disruption exemptions are specific to the exempted person's work and do not transfer to their vaccine pass required under the COVID-19 Protection Framework.

How it has operated

32. As at 26 January 2021, we had received 450 applications for significant service disruption exemptions. Eleven applications had been granted, 1 was returned from the Minister with a request for further information, 235 applications were declined, and 1 application that was before the Minister was not proceeded with. Thirty-one applications have been assessed by the Panel and are awaiting a final decision; nine applications were withdrawn after Panel assessment; and 4 were returned as incomplete after Panel assessment. 158 applications were returned as incomplete from the triage process.



Effect of the mandate

33. Vaccination rates in the health and disability workforce in DHBs were already relatively high (over 75 per cent) by the time the Government effected the Order.
34. This was possibly due to a range of factors, including an understanding of the role of vaccinations (there was pressure from some in the sector seeking early access to the COVID-19 vaccination – as covered by media in early 2021), and their inclusion in Group 3 of the Sequencing Framework (the strategy to implement vaccinations in 2021, targeting those front-line workforces most at risk and those members of our population most

at risk).

35. Vaccination rates in the health and disability workforce is now near universal. A number of factors are likely to have contributed to the rise in vaccination rates in November 2022, including:
- 35.1 the Order;
 - 35.2 the increasing Delta outbreak and its spread to regions outside of Auckland;
 - 35.3 the sequential vaccination roll-out (extending to the general public, the final group of the Sequencing Framework in late July 2021, with everyone 12+ years becoming eligible from 1 September 2021);
 - 35.4 vaccination campaigns, including Super Saturday on 16 October (and the second dose of those who received the vaccine three weeks later);
 - 35.5 the Government's strong messaging about the COVID-19 Protection Framework and the requirement of vaccination passes to use non-essential daily services; and
 - 35.6 Health and Safety at Work and employment relations processes already underway where businesses had determined they would be requiring vaccination of their workers.

AFFIRMED

At Wellington this 11th day
of February, 2022
before me:



Rachel Margaret Mackay



Victoria Maree Rea
Solicitor
Wellington

A Solicitor of the High Court of New Zealand