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21 May 2024

s 9(2)(a)

Ref: H2024039979

Tēnā koe s 9(2)(a)

### 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 – Manatū Hauora (the Ministry) on 22 April 2024 for information regarding section 34A(4) of the Medicines Act 1981. Please find a response to each part of your request below.

*Please provide copies of all analysis and assessment done by you or your predecessor under s34A(4) of the Medicines Act for any off label approval of any Pfizer vaccine.*

*Please include copies of all advice you received prior to each assessment and/ or decision and for each such occasion the information you assessed and relied on about harm or possible harm from the vaccine including:*

*A) any harm known to be associated with the spike protein, harm associated with Polyethylene glycol "PEG" and other components of the nanotech gel and harm from SV40 and other contaminants that may be in the PfizerVax and the cumulative effects of these).*

*B) any information you relied on to support assumptions or hopes that the PfizerVax may prevent infection and/or transmission*

*C) information to explain who or what categories of patients your notice would apply to and analysis to show why.*

*D) any review of the outcomes for those receiving treatment under s34A compared to those who did not and steps taken to obtain this information including the numbers receiving treatment under s34A and the reasons.*

The Director-General of Health has issued three notices under section 34A of the Medicines Act 1981 authorising off-label administration of a Pfizer COVID-19 vaccine:

- 23 June 2022 – ongoing delivery of third dose after three months
- 12 July 2022 – fourth dose (this notice repealed an earlier notice made on 27 June)
- 15 November 2022 – fourth dose for Māori and Pacific people aged 40 to 49.

Information supporting the 23 June 2022 decision is publicly available on the Ministry's website at: [www.health.govt.nz/system/files/documents/pages/dg-memo-notice-under-s34a-for-fourth-dose1.pdf](http://www.health.govt.nz/system/files/documents/pages/dg-memo-notice-under-s34a-for-fourth-dose1.pdf).

Most people in the above categories receiving booster doses of the Comirnaty (Pfizer) COVID-19 vaccine between June 2022 and April 2023 would have received them under Section 34A. The Ministry is not aware of any efforts that have been undertaken to review treatment outcomes for this group in contrast with people receiving additional doses under another mechanism (e.g. under prescription or Immediate Modification Order). Section 34A Notices are

no longer required, as the Comirnaty (Pfizer) COVID-19 vaccine is now approved by Medsafe as a booster dose without the number of boosters being specified.

Further information in scope of this part of your request is outlined in the table in Appendix 1. Where information is withheld under section 9 of the Act, I have considered the countervailing public interest in releasing information and consider that it does not outweigh the need to withhold at this time.

I also refer you to a previous Ministry OIA response (H20222014350) which may be of interest to you. This can be found at: [www.health.govt.nz/system/files/documents/information-release/h20222014350\\_response.pdf](http://www.health.govt.nz/system/files/documents/information-release/h20222014350_response.pdf).

*Please also include equivalent information about the off label administration of remdesivir including information about follow up and analyse of the short and longer term outcome for those treated with remdesivir.*

On 20 May 2024, you were advised that information relating to this part of your request was more closely connected with the functions of Pharmac - Te Pātaka Whaioranga and therefore transferred in accordance with section 14(b)(ii) of the Act. You can expect a response from Pharmac in due course.

I trust this information fulfils your request. If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: [oiagr@health.govt.nz](mailto:oiagr@health.govt.nz).

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](mailto: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 Manatū Hauora website at: [www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests](http://www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests).

Nāku noa, nā



Dr Andrew Old  
**Deputy Director-General**  
**Public Health Agency | Te Pou Hauora Tūmatanui**

## Appendix 1: List of documents for release

#	Date	Document details	Decision on release
1	10 August 2022	Memo: Extending second booster eligibility to 30 to 49 year olds: COVID-19 Vaccine Technical Advisory Group (CVTAG) recommendations	Publicly available at: <a href="http://www.tewhatauora.govt.nz/assets/About-us/Who-we-are/Expert-groups/COVID-19-Vaccine-Technical-Advisory-Group-CV-TAG/Extending-second-booster-eligibility-to-30-to-49-year-olds.pdf">www.tewhatauora.govt.nz/assets/About-us/Who-we-are/Expert-groups/COVID-19-Vaccine-Technical-Advisory-Group-CV-TAG/Extending-second-booster-eligibility-to-30-to-49-year-olds.pdf</a> .
2	September 2022	COVID-19 Mortality in Aotearoa Inequities in Risk	Publicly available at: <a href="http://www.health.govt.nz/system/files/documents/publications/covid-19_mortality_in_aotearoa_inequities_in_risk_september_2022_29_sept.v2.pdf">www.health.govt.nz/system/files/documents/publications/covid-19_mortality_in_aotearoa_inequities_in_risk_september_2022_29_sept.v2.pdf</a> .
3	1 November 2022	Memo: Extending Second Booster Eligibility to Māori and Pacific peoples aged 40 to 49 years: COVID-19 Vaccine Technical Advisory Group (CVTAG) recommendations	Publicly available at: <a href="http://www.tewhatauora.govt.nz/assets/About-us/Who-we-are/Expert-groups/COVID-19-Vaccine-Technical-Advisory-Group-CV-TAG/Extending-Second-Booster-Eligibility-to-Maori-and-Pacific-Peoples-aged-40-49-years.pdf">www.tewhatauora.govt.nz/assets/About-us/Who-we-are/Expert-groups/COVID-19-Vaccine-Technical-Advisory-Group-CV-TAG/Extending-Second-Booster-Eligibility-to-Maori-and-Pacific-Peoples-aged-40-49-years.pdf</a> .
4	15 November 2022	DG Memorandum: Considerations for extending the eligibility for fourth doses of COVID-19 vaccines to Māori and Pacific peoples aged 40 to 49 years	Some information withheld under section 9(2)(h) of the Act, to maintain legal professional privilege.

# DG Memorandum

## Considerations for extending the eligibility for fourth doses of COVID-19 vaccines to Māori and Pacific peoples aged 40 to 49 years

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**Date:** 15 November 2022

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**To:** Dr Diana Sarfati, Director-General of Health

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**Copy to:** Phil Knipe, Chief Legal Advisor, Health Legal

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**From:** Andrew Old, Deputy Director-General

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**For your:** Decision and signing

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### Purpose of report

1. This memo provides:
  - 1.1. background and context on Director-General Notices pursuant to section 34A of the Medicines Act 1981 regarding off label authorisation of COVID-19 vaccines;
  - 1.2. advice to inform a decision whether to extend the eligibility for fourth doses of COVID-19 vaccines to Māori and Pacific people aged 40 years and over beyond those already authorised by Director-General Notice pursuant to section 34A of the Medicines Act 1981 as recommended by CV TAG; and
  - 1.3. seeks your decision under section 34A of the Medicines Act, in line with the CV TAG advice, whether to authorise the administration of fourth doses to Māori and Pacific people aged 40 to 49 years (those over 50 are already eligible).

### Background and context

2. In April 2022 the COVID-19 Vaccine Technical Advisory Group (CV TAG) provided initial advice on the waning of immunity after receiving a third COVID-19 vaccine dose, and the groups in which waning immunity may occur more rapidly. This advice included recommendations for fourth doses (as a second booster) for certain groups, and the dose interval at which a fourth dose should be given.
3. On 16 May 2022 Vaccine Ministers agreed to progress an amendment to the Medicines Act 1981 (the Act) to enable the Director-General of Health to authorise the administration of a consented COVID-19 vaccine otherwise than in accordance with the approved data sheet for that vaccine (HR20220797 refers).
4. On 22 June 2022 the Medicines Amendment Bill (No.2) received Royal Assent and is now in force. The Act now enables the Director-General to authorise the administration of a consented COVID-19 vaccine otherwise than in accordance with the approved data sheet for that vaccine

by issuing a Director-General Notice. The Director-General may only issue a notice in respect of a COVID-19 vaccine that has already been given consent or provisional consent under sections 20 or 23 of the Act.

5. Before issuing a notice, the Director-General must:
  - have regard to the likely therapeutic value of the proposed administration of that COVID-19 vaccine, and the risk (if any) of the proposed administration injuriously affecting the health of any person (section 34A (4)(a)).
  - be satisfied that the proposed administration of the COVID-19 vaccine is an appropriate measure to manage the risks associated with the outbreak or spread of COVID-19 (section 34A (4)(b)).
6. The Director-General may specify by notice published in accordance with the Legislation Act 2019:
  - i. who may receive the vaccine;
  - ii. the recommended number and frequency of doses;
  - iii. the recommended manner of administration; and
  - iv. any other circumstances in which the vaccine may be administered.
7. Any person or class of persons permitted by the Act or by regulations to administer the relevant COVID-19 vaccine may administer that vaccine in accordance with a notice issued under section 34A. This means all vaccinators currently administering COVID-19 vaccines as part of the COVID-19 Immunisation Programme are able to administer any vaccines authorised by notice under section 34A.

#### *Current Director-General Notices*

8. Pfizer has not yet applied to Medsafe for approval of any further doses beyond the third dose. Therefore, vaccines used outside of their approved indications are supplied "off label" and are only able to be administered in accordance with sections 25 or 29 of the Medicines Act. Issuing a Director-General Notice under section 34A of the Act enables specified off-label COVID-19 vaccination to occur without relying on sections 25 or 29.
9. As at 13 July 2022 the following notices issued by the Director-General pursuant to section 34A of the Act are in force (the Director-General memoranda for these notices are attached in Appendices 1, 2 and 3):
  - 9.1. 23 June Director-General Notice – authorised off-label administration of COVID-19 vaccine – interval between second and third doses at a reduced 3 month dose interval since completing a primary COVID-19 vaccine course.
  - 9.2. 12 July 2022 Director-General Notice - authorised the administration of fourth doses of the Pfizer/BioNTech (Comirnaty) COVID-19 vaccine (Pfizer vaccine) to:
    - a. any person aged 50 years and over;
    - b. residents of aged care and disability care facilities, aged 16 years and over;



- c. severely immunocompromised people who received a three-dose primary course and a fourth dose as a first booster (noting this would be a fifth dose for these people);
- d. people aged 16 years and over who have a medical condition that increases the risk of severe breakthrough COVID-19 illness;
- e. disabled people aged 16 years and over with significant or complex health needs or multiple comorbidities which increases the risk of poor outcomes from COVID-19;
- f. healthcare workers, including disability workers and aged care workers, aged 30 years and over–

at an interval of not less than six months since their last dose of a COVID-19 vaccine

9.3. On 13 July 2022 Director-General Notice authorised similar criteria for fourth doses of the Novavax Nuvaxovid COVID-19 vaccine. The difference between this notice and the one for the Pfizer vaccine is that Novavax Nuvaxovid COVID-19 vaccine is only available to those aged 18 years and over.

10. The changing situation of the current COVID-19 outbreak, and the further advice from CV TAG, has prompted the need for the Director-General to consider whether any additional groups should be eligible for fourth doses to manage the risks associated with the outbreak or spread of COVID-19

***CV-TAG has considered expanding the fourth dose to Māori and Pacific people aged 40 years and over***

11. On 10 August 2022, advice from CV TAG was received (see Appendix 4) on the benefit of expanding the eligibility for fourth doses to Māori and Pacific peoples aged 40 years and over. This advice recommended expanding the eligibility for fourth doses to Māori and Pacific peoples aged 40 years and over.
12. In that advice, CV TAG noted that the total number of deaths where COVID-19 has been identified as the underlying cause or a contributing factor for those aged under 50 years had been low<sup>1</sup>. However, the death rates (based on small numbers) were higher among Māori and Pacific Peoples in this age group than for those of other ethnicities.
13. At that time, you asked for further information on this recommendation before you agreed to expand the eligibility. Following this, the Public Health Agency's 'COVID-19 Mortality in Aotearoa: Inequities in Risk' report (the Mortality Report, Appendix 5) of September 2022 indicated a higher risk of COVID-19 mortality for Māori, Pacific People, and people residing in

<sup>1</sup> Appendix 4 – CV TAG Memorandum 10 August 2022 – paragraph 14.

highly socio-economically deprived regions, after accounting for the effects of age, comorbidity, and vaccination uptake.

14. On 1 November, CV TAG provided that further advice to you (Appendix 6), which you have accepted.

## **Considerations of whether extending eligibility for fourth doses will help to manage the risks associated with the outbreak and spread of COVID-19**

### *The current Omicron outbreak*

15. COVID-19 remains a significant public health risk. Variant BQ.1.1. is now in the community and previous experience with other variants and from overseas suggests it is possible that new waves will occur with new variants.
16. In early October 2022, COVID-19 case numbers began to increase again, tracking above the modelled median. The case rate at 30 October showed a 25.4% increase in cases from the previous week.
17. Death and hospitalisation rates have also correspondingly increased, but are still strongly associated with the older age groups. While there is a higher risk of severe outcomes for this age group, the risk for Māori and Pacific people in this age group is generally higher due to additional factors contributing to the risk, such as co-morbidities and socio-economic deprivation.
18. While it is not anticipated COVID-19 will be eliminated in New Zealand, the most likely scenario going forward will be that we would offer pre-winter COVID-19 vaccinations similar to influenza. Further waves of the current outbreak have been modelled, and vaccination remains our most important tool for managing the impacts.

### *The COVID-19 vaccination programme*

19. The aim of the COVID-19 vaccination programme offering a fourth dose is to maintain the population protection already gained through COVID-19 vaccination and prevent severe disease caused by COVID-19.
20. The near future of COVID-19 vaccinations will involve bivalent vaccinations and likely further doses (third dose and beyond). Medsafe is awaiting further information from Pfizer to progress the applications for consent.
21. In the interim, CV TAG has recommended that focus remains on improving the uptake of third doses to those eligible. The current focus of the vaccination programme is on ensuring uptake across all Māori and Pacific peoples who are eligible and due for their third and fourth doses are prioritised.
22. The COVID-19 Programme is able to adjust its focus as needed, depending on decisions made.
23. The Programme also notes that changing eligibility or availability can result in “vaccine fatigue”, which can hamper vaccination uptake efforts.

*Advice from the Office of the Director of Public Health*

24. The Office of the Director of Public Health (ODPH) notes the most effective way to prevent severe disease and hospitalisations due to COVID-19 is to ensure those at greatest risk of severe disease and hospitalisation are up-to-date with their recommended COVID-19 vaccinations. These groups are already included in the recommended groups for the fourth dose.
25. There is still a significant proportion of the population who are not up-to-date with their COVID-19 vaccinations (including third doses, and those who are currently recommended for a fourth dose), and this includes the populations at higher risk of severe disease and hospitalisation).
26. It is important to ensure higher coverage in populations for both third and fourth doses. In particular, improving coverage (for all those eligible) and addressing inequities (particularly for Māori and Pacific peoples) in third dose coverage should be a priority.
27. The ODPH notes that the CV TAG recommends that the age eligibility criteria for fourth doses among Māori and Pacific Peoples should be lowered to 40 years. This would help remove a barrier to access, and also has strong support from Māori. The CV TAG also recommend prioritising third dose coverage and addressing inequities in coverage for Māori and Pacific peoples.
28. The opportunity cost of expanding eligibility needs to be considered to ensure the most effective and cost-effective option for the response, whilst also improving equity, and preventing hospitalisations and deaths.
29. The ODPH supports the expanding of eligibility, although the priority should be to improve equitable coverage of third and fourth doses for all currently eligible Māori and Pacific populations .

*Te Tiriti considerations*

30. When making any decision relating to the expansion of COVID-19, the Ministry must uphold our Te Tiriti obligations and the impact that this will have on Māori, especially evaluating the effect on equity and health outcomes.
31. A 2021 Waitangi Tribunal report entitled *Haumarū: The COVID-19 Priority Report* highlighted the need to undertake a targeted roll out for vaccinating Māori. Evidence in this Tribunal report has pointed to examples where the vaccination roll out could have been better targeted to Māori and had better accessibility for Māori.
32. There are a number of statements in that report that speak to the issues being considered in this memorandum.
  - 32.1. The Tribunal quotes the Ministry of Health's own statement in papers concerning the sequencing framework (from December 2020) "there is a high level of evidence that there is high strength of association between COVID-19 infections and transmission, and population groups with shared sleeping and living arrangements."
  - 32.2. The Tribunal accepted the evidence of Dr Rawiri Jansen that "The science said very clearly that Māori are at risk from the age of 44 in an equivalent way to a 65 year old Pakeha man. This [younger] age group should therefore have been prioritised in the vaccine rollout."



32.3. . . . and of Dr George Laking that: "As such, the relationship between age and COVID-19 may be different for Māori and potentially affect the population younger than other populations. In addition, Māori households often have more people than the New Zealand average, which places more people at risk from exposure to infectious diseases – but, conversely, more people in the household stand to benefit from preventative actions".

32.4. The Tribunal itself found "due to co-morbidities and the social determinants of health, younger Māori are about as vulnerable as older pakeha [4.1.6]".

33. The Waitangi Tribunal's *Haumarū: The COVID-19 Priority Report* has identified a number of areas where the Crown could make improvements to its COVID-19 response in order to give greater effect to its obligations under Te Tiriti o Waitangi, including upholding tino rangatiratanga and ensuring Māori do not suffer from inequity, as well as making better informed decisions on matters affecting the interests of Māori.

#### *COVID-19 and Māori and Pacific people*

34. A higher risk of COVID-19 attributed death was found for Māori and Pacific peoples as a whole population group compared to the "European and Other" group (respectively 2.0 and 2.5 times the risk) after accounting for age.
35. The advice that the Ministry is delivering in this memo relies on data and advice prepared by the Ministry. We note the Tribunal report highlighted potential discrepancies with Ministry data and that other, Māori-centric entities have delivered what they consider to be more robust, complete data about the impact of COVID-19 on Māori. This data demonstrates the need for vaccination in general to cover more of the Māori population.

#### Mortality associated with COVID-19

36. The CV TAG report notes that factors associated with COVID-19 mortality risk include age, comorbidities, socio-economic deprivation, and vaccination status, all of which are negatively experienced by Māori and Pacific peoples. However, mortality rates are low in those aged 50 years and under.
37. The Mortality Report found that although COVID-19-attributed mortality was much lower in younger people than in older age groups, the age-adjusted estimates for those aged under 60 years showed that the risk was 3.7 times higher for Māori and 3.9 times for Pacific Peoples as compared to European and Other.
38. However, while 78 COVID-19 attributed deaths were reported in those under the age of 60 years (4% of all COVID-19 attributed deaths), for those without comorbidities, only one was under 50 years (and was not Māori or Pacific). Therefore, almost all of these fatalities would have been eligible for a fourth dose based on age and/or their underlying health condition.

#### Morbidity associated with COVID-19

39. Preliminary analyses of Aotearoa New Zealand COVID-related-hospitalisation data for 2022 show that Māori aged 40 to 49 years have around twice the risk of COVID-related hospitalisation in comparison to their "European and Other" counterparts. Pacific peoples aged 40 to 49 years were even more likely to be hospitalised, at around 2.5 times the risk of "European and Other" people in the same age group.
40. The CV TAG report notes the analysis of 5,620 hospitalisations from the Northern Region, (Figure 2) since 3 January 2022 show that both Māori and Pacific peoples are hospitalised with

COVID-19 at a lower age (at an average of around 46 years) than other ethnicities (average of 49 years).

41. The *Ka Mātau, Ka Ora* study found that Māori participants had high rates of pulmonary disease (primarily asthma) which may contribute to higher hospitalisation rates from COVID-19. Pacific Peoples were more likely to have diabetes which was associated with a reduction in antibody responses. These people are already eligible for the fourth dose if they are aware of their comorbidities.
42. However, comorbidities are likely to be underestimated in these population groups, due to the way data are collected (mainly from primary care information) and undiagnosed, as a result of difficulties in accessing healthcare (cost, availability and appropriateness of health services).
43. Long COVID, cardiovascular disease and neurological disorders appear to be more common among people who have severe COVID-19 symptoms during acute illness, and with less vaccine protection. Māori and Pacific Peoples are likely to face a higher burden of this impact of infection.
44. Additionally, Māori and Pacific peoples who wish to access a COVID-19 vaccination, but who are not eligible, have greater difficulty in accessing one particularly if they require a prescription.
45. Expanding the eligibility of fourth doses to include Māori and Pacific peoples aged 40 to 49 years would increase the eligible population for Māori by 29,705, and for Pacific peoples by 19,658 (accounting for recent infection).

#### Vaccination status

46. Data on the uptake of COVID-19 vaccines shows that primary course vaccination in those aged 12 years and older is high at 90% of the eligible population vaccinated to date. Primary course vaccination in Māori and Pacific Peoples is also high at 84% and 90% respectively. However, coverage of third doses is lower (particularly among Māori and Pacific Peoples, where 59% and 64% aged 18 years and older respectively have had a third dose compared with 79% of all other ethnicities).
47. Inequities are also observed in fourth dose coverage, where only 34% and 33% of Māori and Pacific peoples respectively, who are eligible for a fourth dose, have received it, as compared to 41% of other ethnicities
48. Vaccination status, specifically inequities in third and fourth doses (not broken down by third or fourth doses) accounted for approximately a quarter of the increased risk of death and hospitalisation.
49. By enabling the fourth dose to be available without a prescription removes the cost barrier and enables health services to deliver the vaccinations through a whānau-centred approach.

#### Ethnicity

50. The Mortality Report reports that when corrected for age, Māori and Pacific peoples still show an increased risk of poor outcomes with COVID-19 infections. There are excess risks associated with ethnicity, that are not explained by the variables examined in the analysis.

51. Advice from Hauora Māori and Pacific advisors strongly supports the lower eligibility age group of 40 to 49 years for Māori and Pacific people, based on the stated equivalency, of a 44 year old Māori to a 65 year old non-Māori, in the *Haumaru: the COVID-19 Priority Report* from the Waitangi Tribunal. Additionally, advisors highlight the possibility of undetected co-morbidities, and the new research indicating that ethnicity and deprivation as strong factors in the risk of poor outcomes.

### **Consideration of the criteria under section 34A of the Medicines Act**

#### ***Considering s34A (4)(a) - regard to therapeutic value and risk of injuriously affecting the health of a person***

52. There is limited but growing data on the safety and efficacy of a fourth dose in populations younger than 65 years of age, in healthy individuals, in people with social risk factors, and in pregnant people. This is because in most countries where fourth doses have been made available to date, they have been targeted to older and at-risk population groups. Healthy young people (aged under 30 years) appear to produce a strong immune response to three doses and are considered to have continued good protection from adverse outcomes of COVID-19 infection.

#### *Effectiveness*

53. A growing body of international evidence is emerging in the form of real world data from those at-risk populations who have already received a fourth dose.
54. Studies have shown that the relative vaccine effectiveness of a fourth dose in boosting immunity back to levels similar to those gained from a third dose is substantial and sustained against severe disease, hospitalisation and death but less so against infection. A fourth dose may recover the immunity lost from waning, which can provide an important boost over the winter months and during periods of surging infection.

#### *Safety*

55. The growth in the availability of real world data is contributing to studies such as a nationwide study undertaken by the University Hospital Southampton in the UK, published in August 2022, that found fourth doses of the Pfizer COVID-19 vaccine proving to be both safe and even more effective than third doses at boosting immunity against COVID-19.
56. CV TAG has considered the safety profile of fourth doses of the Pfizer and Novavax vaccines in New Zealand. From the data available so far reported adverse reactions appear to be similar as for primary course and third doses – for most people mild – and more commonly reported in younger age groups than in those over 60 years of age. In the Māori and Pacific peoples aged 40 to 49 years, the rates of severe adverse reactions are low.
57. For myocarditis and pericarditis following mRNA COVID-19 vaccination, the risk is highest among young male individuals following the fourth dose. The incidence ratio for people aged 40 to 59 years following a fourth dose in Aotearoa New Zealand is estimated at 3.62 per 100,000 population, in comparison to 25.84 for those aged 5 to 19 years of age or 6.50 for those aged 20-39 years. The risk of myocarditis/pericarditis remains significantly greater from a COVID-19 infection than from the vaccine itself.

58. The Centre for Adverse Reaction Monitoring has recorded 34 reported cases of myocarditis and/or pericarditis in the 40 to 49 year age group after a COVID-19 vaccine (as at 4 October 2022). Seven cases have been in Māori and five cases in Pacific people. Due to the low numbers, no analysis can be carried out.
59. Cases of myocarditis/pericarditis usually recover fully with no long lasting effects, especially when the symptoms are acted upon early. All providers are required to make people aware of the symptoms when they receive their dose.

***Considering s34A (4)(b) – be satisfied that administration is an appropriate measure to manage the risks associated with the outbreak or spread of COVID-19***

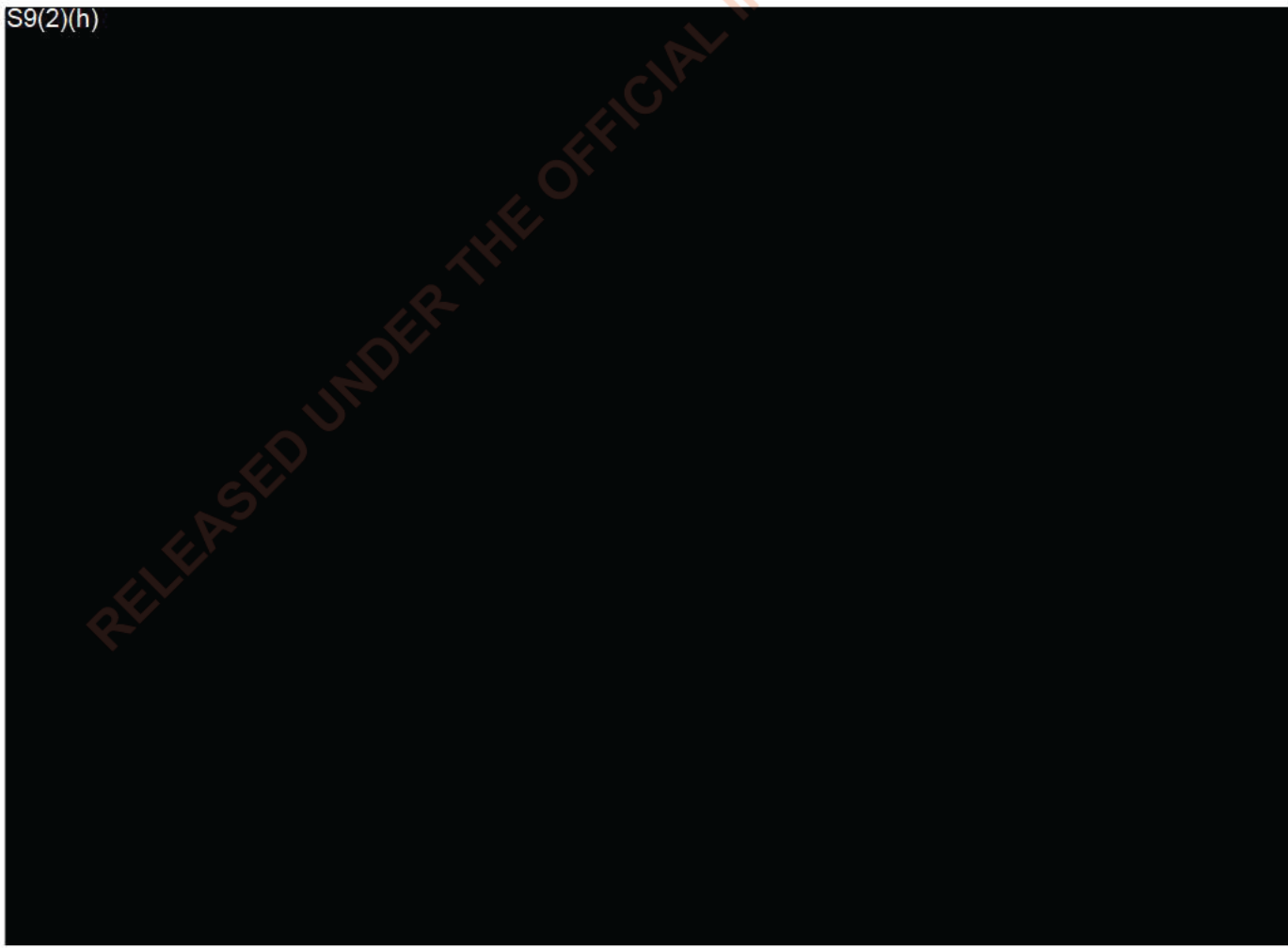
60. In June 2022, prior to the peak of infections and when the groups were first considered by the Director-General, the Ministry's view was that targeting the recommended groups was justified due to their vulnerability to serious outcomes from COVID-19 or high risk of exposure. The data at the time from the Omicron outbreak clearly showed those who are developing severe illness, and those who are dying from COVID-19, were for the most part in the recommended groups.
61. It is not anticipated that COVID-19 will be eliminated. COVID-19 will continue to circulate in Aotearoa New Zealand and it is expected we will experience increases in case numbers at times. Currently, Aotearoa New Zealand is experiencing another increase. There is currently an average of 2,967 new reported cases per day nationally (7 day rolling average to 4 November). In contrast, the 7 day rolling average to 9 October was 1,598.
62. COVID-19 remains in the community and with sub-variants such as BQ.1.1. having an apparent growth advantage of 10%, modelling suggests that further waves will occur.
63. As the current Omicron outbreak has continued, the data shows those most at risk of severe outcomes continue to be those already targeted in the groups covered through the current Director-General Notices. However, Māori and Pacific people aged 40 to 49 years, experience significantly higher rates of poor outcomes with a COVID-19 infection than other groups who are not currently eligible for a fourth dose.
64. Age-adjusted estimates for those aged under 60 years shows that the mortality risk was 3.7 times higher for Māori and 3.9 times for Pacific peoples as compared to European and Other, and is also increased by age, comorbidities, socioeconomic deprivation and vaccination status, all negatively experienced by Māori and Pacific peoples. The data do not, however, indicate that there is a higher death rate in those aged 40 to 49 years.
65. While there is no evidence of a higher death rate, hospitalisation is twice the risk for Maori aged 40 to 49 years, and 2.5 times for Pacific peoples of the same age when compared to European and Other. They are also more likely to have comorbidities that are more likely to be undiagnosed (and therefore they would not know they are eligible for the fourth dose) that may contribute to higher hospitalisation rates from COVID-19 and subsequently Long COVID, cardiovascular disease and neurological disorders.
66. Hospitalisations have an impact on the health system that is already under significant pressure.
67. While ethnicity in and of itself is not clearly a risk factor, excess risks are associated with ethnicity that are not explained by the variables examined in the analysis.



68. CV TAG noted in its 1 November 2022 report that there is likely to be high levels of hybrid immunity in Aotearoa New Zealand due to high vaccination rates. However, inequities in third and fourth doses are identified as increasing the risk of severe outcomes, and vaccination is the one of the strongest modifiable risks. Immunity does wane and there will still be some in our community who have poor or no immunity.
69. Eligibility is not being extended for all population groups aged 40 to 49 at this time. Māori and Pacific peoples morbidity is higher than in other ethnicities at lower ages, and extending the eligibility seeks to mitigate higher hospital admissions and known access issues for these groups with evidence of greater risk. Consideration of additional doses for the wider population is being considered in the context of pre-winter 2023 COVID-19 vaccination campaigns.
70. It is considered that the health advice and modelling provide a reasonable basis for you as Director General to be satisfied that administration of the vaccine is an appropriate measure to manage the risk of the outbreak. On this basis, having regard to the favourable risk benefit profile of a fourth dose (based on the limited evidence available), it is recommended that you issue a notice under section 34A to make fourth doses available to Māori and Pacific people aged 40 years and over.

**Crown Law Advice [Legally privileged]**

S9(2)(h)



RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982



S9(2)(h)

## Conclusion

74. With regard to lowering the age of the fourth dose to Māori and Pacific people aged 40 years and over, these groups still experience higher rates of poor outcomes with a COVID-19 infection. Additionally, this group experiences greater access difficulties if they need to obtain a vaccination with a prescription and are over-represented in deprived areas that see poorer COVID-19 outcomes.
75. The overall mortality risk from COVID-19 infection among those under the age of 60 is very low, as highlighted in advice from CV TAG and as outlined in the Mortality Report, but there is an increased risk of hospitalisation and ongoing effects of a severe infection.
76. There is a strong view that making the COVID-19 vaccinations available to Māori and Pacific peoples aged 40 to 49 years meets the threshold of s34A(4)(b) by managing the risks of the outbreak, which includes the risks of death and hospitalisation and reducing the burden on the health system. We therefore propose that you make available for fourth doses for Māori and Pacific people aged 40 years and over.
77. The current priority for the COVID-19 vaccination programme remains increasing uptake of third (or booster) COVID-19 doses, particularly across the Māori and Pacific populations, and then increasing the uptake of fourth doses for those in the targeted groups.
78. Failure to address the causes of low and inequitable coverage of third doses, will result in the same failures in the roll out of fourth doses (regardless of the eligibility criteria for fourth doses).

## Next steps

79. Should you choose to expand the criteria, a Director-General Notice is attached for your signature. The Notice will be published on the Ministry of Health website and in the *New Zealand Gazette* on the day of signature, and Māori and Pacific people who wish to book their fourth dose vaccinations will be able to do so from Friday 18 November 2022.
80. The CV TAG recommendation is expected to be communicated at the Wednesday Stand Up on 16 November 2022.
81. The Ministry will continue to monitor the current COVID-19 outbreak and the available scientific and technical advice in regard to fourth doses and provide further advice when required, should the situation change.

## Recommendations

It is recommended that you:

1.	note	section 34A of the Medicines Act 1981 empowers the Director-General of Health to authorise, by Notice, the use of a consented COVID-19 vaccine otherwise than in accordance with the approved data sheet	Noted ✓
2.	note	to issue a notice under new section 34A, as Director-General you:  (a) must be satisfied that the proposed administration of the COVID-19 vaccine is an appropriate measure to manage the risks associated with the outbreak or spread of COVID-19; and  (b) must have regard to the likely therapeutic value of the COVID-19 vaccine, and its risk (if any) of injuriously affecting the health of any person	Noted  ✓
3.	note	on 23 June 2022 the previous Director-General of Health issued a notice pursuant to section 34A authorising the off-label administration of already consented COVID-19 vaccines at a reduced interval between the second and third doses (see Appendix 1)	Noted ✓

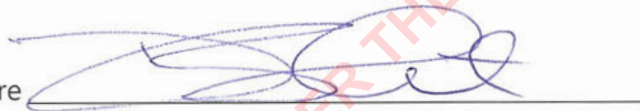


6.	note	In their advice of 1 November, attached to this memo (Appendix 6), CV TAG has recommended that the age eligibility for fourth doses for Māori and Pacific people be lowered to 40 years of age and over	Noted ✓
7.	note	that cases are increasing, tracking above the modelled median, with the case rate at 30 October showed a 25.4% increase in cases from the previous week	Noted ✓
8.	note	COVID-19 is not likely to be eliminated in Aotearoa New Zealand and that it is anticipated case increases like the one we are currently experiencing will occur regularly as new variants continue to arrive in New Zealand	Noted ✓
9.	note	that while the 40 to 49 age group is at lower risk than older age groups, this age group for Maori and Pacific people has higher risk of severe outcomes from COVID-19 (Māori at twice the risk, and Pacific people at 2.5 times the risk). Ethnicity itself appears to be a risk factor	Noted ✓
10.	note	the safety and efficacy of COVID vaccines has been established for up to three doses and there is no evidence that the fourth dose will have a greater safety risk and there is evidence a fourth dose boosts immunity back to levels similar to those gained from a first booster dose and provides protection against severe disease, hospitalisation and death but less so against infection.	Noted ✓
11.	note	that expanding eligibility for a fourth dose to include Māori and Pacific people aged 40 to 49 years is consistent with the findings of the 2021 Waitangi Tribunal report entitled <i>Haumarū: The COVID-19 Priority Report</i>	Noted ✓
12.	note	that the age range is not extended to other population groups as evidence indicates a higher morbidity rate for Māori and Pacific people than in other ethnicities at lower ages, and extending eligibility seeks to mitigate this morbidity rate and known access issues	Noted ✓
13.	note	that consideration of additional doses for the wider population is being considered in the context of pre-winter 2023 COVID-19 vaccination campaigns.	Noted ✓
14.	agree	you are satisfied that authorising the administration of fourth doses of the Pfizer COVID-19 vaccine or the Novavax COVID-19 vaccine to Māori and Pacific people aged 40 to 49 years, at an interval of not less than six months since their last dose of a COVID-19 vaccine is an appropriate measure to manage the risks associated with an outbreak or spread of COVID-19	Yes/No



15.	agree	you are satisfied that the likely therapeutic value of a fourth dose of the Pfizer COVID-19 vaccine or the Novavax COVID-19 vaccine to Māori and Pacific people aged 40 to 49 years outweighs the risk, if any, of a fourth dose injuriously affecting the health of any person in those groups	Yes/No
16.	authorise	pursuant to section 34A of the Medicines Act 1981, the administration of fourth doses of the Pfizer COVID-19 vaccine and the Novavax COVID-19 vaccine to Māori and Pacific people aged 40 to 49 years at an interval of not less than six months since their last dose of a COVID-19 vaccine (in line with the CV TAG recommendation) and sign the draft notice attached for this purpose	Yes/No
17.	note	that upon your signing of the notice attached, this will come into effect immediately and be published on the Ministry website and in the <i>New Zealand Gazette</i>	Noted ✓
18.	note	the National Immunisation Programme will implement the changes by 18 November 2022.	Noted ✓

Signature



Date: 15 / 11 / 22

Dr Diana Sarfati  
**Director-General of Health**  
**Te Tumu Whakarae mō te Hauora**

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