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5 July 2022

s 9(2)(a)

By email: <u>s 9(2)(a)</u> Ref: H202206708

Tēnā koe<sup>s 9(2)(a)</sup>

#### 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 20 May 2022. Each point of your request is answered in turn.

Please provide all information held by the Ministry relating to naturally acquired immunity against Covid 19, including all advice provided about naturally acquired immunity against Covid 19

Immunity, as a result of infection, is called infection-induced immunity and for a vaccine is called vaccine-induced immunity. Natural immunity usually means immunity that a person has without being vaccinated or infected, however, it is sometimes used to indicate immunity after infection (as opposed to vaccination). For the purposes of answering your request we have assumed you intend the latter meaning. A more detailed description of infection-induced or vaccination-induced immunity is available here: <a href="https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/covid-natural-immunity-what-you-need-to-know">www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/covid-natural-immunity-what-you-need-to-know</a>.

The Ministry has searched for information relating to your request. One document was identified, entitled *COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations: Vaccination after infection with SARS-CoV-2.* This was issued to the Director-General of Health on 22 March 2022, after consultation with the CV TAG. The memo is attached to this letter as Document 1 and is released to you in full. This details evidence of COVID-19 reinfection, and vaccination providing better protection than prior infection.

On 31 March 2022, the following information was published on <u>www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/getting-covid-19-vaccine-if-youve-had-covid-19</u>.

- Being infected with COVID-19 does not provide the same level of protection as vaccination.
- Although your antibodies will be high after an infection it's unknown how long this natural immunity will keep you protected from another COVID-19 infection.
- Getting your COVID-19 vaccinations is your best defense against COVID-19 and can help protect you against future variants of COVID-19.

The variants update on the 'COVID-19: Science News' page provides information of SARS-CoV-2 variants that are of interest and concern. It also contains information on infection-induced immunity against (sub-) variants currently present in New Zealand: <u>www.health.govt.nz/covid-19-novel-coronavirus/covid-19-resources-and-tools/covid-19-science-news#variants</u>.

...and the Covid 19 vaccine mandates

The Ministry has identified one briefing, entitled *Policy decisions required for further amendments to the COVID-19 Public Health Response (Vaccinations) Order 2021,* within the scope of your request. Please find this enclosed as Document 2, with some information withheld under the following sections of the Act:

- Section 9(2)(a) to protect the privacy of natural persons; and
- Section 9(2)(h) to maintain legal professional privilege.

I have considered the countervailing public interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

Please also refer to clause 7A of the COVID-19 Public Health Response (Vaccinations) Order 2021, available at: <a href="https://www.legislation.govt.nz/regulation/public/2021/0094/latest/LMS693874.html">www.legislation.govt.nz/regulation/public/2021/0094/latest/LMS693874.html</a>.

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: <u>info@ombudsman.parliament.nz</u> or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: <u>www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests</u>.

Nāku noa, nā

Gul Hall

Gill Hall Group Lead Intelligence, Surveillance and Knowledge Interim Public Health Agency, Ministry of Health/Manatū Haoura



# Memo

## COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations: Vaccination after infection with SARS-CoV-2

Date:	22 March 2022
То:	Dr Ashley Bloomfield, Director-General of Health
Cc:	Astrid Koornneef, Director, National Immunisation Programme Maree Roberts, DDG, System Strategy and Policy Dr Caroline McElnay, Director of Public Health
From:	Dr Ian Town, Chief Science Advisor
For your:	Consideration

### **Purpose of report**

1. To summarise the COVID-19 Vaccine Technical Advisory Group's (CV TAG) recommendations on COVID-19 vaccination after infection in circumstances when the recommended course of vaccination has not been completed.

### Background

- 2. COVID-19 is an acute viral infection caused by the SARS-CoV-2 virus, which provokes antibody and cellular immune responses.
- 3. Studies using samples from previously infected (but not vaccinated) people have shown that the level of detectable antibodies varies among individuals. [1-4] However, most of these studies were performed before the emergence of the Delta or Omicron variants, and thus rely on data about infection with earlier variants.
- 4. The proportion of people with detectable antibody might vary depending on whether infections are symptomatic. In one study, 81% of (symptomatic) COVID-19 outpatients had detectable antibodies after infection. However, this value was only 15% in asymptomatic patients, suggesting that the majority of asymptomatic patients could be susceptible to early re-infection. [4] Other studies have shown that more than 90% of infected individuals have antibody and cellular responses lasting up to 8 months. [1] However, to date, no studies have investigated responses longer than 8 months.
- 5. The protection gained from infection prior to vaccination has been shown to be inferior compared to protection conferred by COVID-19 vaccination after infection. Individuals who have been infected but not vaccinated are around twice as likely to get re-infected than those who have been fully vaccinated (2 doses). [5] Individuals who have been infected with COVID-19 and then become re-infected are 5.5 times more likely to have a severe infection



necessitating hospitalisation than those who have immunity through vaccination alone, noting this research was done before the emergence of the Omicron variant. [6]

- 6. The Omicron variant has increasingly been associated with re-infection. It has been noted that approximately 65% of Omicron infections in England occurred in individuals who have previously had COVID-19 infection. [7]
- 7. There are two sub-lineages of Omicron currently circulating in New Zealand, designated as BA.1 and BA.2. Non-peer reviewed research suggests that infection with one of these sub-lineages has 85-95% effectiveness at preventing reinfection with the other, when evaluated at more than 35 days after infection. [8] However, it should be noted that the median follow-up time was only 2 weeks in this study, so at this stage it is challenging to ascertain how long this immunity lasts or if it will protect from a new variant. Vaccination remains the best way to protect against new variants.
- COVID-19 vaccination after infection is generally well-tolerated. Previous COVID-19 infection is associated with a slight increase in side effects after subsequent vaccination, particularly fatigue (29% vs 20%), myalgia (30% vs 15%), fever (8% vs 2%) and lymphadenopathy (4% vs 1%),. [9] There are currently no reports of increased post-vaccine related myocarditis in those who have been vaccinated following infection.

# Status of overseas jurisdictions regarding COVID-19 vaccination after infection

- 9. Currently, peak bodies representing Australia, Canada, United Kingdom, United States, and Singapore provide a range of recommendations regarding COVID-19 vaccination after infection.
- 10. **The Australian Technical Advisory Group for Immunisation (ATAGI) recommend that:** [10]
  - Past SARS-CoV-2 infection is not a contraindication to vaccination. People who have had COVID-19 are advised to receive the same number of COVID-19 vaccine doses as people who have never been infected.
  - People with SARS-CoV-2 infection can be vaccinated when they have recovered following their confirmed infection or can defer for up to 4 months after the onset of the infection (with or without symptoms). Commencement or continuation of further vaccination should not be deferred for more than 4 months. People who have prolonged symptoms of COVID-19 can still be vaccinated but the optimal timing should be determined on a case-by-case basis in consultation with their healthcare provider.
  - Individuals should consider vaccination soon after infection and recovery if they:
    - have a risk factor (e.g. an underlying medical condition) that puts them at high risk of severe disease from COVID-19
    - have a higher risk of being exposed to COVID-19 (e.g. occupational risk factor)
    - have not completed a COVID-19 vaccination primary course
    - $\circ$   $\,$  are unsure if they have had an infection with SARS-CoV-2  $\,$
  - Individuals can consider deferring vaccination for up to 4 months after the onset of infection if they are younger and have no risk factors for severe illness from COVID-19 and they have recently completed their COVID-19 vaccination primary course.



 Allowing a longer interval between recovery and vaccination may enhance the immune response to vaccination. Deferring vaccination after infection may also reduce the risk of misattribution of post-vaccination side effects to symptoms from post-COVID-19 complications and vice versa.

#### 11. The Canadian National Advisory Committee on Immunisation (NACI) recommends: [11]

- Individuals who experienced SARS-CoV-2 infection before starting or completing their primary COVID-19 vaccine series may receive their next dose 8 weeks after symptoms started or after testing positive (if no symptoms were experienced).
- Individuals who are recommended to receive a booster dose and who experienced SARS-CoV-2 infection after completing their primary series may receive a booster dose 3 months after symptoms started or after testing positive (if no symptoms were experienced) and provided it is at least 6 months after completing a primary series.
- 12. In the United Kingdom, the Joint Committee on Vaccination and Immunisation (JCVI) recommend timing of vaccination for: [12]
  - Adults 4 weeks after onset of symptoms or from the first confirmed positive specimen. This interval may be reduced to ensure operational flexibility when rapid protection is required, for example high incidence or circulation of a new variant in a vulnerable population.
  - Children 17 and under 12 weeks from onset (or sample date) for those who are not in high-risk groups. This interval may be reduced to 8 weeks in healthy individuals when rapid protection is required.

#### 13. In the US, the Centers for Disease Control and Prevention (CDC) recommends: [13]

- COVID-19 vaccination for everyone ages 5 years and older, regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection. This includes people with prolonged post-COVID-19 symptoms and applies to primary series and booster doses. This recommendation also applies to people who experience SARS-CoV-2 infection before or after receiving any COVID-19 dose.
- People with known current SARS-CoV-2 infection should defer any COVID-19
  vaccination, including booster vaccination, at least until recovery from the acute illness (if
  symptoms were present) and criteria to discontinue isolation have been met. Current
  evidence demonstrates a robust immune response to vaccination after infection, but
  information is lacking about whether and how the amount of time since infection affects
  the immune response to vaccination.

#### 14. The Singaporean Ministry of Health recommends: [14]

- Persons who had recovered from COVID-19 and were fully vaccinated before their infection are considered to have completed their primary series. Persons who have not completed their primary vaccination series before recovering from a COVID-19 infection, are recommended to receive a single dose of an mRNA vaccine.
- If the person is due for vaccination based on the schedules recommended in the national vaccination programme (e.g. to receive a booster dose about 5 months after two doses of mRNA vaccines), the person may receive the next vaccine dose 28 days after infection, although it is recommended to do so three months from the infection for better effectiveness.



## **Current recommendations in New Zealand**

- 15. In February 2021, CV TAG provided advice regarding a booster dose after infection. It was recommended that for those with PCR-confirmed COVID-19 infection after their primary course, a COVID-19 vaccine booster dose should be offered 3 months after recovery from acute illness.
- 16. As at 17 February 2022, the New Zealand Immunisation Handbook advises that: [15]
  - Vaccination should be offered regardless of an individual's history of symptomatic or asymptomatic SARS-CoV-2 infection.
  - In a person who has had a previous SARS-CoV-2 infection, an individual is considered fully vaccinated after two doses of mRNA-CV (or another COVID-19 vaccine). In these individuals, vaccination is recommended 4 weeks after recovery, or 4 weeks from the first confirmed positive PCR test if asymptomatic, and when cleared to leave isolation. This also applies to the second dose for individuals who have SARS-CoV-2 infection after their first dose.
- 17. The Immunisation Advisory Centre (IMAC) currently recommends that COVID-19 vaccination can occur from 3 months after recovery from a COVID-19 infection, regardless of whether the person has not had any vaccination doses, if they were not fully vaccinated (e.g., had one dose only), or if they were fully vaccinated (e.g., had two doses). [16]

### Recommendations

- 18. Given the differences in advice for timing of vaccination after infection, the COVID Vaccine Immunisation Programme and IMAC have requested CV TAG recommendations for clarification on this topic.
- 19. CV TAG met on 8 March 2022 to discuss recommendations on COVID-19 vaccination after infection in circumstances when the recommended course of vaccination has not been completed.

#### 20. CV TAG noted that:

- a) There is variation in the international advice on COVID-19 vaccination after infection.
- b) Vaccination after infection has been shown to produce superior immune responses compared to infection alone and is generally well-tolerated.
- c) For children and adolescents, there has been less time for data to accumulate about vaccination after infection than for adults, and data remain scarce in this age group.

#### 21. CV TAG recommends that:

- a) COVID-19 vaccination (as per current schedule and eligibility criteria) can occur any time following infection, from the time of recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.
- b) An interval of 3 months after infection is recommended as it allows for a better immunological response to develop, particularly for 5-17-year-olds. The interval for 5-17-year-olds should only be shorter in exceptional circumstances, where risk of COVID-19 is clinically determined to outweigh the risk of an earlier vaccination.
- c) Clinical discretion can be applied when considering vaccination prior to 3 months after infection. This may be appropriate for those individuals considered to be at high risk of severe disease from COVID-19 re-infection.



- d) This recommendation applies to any dose of the primary course or a booster, for any COVID-19 vaccine currently offered in New Zealand.
- CV TAG will continue to monitor all relevant information and will update their 22. recommendations as further evidence becomes available.

Dr lan Town

**Chief Science Advisor and** 

REFERSED UNDER THE OFFICIAL INFORMATION ACT 1982 Chair of the COVID-19 Vaccine Technical Advisory Group



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- 1. Dan, J.M., et al., *Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection*. Science, 2021. **371**(6529).
- 2. National institutes of Health. *Lasting immunity found after recovery from COVID-19*. 26 Jan 2021; Available from: <u>https://www.nih.gov/news-events/nih-research-matters/lasting-immunity-found-after-recovery-covid-19</u>.
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- 4. Wellinghausen, N., et al., SARS-CoV-2-IgG response is different in COVID-19 outpatients and asymptomatic contact persons. J Clin Virol, 2020. **130**: p. 104542.
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- 6. Bozio, C.H., et al., Laboratory-Confirmed COVID-19 Among Adults Hospitalized with COVID-19-Like Illness with Infection-Induced or mRNA Vaccine-Induced SARS-CoV-2 Immunity - Nine States, January-September 2021. MMWR Morb Mortal Wkly Rep, 2021. **70**(44): p. 1539-1544.
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- 9. Raw, R.K., et al., *Previous COVID-19 infection, but not Long-COVID, is associated with increased adverse events following BNT162b2/Pfizer vaccination.* The Journal of infection, 2021. **83**(3): p. 381-412.
- 10. Australian Government Department of Health. *Clinical recommendations for COVID-19 vaccines*. 2 March 2022; Available from: <u>https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/advice-for-providers/clinical-guidance/clinical-recommendations</u>.
- 11. Public Health Agency of Canada. *Updated guidance on COVID-19 vaccination timing for individuals previously infected with SARS-CoV-2*. 4 February 2022; Available from: <u>https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/naci-summary-rapid-response-updated-guidance-covid-19-vaccination-timing-individuals-previously-infected-sars-cov-2.pdf.</u>
- 12. UK Government. *COVID-19 Greenbook Chapter 14a*. 28 February 2022; Available from: <u>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\_dat</u> <u>a/file/1057798/Greenbook-chapter-14a-28Feb22.pdf</u>.
- CDC. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States. 22 February 2022; Available from: <u>https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html</u>.
- 14. Singapore Ministry of Health. *FAQs Booster Doses*. 3 March 2022; Available from: <u>https://www.moh.gov.sg/covid-19/vaccination/faqs---booster-doses</u>.
- 15. Ministry of Health New Zealand. *Immunisation Handbook 2020, Chapter 5. Coronavirus disease* (COVID-19). 17 February 2022; Available from: <u>https://www.health.govt.nz/our-</u> work/immunisation-handbook-2020/5-coronavirus-disease-covid-19.
- 16. The Immunisation Advisory Centre (IMAC). *Vaccination after COVID-19 infection*. 9 March 2022; Available from: <u>https://covid.immune.org.nz/faq/vaccination-after-covid-19-infection</u>.



# **Briefing**

## Policy decisions required for further amendments to the COVID-19 Public Health Response (Vaccinations) Order 2021

Date due to MO:	6 April 2022	Action required by:	8 April 2022
Security level:	IN CONFIDENCE	Health Report number:	20220544
То:	Hon Chris Hipkins, Minister for COVID-19 Response		
Copy to:	Hon Andrew Little, Min	ister of Health	AA
			O.

## **Contact for telephone discussion**

Contact for telephone discussion			
Name	Position	INF	Telephone
Maree Roberts	Deputy Director-G and Policy	General, System Strategy	S9(2)(a)
Alison Cossar	Manager, Public H Health System Pol Policy	lealth Policy, Public licy, System Strategy and	S9(2)(a)

## Minister's office to complete:

	□ Decline	□ Noted
Needs change	□ Seen	$\Box$ Overtaken by events
See Minister's Notes	□ Withdrawn	
Comment:		

# Policy decisions required for further amendments to the COVID-19 Public Health Response (Vaccinations) Order 2021

Security level:	IN CONFIDENCE	Date:	6 April 2022	
To:	Hon Chris Hipkins, Mir	nister for COV	ID-19 Response	

#### **Purpose of report**

- 1 This report provides advice on further amendments to the COVID-19 Public Health Response (Vaccinations) Order 2021 to:
  - i. expand the recognised list of COVID-19 vaccines for booster doses under Schedule 4 of the Order;
  - provide for a more streamlined Specified COVID-19 Vaccination Exemption process for affected workers, who have recently recovered from, or tested positive for COVID-19 and consistent with medical advice should wait three months before receiving their next COVID-19 vaccine (booster or second dose) to receive a temporary medical exemption and;
  - iii. enable border and managed isolation and quarantine facilities (MIQF) workers to be eligible for a temporary medical exemption; and
  - iv. seek your agreement to issue drafting instructions for the amendments.
- 2 This report discloses all relevant information and implications known at this time.

#### Summary

- 3 For workers under the COVID-19 Public Health Response (Vaccinations) Order 2021 (the Order), policy decisions are required to ensure that the Order remains workable and relevant. This paper seeks three amendments:
- 4 Amendment 1 Amendments to the Order are needed to update and expand the list of recognised booster vaccines under Schedule 4 of the Order. This allows for recognition of booster doses given overseas and ensure such workers are considered compliant with the Order.
- 5 Amendment 2 With the Omicron variant in the community, a number of workers will have had COVID-19 before receiving their required second or booster dose. To bridge the gap between recovering from COVID-19 and receiving their next dose a temporary medical exemption is granted. However, this process is currently administratively intensive due to the significant increase in numbers of applications.
- 6 A more streamlined approach to the temporary medical exemption process is required. This paper outlines two options. Both options shift the responsibility to a Persons Conducting a Business or Undertaking (PCBU) rather than a medical or nurse practitioner. The difference between the options is that the first option requires PCBUs to notify the Ministry of Health (the Ministry), removing the Ministry's involvement in the approval process. The second option retains the Ministry's involvement in the exemption approval process.

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8 If you agree to the Ministry of Health (the Ministry) issuing drafting instructions to the Parliamentary Counsel Office (PCO), the Ministry will provide you with an Order for Ministerial consultation, signing and gazettal as soon as practicable.

## Recommendations

- a) **Note** that the amendments to the COVID-19 Public Health Response (Vaccinations) Order 2021 are required to ensure that the mandatory vaccinations provisions are workable and relevant
- b) **Note** that the Chief Science Advisor and chair of the COVID-19 Vaccine Technical Advisory Group (CV TAG) has advised that it would be pragmatic to recognise vaccines for a booster dose that have been approved by Medsafe or as a World Health Organisation Emerging Use Listing (WHO EUL) vaccine. This would enable workers who have received a different booster dose overseas to be compliant with the requirements of the Order
- c) **Agree** to expand the list of COVID-19 vaccines recognised as a booster dose under the Order to include eight additional vaccinations recognised by WHO EUL
- d) Note that with the Omicron outbreak, the Ministry has received high numbers of Specified COVID-19 Vaccination Exemption applications and an amendment to the Order is required to make the process more streamlined.
- e) **Agree** to amend the Order to allow for a more streamlined Specified COVID-19 Vaccination Exemptions process
- f) If **Yes** to the recommendation above, then either

**Option 1: Agree** to amend the Order to shift the responsibility to the PCBU to verify evidence of a COVID-19 infection and to notify the Ministry of workers for whom a temporary medical exemption applies **[Recommended]** 

or

Briefing: HR 20220544

**Option 2: Agree** to amend the Order to shift the responsibility to a PCBU to verify evidence of a COVID-19 infection and to apply to the Ministry for a Specified COVID-19 Vaccination Exemption (temporary medical exemption) on behalf of a group of affected workers





Yes<mark>/N</mark>o

Yes/No



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## S9(2)(h)

- h) **Agree** to amend the Order to enable border and MIQF workers to be eligible for a temporary medical exemption
- i) **Agree** the Ministry will issue drafting instructions to Parliamentary Counsel Office to draft the COVID-19 Public Health Response (Vaccinations) Amendment Order (No. 4) 2022
- j) **Note** that under section 9(1)(c) of the COVID-19 Act you are required to consult with the Prime Minister, Minister of Justice and Minister of Health before making or amending a COVID-19 Order.

(AAObet)

Maree Roberts Deputy Director General **System Strategy and Policy** Date:

ELEASED UNDER

Hon Chris Hipkins Minister for Covid-19 Response Date: 10/4/2022





### Policy decisions required for further amendments to the COVID-19 Public Health Response (Vaccinations) Order 2021

### Background

- 9 The COVID-19 Public Health (Vaccinations) Order 2021 came into force on 1 May 2021 and makes it mandatory for certain work to be carried out by affected persons who are vaccinated.
- 10 As the COVID-19 outbreak evolves within New Zealand, it is apparent that there are different requirements for what is needed to maintain population protection as well as to protect the community at the same time ensure the Order remains workable and relevant. As such, several subsequent amendments have been made to the Order, including the COVID-19 Public Health (Vaccinations) Amendment Order 2022 which came into force on 23 January 2022 (HR20212779 refers). This amendment required workers aged 18 years and over, working at MIQF, border, health and disability sector, corrections prisons, and in education sector to receive a COVID-19 booster dose (boosters).
- 11 On 21 March 2022, Cabinet agreed to remove the vaccination mandates for early childhood and schooling education workers (Schedule 2 Part 9) as well as groups in relation to setting where Covid Vaccine Certificates are required (Schedule 2 Part 10) (CAB-22-MIN-0086 refers).
- 12 At the same time, Cabinet also agreed that the following workforces covered by the Order are retained:
  - a. Health and disability sector workers, including aged care workers (Schedule 2 Group 7);
  - b. Prison staff (Schedule 2 Part 8) and;
  - c. Border and MIQ workers (Schedule 2 Parts 1 6).
- 13 Currently, boosters required in the Order are limited to those vaccines that are available in New Zealand as at December 2021. As New Zealand reopens its borders, this is no longer practical, especially as people are returning to New Zealand and may have received other boosters and as such amendments to the Order are needed to recognise this.
- 14 With the Omicron variant, we are also in a situation where more affected workers will have had or been infected with COVID-19 before having received their required second or booster dose. The current exemption process allows for a gap between being recovered from COVID-19 and receiving the next dose of vaccine if the timeframe cannot be met due to this reason. However, with affected organisations having large numbers of staff in this scenario, a more streamlined approach to the exemption process is required.
- 15 Further, border workers and MIQF workers are currently ineligible to apply for a temporary medical exemption. \$9(2)(h)
- 16 This paper seeks to make further amendments to the Order, capturing the next raft of changes that are required. The briefing to support the amendments to the Order that will affect Cabinet's decisions on removing certain groups from the Order (CAB-22-MIN-0086 refers) will be provided separately.

### Comment

# Amendments to the list of recognised COVID-19 vaccines acceptable as a booster in New Zealand

- 17 On 23 January 2022, following policy decisions (HR20212779 refers), the Order came into force, requiring workers aged 18 years and over, working at managed quarantine facilities (MIQ) and managed isolation facilities (MIF), border, health care, corrections prisons, and in education services, to receive a booster dose. With the latest group to have received their booster dose by 1 March 2022, or within 183 days of their last dose.
- 18 Schedule 4 of the Order lists the types of COVID-19 vaccines accepted as a booster dose for the purposes of the Order. These are:
  - a. 1 dose of Pfizer/BioNTech (Comirnaty, Tozinameran, BNT162b2)
  - b. 1 dose of AstraZeneca (Oxford/AstraZeneca, Vaxzevria, AZD1222)
- 19 As New Zealand opens its borders, and booster programmes are rolled out in some overseas jurisdictions, some new arrivals may seek employment in sectors where there is a booster dose requirement but may have received a booster vaccine other than the Pfizer/BioNTech or AstraZeneca vaccine.
- 20 Data is emerging on vaccines used overseas but continues to be partial. Given the limited availability of scientific data, a pragmatic decision is required to enable workers who have received a different booster dose overseas to be compliant with the requirements of the Order.
- 21 The Chief Science Advisor and Chair of the COVID-19 Vaccine Technical Advisory Group (CV TAG) has advised that there is currently limited scientific evidence available on different types of vaccines as boosters. Most of the available data for boosters pertains to mRNA vaccines (Pfizer and Moderna), and to some extent the AstraZeneca vaccine. It would therefore be difficult to make recommendations for each individual booster vaccine.
- 22 Permitting the use of the WHO EUL vaccines as boosters would be appropriate to ensure that individuals vaccinated overseas with these vaccines are not required to have further vaccines to work. This is a reasonable approach as to be approved for the WHO EUL, as a primary course, vaccines are required to have an efficacy of 50 percent or above. It is necessary to ensure that the ability of new arrivals to New Zealand to work in affected roles is not unreasonably limited.
- 23 The Ministry recommends amending Schedule 4 of the Order to include the following additional vaccines:
  - i. 1/2(half) or 1 dose of Moderna (Spikevax, mRNA-1273)
  - ii. 1 dose of Novavax (Nuvaxovid, NVX-CoC2373)
  - iii. 1 dose of Covovax (Serum Institute India Novavax formulation)
  - iv. 1 dose of AstraZeneca (Covishield, Serum Institute India formulation)
  - v. 1 dose of Sinovac (CoronaVac, PiCoVacc)
  - vi. 1 dose of Sinopharm, Beijing (BBIBP-CorV, BIBP vaccine, Covilo)
  - vii. 1 dose of Bharat Biotech (Covaxin, BBV152)

- viii. 1 dose of Janssen / Johnson & Johnson (Janssen COVID-19 Vaccine, Ad26.COV2.S1, JNJ-78436735)
- 24 It is noted that no evidence was found for the Covovax (Serum Institute India Novavax formulation) vaccine as being utilised as booster in overseas jurisdictions (see Appendix 1).
- The Ministry recommends that you agree to update the specified list of vaccines in Schedule 4 of the Order to include the additional eight vaccines as per paragraph 22 above.



Amendment to allow for a more streamlined approach to Specified COVID-19 Vaccination Exemptions (temporary medical exemptions) for workers who have returned a positive COVID-19 test

- 28 New Zealand is currently experiencing an Omicron outbreak. Subsequently, there are affected workers under the Order who have not yet received their second dose of COVID-19 vaccine or booster dose and have recently tested positive for, or recently recovered from, COVID-19. Current clinical advice provides that people should wait three months after recovery from a COVID-19 illness before receiving their next dose.
- 29 There is a currently a mechanism under Clause 9B of the Order, for the Director-General to grant an application for a Specified COVID-19 Vaccination Exemption (temporary medical exemption) if a suitably qualified medical practitioner or nurse practitioner applies on behalf of a person who is:
  - i. not vaccinated (including partially vaccinated), or
  - ii. has not received a booster dose.
- 30 The criteria for a Specified COVID-19 Vaccination Exemption are published in the Gazette, as determined by the Director-General of Health, under section 5(3)(a) of the COVID-19 Public Health Response Act 2020 (the Act) and includes acute illness from COVID-19 infection (Category 1A criteria).
- 31 Recent operational improvements have been made to the temporary exemption applications process enabling PCBUs to submit a group application (an application that covers two or more employees) to the Ministry [Status Quo].
- 32 This process requires the application to be signed off by a Medical or Nurse practitioner, for that practitioner to verify the positive PCR or Rapid Antigen Test (RAT) result and be satisfied that these belong to each individual covered by the group application.

- 33 For completeness, for individuals who are self-employed, and are required to be vaccinated or have received a booster dose under the Order, a Medical or Nurse practitioner applies on the persons behalf.
- 34 The disadvantages of the current process are that this requires sighting and verification of a positive test result by a Medical or Nurse practitioner, a process which could be undertaken by the PCBU. Further, access to Medical or Nurse practitioners is problematic for some PCBUs and can cause delays in the process. An application form is required to be submitted to the Ministry and approved, meaning the process is time intensive for PCBUs and the Ministry.
- For context, eight Category 1A applications were received for the week beginning 7 February 2022 and have increased to 533 applications for the week beginning 14 March 2022.
- 36 There are risks with the Status Quo in that although a Medical or Nurse practitioner has the responsibility to be satisfied that the positive results belong to each individual covered by the application, with self-reported RATs there remains the risk of fraudulent results uploaded into My Covid Record. It is difficult for nurse or medical practitioners to investigate or identify this, and some practitioners are uncomfortable with verifying a self-test that they have not witnessed.
- 37 Due to the Omicron outbreak, there are many workplaces currently experiencing large numbers of staff who have tested positive for COVID-19. This has had a flow on impact of significantly increasing the number of Specified COVID-19 Vaccination Exemption applications for a temporary medical exemption thereby delaying workers ability to return to work.
- 38 Given this significant increase in Specified COVID-19 Vaccination Exemption applications the current system is proving not fit for purpose and an amendment to the Order is recommended to enable a more streamlined process. Maintaining the Status Quo is not recommended as it is not currently meeting the demand.
- 39 The proposed amendment would only target workers who are due to have their second or booster COVID-19 vaccination but have tested positive for COVID-19 or have recently recovered from COVID-19 infection, therefore impacting their ability to receive their next dose. The proposed amendment will streamline the process to better facilitate workers to wait the appropriate time before their next vaccination. Upon the expiry of the temporary medical exemption, affected workers under the Order will be required to receive their next COVID-19 vaccine before carrying out certain work.

#### Summary of options

- 40 Throughout the pandemic, New Zealand has employed a high-trust model which has served us well in protecting New Zealanders from earlier outbreaks when vaccines were not available.
- 41 Enabling a more streamlined process for temporary medical exemptions will ease the burden on PCBUs, as well as alleviating stress for workers who may be stood down, and potentially lose pay while an exemption is being processed. Streamlining the process may enable faster return to work once the employee has recovered from COVID-19.
- 42 The status quo and the below amendment options rely on a high-trust model. Option 1 and Option 2 are more streamlined and less administratively burdensome than the current application system requirements. Option 1 has the added benefit of removing the requirement for an application process altogether but retains Ministry oversight by including a notification requirement.

43 Should you agree to streamline the exemption process and amend the Order accordingly, we propose two potential amendment options:

## **Option 1** [recommended] - **PCBUs verify a positive COVID-19 test and a temporary medical** *exemption automatically applies.*

- 44 An amendment to the Order to allow for:
  - 44.1.1 The requirement for an application to the Director General is removed for Category 1A;
  - 44.1.2 the PCBU is responsible for informing the affected person that they can wait the specified time before their next vaccination;
  - 44.1.3 the evidence provided (positive COVID-19 test result as recorded in 'My Covid Record, or equivalent') is sighted by the PCBU;
  - 44.1.4 the person would automatically qualify for an exemption under the Category 1A criteria;
  - 44.1.5 the exemption timeframe would be 100 days;
  - 44.1.6 the PCBU must notify (in writing) to the Ministry of Health of all affected workers where an exemption has been applied;
  - 44.1.7 The process would apply only on behalf of two or more persons or employees (group notification);
  - 44.1.8 the PCBU is responsible for notifying the person when their next dose of COVID-19 vaccine is due, as per the current requirements; and
  - 44.1.9 if an affected person is subsequently re-infected with COVID-19 before their next required vaccination is due, then the persons medical practitioner or nurse practitioner must apply for a COVID-19 Vaccination Exemption application on the persons behalf.
- 45 The benefits of this option are that it is a more streamlined process than Option 2 due to the removal of the 'application process' requirement. Further reducing the administrative burden on PCBUs who are likely facing operational strains due to reduced staffing numbers, will be a positive outcome. It would also remove a large amount of administrative work for the Ministry.
- 46 For completeness, this option would only apply for PCBUs making notifications on behalf of two or more employees, for individuals who are self-employed, and are required to be vaccinated or have received a booster dose under the Order, a Medical or Nurse practitioner applies on the persons behalf.
- 47 By incorporating a notification requirement, the Ministry will still maintain some oversight of the temporary medical exemptions.
- 48 My Vaccine Passes may also be updated in the future to include information on boosters (CAB-22-MIN-0086 refers). By retaining some Ministry oversight, an administrative record can be kept within the system which records that a person has received a temporary medical exemption.

Risks

- 49 A risk of this option is that the Ministry would not be involved in the application and approval process. There is also the added risk of fraudulent self-reported positive cases and fraudulent notifications (or no notification) from PCBUs on behalf of their employees, undermining the intent of the Order. This risk may be exacerbated if the Ministry approval step is removed from the process.
- 50 The Ministry is adopting a high-trust model and is relying on PCBUs to understand and abide by their obligations. By including the notification requirement, the Ministry can maintain oversight of this process and the volumes of notifications provided. This will help enable the Ministry to understand if there was to be any abuse of this process and to revisit any policy decisions if it was thought that the process was being abused.
- 51 Although there are responsibilities under the Health and Safety at Work Act 2015 (HSWA) and under the Order, there are risks that PCBUs may not comply with the requirements in such a high-trust model and as such there will be accompanying enforcement challenges in such an environment. However, this option moves towards a more 'business as usual model' where PCBUs are trusted to comply and are expected to keep their workers safe. This aligns with the HSWA responsibilities of a PCBU.
- 52 This option is recommended as there will benefits to PCBUs, the Ministry, and affected persons with a much more streamlined process.

# Option 2 – PCBUs verify a COVID-19 positive test result and make an application on behalf of their employees

- 53 An amendment to the Order to allow for:
  - 53.1.1 the PCBU (instead of a suitably qualified medical or nurse practitioner) to make an application for a Specified COVID-19 Vaccination Exemption on behalf of their employees who have tested positive for COVID-19;
  - 53.1.2 an application to be made on behalf of two or more persons or employees (group application);
  - 53.1.3 the evidence provided, through a positive COVID-19 test result (including a positive RAT), in support of the Specified COVID-19 Vaccination Exemption application is sighted by the PCBU; and
  - 53.1.4 the person(s) makes a suitable declaration certifying that the information they have provided to the applicant is accurate, and to not require the person to sign the application form.
- 54 The benefit of this option is that it would no longer be required for a suitably qualified medical practitioner or nurse to verify a positive test for the group of people. The verification step would be conducted by the PCBU. This enables a more streamlined process and will ease some of the administrative burden on PCBUs as well as their employees.
- 55 For completeness, this option would only apply for PCBUs making applications for two or more employees, for individuals who are self-employed, and are required to be vaccinated or have received a booster dose under the Order, a Medical or Nurse practitioner applies on the persons behalf.
- 56 The additional verification and approval step undertaken by the Ministry will still enable a record of the temporary medical exemption to be kept by the Ministry.

- 57 The disadvantages of this option are that an application must still be submitted to the Ministry and approved, meaning the process is still time intensive for PCBUs and the Ministry. Additionally, as per Option 1, there is risk of fraudulent self-reported positive RATs as well as risk that some PCBUs may oppose the vaccination order and may make fraudulent applications to the Ministry of behalf of employees, undermining the intent of the Order.
- 58 Like Option 1, this Option moves towards a more business as usual model where PCBUs are trusted to comply and are expected to keep their workers safe and aligns with the HSWA responsibilities of an employer.
- 59 This option is still administratively intensive for the PCBU and Ministry, as such, this option is not recommended.

# Amendment to enable border and MIQF workers to be eligible for receiving a temporary medical exemption

60 Currently, applications for temporary medical exemptions only apply to groups specified in Schedule 2 Part 6, 7, 8, 9 or 10 of the Order. Border and MIQF workers, groups specified in Schedule 2 Part 1, 2, 3, 4 or 5 of the Order, are currently ineligible to receive a temporary medical exemption.

59(2)(h)	

- 62 With an amendment, workers can be eligible for exemption and return to work at the border, if an exemption is granted, without further risk to the community.
- 63 To remove any doubt, the prosed amendment to streamline the process for affected workers, who have recently recovered from, or tested positive for COVID-19 and have received medical advice to wait three months before receiving their COVID-19 (booster or second dose) to receive a temporary medical exemption would also apply to PCBUs of affected border and MIQF workers.
- 64 Border or MIQF workers who may qualify for a temporary medical exemption for a reason other than having COVID-19, will follow the current process whereby the persons medical or nurse practitioner applies to the Ministry on behalf of the person.

## **Human Rights**

- 65 Previous New Zealand Bill of Rights Act 1990 (BORA) advice has been given on the policy decisions requiring amendments to the Order requiring certain workers aged 18 years and over to receive a booster dose (HR20212779 refers).
- 66 We do not consider the proposed changes will have any further implications in relations to obligations under BORA 1990. This is mainly because the proposed amendments do not change the coverage of the mandated workers within the Order.
- 67 The proposed amendments would benefit certain parts of the population through providing a wider choice of vaccines that allow them to meet their obligations under the Order. With a more streamlined process for Specified COVID-19 Vaccination Exemptions applications, allow persons who would otherwise be restricted from work without a booster dose, to go back

quicker once they have recovered from COVID-19 and received a temporary medical exemption.

68 Enabling border and MIQF workers to be eligible for temporary medical exemptions would also reduce rights impacts.

### Equity

- 69 Increasing the recognised COVID-19 vaccines in Schedule 4 provides additional options for affected workers returning from overseas and is an integral part of the Reconnecting New Zealand strategy as we start to open the borders and reconnect globally.
- 70 Workers subject to the Order (i.e., "affected persons"), may be redeployed by their employers or may have their employment terminated (following appropriate human resource processes) if they are unvaccinated or have not received a booster dose.

#### Te Tiriti o Waitangi implications

- 71 The Ministry and other stakeholders will continue to work with Māori (and Pacific) providers to increase the number of kaimahi (staff) able to deliver the COVID-19 vaccinations. This will remain a critical enabler for lifting Māori (and Pacific) vaccination rates, encouraging uptake and increasing trust and transparency.
- 72 Māori and Pacific vaccination rates have generally been lower than non-Māori, non-Pacific. This is particularly evident for booster uptake in younger age group (18 to 34) where only 39 percent of eligible Māori and 43 percent of eligible Pacific peoples have received a booster dose, compared to 59 percent of non- Māori, non- Pacific.
- 73 While a streamlined process for temporary medical exemptions may ease the burden on PCBUs and employees, and faster return to work, ongoing work is required to ensure equitable access and uptake of booster vaccinations.
- 74 There are unlikely to be any further Te Tiriti o Waitangi implications in this Amendment Order.
- 75 The Order supports health system resilience, the minimisation of community outbreaks, and any associated increase in restrictions. This is critical to minimising and addressing existing inequities and is consistent with Te Tiriti principle of active protection.

#### Next steps

- 76 Officials will prepare material to support communication with key stakeholders. Clear communication is important to provide support for, and facilitate compliance with, these requirements.
- 77 Officials recommend you sign this report as soon as practicable, such that drafting of the amendments can be undertaken by Parliamentary Counsel Office.
- 78 The final Order will be provided to you in due course for signature.

## **Appendix 1**

Vaccine Type	Evidence of use as a booster in other jurisdictions
WHO EUL or Medsafe approved for primary course	
Moderna (Spikevax, mRNA-1273)	Australia <sup>1</sup> , the United States of America <sup>2</sup> , and the United Kingdom <sup>3</sup> are offering the Moderna vaccine (1/2 dose) as a booster
Novavax (Nuvaxovid, NVX-CoC2373)	Medsafe approved as a primary course, <u>not</u> booster. The Australian Technical Advisory Group on Immunisation (ATAGI) has recommended the use of the Novavax vaccine as a booster in Australians aged 18 and over where an mRNA vaccine is not suitable <sup>4</sup> .
Covovax (Serum Institute India Novavax formulation)	Not know to be currently utilized as a booster in any jurisdiction. Phase-3 clinical trials for Covovax as a booster dose proposed <sup>5</sup>
AstraZeneca (Covishield, Serum Institute India formulation)	India are offering AstraZeneca (Covishield) as a third 'precautionary dose' for Health and frontline workers, as well as those over 60 who are eligible (39 weeks after second dose) <sup>6</sup> .
Sinovac (CoronaVac, PiCoVacc)	Adults in Malaysia who received a primary course of Sinovac can be offered a Sinovac booster dose if they prefer. However, the Malay Ministry of Health recommends Pfizer or AstraZenaca as the preferred booster <sup>7</sup> .
Sinopharm, Beijing (BBIBP-CorV, BIBP vaccine, Covilo)	Individuals from 16 years and above in the United Arab Emirates who received a primary course of Sinopharm

<sup>1</sup> https://www.health.gov.au/news/atagi-statement-on-defining-up-to-date-status-for-covid-19-vaccination

<sup>2</sup> https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html

<sup>3</sup> <u>https://www.gov.uk/government/publications/covid-19-vaccination-booster-dose-resources/covid-19-vaccination-a-guide-to-booster-vaccination-for-individuals-aged-18-years-and-over</u>

<sup>4</sup> <u>https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/atagi-recommends-novavax-for-use-as-a-covid-</u> <u>19-booster</u>

<sup>5</sup> https://www.business-standard.com/article/current-affairs/govt-panel-allows-phase-3-trial-of-covovax-as-boosterdose-in-adults-122030600490\_1.html

<sup>6</sup> <u>https://www.cowin.gov.in/</u>

<sup>7</sup> <u>https://www.malaymail.com/news/malaysia/2022/02/12/walk-in-for-sinovac-covid-19-vaccine-booster-available-starting-feb-14/2041171</u>

	vaccine can receive a Sinopharm booster dose 6 months after the second dose <sup>8</sup> .
	Individuals in Indonesia aged 18 years and over who have who received a primary course of Sinopharm vaccine can receive a Sinopharm booster dose <sup>9</sup> .
Bharat Biotech (Covaxin, BBV152)	India are offering Covaxin as a third 'precautionary dose' for Health and frontline workers, as well as those over 60 who are eligible (39 weeks after second dose) <sup>10</sup> .
Janssen / Johnson & Johnson (Janssen COVID-19 Vaccine, Ad26.COV2.S1, JNJ- 78436735)	Although not preferred, Australia, the United States of America, and the United Kingdom do offer the Janssen vaccine as a 'booster'.
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<sup>&</sup>lt;sup>8</sup> https://u.ae/en/information-and-services/justice-safety-and-the-law/handling-the-covid-19-outbreak/eligibility-forcovid19-booster

<sup>&</sup>lt;sup>9</sup> https://setkab.go.id/en/bpom-issues-eua-for-sinopharm-vaccine-as-booster-shot/

<sup>&</sup>lt;sup>10</sup> https://www.cowin.gov.in/