

Briefing

Updated eligibility criteria for fourth doses of Pfizer COVID-19 vaccine

Date due to MO: 23 June 2022 **Action required by:** 23 June 2022

Security level: IN CONFIDENCE **Health Report number:** 20221130

To: Hon Dr Ayesha Verrall, Minister for COVID-19 Response

Copy to: Hon Andrew Little, Minister of Health

Contact for telephone discussion

Name	Position	Telephone
Allison Bennett	Acting Group Manager, Public Health System Policy, System Strategy and Policy	S9(2)(a)
Caroline Flora	Acting Deputy Director-General, System Strategy and Policy	S9(2)(a)

Minister's office to complete:

- | | | |
|---|------------------------------------|--|
| <input type="checkbox"/> Approved | <input type="checkbox"/> Decline | <input type="checkbox"/> Noted |
| <input type="checkbox"/> Needs change | <input type="checkbox"/> Seen | <input type="checkbox"/> Overtaken by events |
| <input type="checkbox"/> See Minister's Notes | <input type="checkbox"/> Withdrawn | |

Comment:

Updated eligibility criteria for fourth doses of Pfizer COVID-19 vaccine

Security level: IN CONFIDENCE **Date:** 23 June 2022

To: Hon Dr Ayesha Verrall, Minister for COVID-19 Response

Purpose of report

1. This report informs you of further advice received from the COVID-19 Vaccine Technical and Advisory group (CV TAG) on the recommended groups to receive a fourth dose of the Pfizer/BioNTech COVID-19 vaccine.
2. It also updates you on the Director-General of Health's (Director-General) intention to expand the eligibility criteria via a Notice under the new section 34A of the Medicines Amendment Act 2022.

Summary

3. On 1 April 2022 CV TAG provided advice on the waning of immunity after a third COVID-19 vaccine dose, and the groups in which waning may occur more rapidly. That advice included recommendations for fourth doses for certain groups, and the dose interval at which this should be given.
4. The following groups were recommended to receive a fourth dose, at an interval of six months since their previous dose:
 - a. people aged 65 years and over
 - b. Māori and Pacific peoples aged 50 years and over
 - c. residents of aged care and disability care facilities
 - d. 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).
5. Further to its initial advice, CV-TAG was asked to provide updated advice and have included the following additional groups:
 - a. people aged 16 years and over who have a medical condition that increases the risk of severe breakthrough COVID-19 illness
 - b. disabled people aged 16 years and over with significant or complex health needs or multiple comorbidities that increase the risk of poor outcomes from COVID-19.
6. The Director-General of Health, after considering CV TAG advice and reviewing additional information, will also include in the Notice:
 - All people over 50 years

- Healthcare workers 30 years and over
- 7. The COVID-19 Vaccination Programme should target efforts towards populations as recommended by CV-TAG, whilst making it available to those populations over 50 and healthcare workers over 30 years of age.
- 8. On 21 June 2022 the Medicines Amendment Bill (No 2) passed through Parliament. It received Royal Assent on 22 June 2022 and will be in force from 23 June 2022.
- 9. The Director-General has issued a notice on 23 June 2022 under section 34A of the Act to authorise the ongoing delivery of third (or booster) doses of the Pfizer COVID-19 vaccine at the reduced 3-months dose interval since completion of a primary COVID-19 vaccine course.
- 10. The Director-General intends to issue a Notice on Monday, 27 June 2022 under the new section 34A to provide for the roll out of fourth doses to the recommended groups from Tuesday, 28 June 2022.

Recommendations

We recommend you:

- a) **note** the Medicines Amendment Act 2022 has come into force and enables 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 the applicable vaccine if the Director-General is satisfied that this is an appropriate measure in order to manage the risks associated with a COVID-19 outbreak Noted
- b) **note** that CV TAG have extended their recommendations which now include the following groups to receive a fourth dose, at an interval of six months since their previous dose: Noted
 - a) people aged 65 years and over
 - b) Māori and Pacific peoples aged 50 years and over
 - c) residents of aged care and disability care facilities
 - d) 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)
 - e) people aged 16 years and over who have a medical condition that increases the risk of severe breakthrough COVID-19 illness and
 - f) people aged 16 years and over who live with disability with significant or complex health needs or multiple comorbidities
- c) **note** the Director-General will on 27 June 2022, by Notice pursuant to the new section 34A of the Medicines Act, authorise fourth doses of COVID-19 vaccines to be administered without a prescription to the CV TAG recommended groups Noted

d) **note** that the Director-General of Health will also include in that Notice the following groups as eligible for a fourth dose: **Noted**

- all people aged over 50 years
- healthcare workers aged over 30 years

e) **note** the Director-General has also authorised the administration of third (booster) doses of the Pfizer/BioNTech COVID-19 vaccine at the reduced three month dose interval via a Notice under the new section 34A on 23 June 2022 **Noted**

f) **note** Ministers will continue to receive advice to support key decisions relating to COVID-19 vaccination options based on the latest scientific and technical advice **Noted**

g) **note** the roll out of fourth doses to the recommended groups will commence from Tuesday, 28 June 2022 **Noted**



Dr Ashley Bloomfield

Te Tumu Whakarae mō te Hauora

Director-General of Health

23 June 2022



Hon Dr Ayesha Verrall

Minister for COVID-19 Response

23/6/22

Updated eligibility criteria for fourth doses of Pfizer COVID-19 vaccine

Background

11. The Medicines Amendment Act 2022 (the Act) came into force on 23 June 2022. The Act inserts a new provision to the Medicines Act 1981 that enables the Director-General of Health (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 notice under section 34A of the Act (the Notice).
12. The Director-General must be satisfied that administration of the vaccine is an appropriate measure to manage the risks associated with the outbreak or spread of COVID-19.
13. 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.
14. The Director-General must also 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.
15. 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.
16. Section 34A provides for ongoing COVID-19 vaccine requirements, such as additional doses, changes to dose intervals, or targeting different population groups.
17. Any decisions by the Director-General to authorise further vaccine doses will be based on the latest international scientific and technical advice on safety, quality and efficacy, supported by real-world data.
18. CV TAG's initial advice on fourth doses came after they considered the relevant evidence available in March 2022 and provided a memo to the Director-General on 1 April 2022.
19. Since that time, further evidence has become available as more countries around the world have rolled out fourth doses to target groups in their populations. This has provided real world data on the impact of fourth doses that has also supported further recent studies on the safety and efficacy of fourth doses.
20. CV TAG has provided further advice on the groups who should be eligible for fourth doses.
21. The Director-General has carefully considered the latest CV TAG advice and reviewed the summary of evidence in that advice.

Why a fourth dose is needed to manage the risks associated with the outbreak and spread of COVID-19

22. After the peak of the current COVID-19 outbreak in March 2022, there was a steady decline of cases to the week of 17 April 2022. Following that, the rate of decline has slowed. The weekly COVID-19 case rate was 9.3 per 1000 people for week ending 5 June 2022, which is a decrease on the week prior and consistent with an overall trend downwards, with some variation across regions.
23. Precise case numbers remain uncertain. During the Omicron outbreak, the results of surveillance testing in border workers have been used to approximate the 'true' rate of infection in the community. In the week ending 5 June 2022, border workers had a case rate of 14 per 1000 people compared with 9.3 per 1000 people in the general population. Given border workers are considered a proxy for prevalence in the community and undertake routine surveillance testing, this suggests there are approximately 50 percent more cases in the community than testing data is showing. Similar estimates earlier in the outbreak were that there were around twice as many cases as testing data showed.
24. In addition, wastewater testing shows that infection levels may be higher than self-reported cases, as wastewater RNA levels have remained relatively constant since early April.
25. CV-TAG has noted that there is evidence of waning immunity following the third (or booster) dose. Immunity also appears to wane faster in some populations, such as the elderly and immunocompromised people, who may also have a lower immune response to the vaccines.
26. Third (booster) doses began to be administered in New Zealand from 29 November 2021, and therefore many people in the recommended groups are now, or soon will be, six months from receiving their third dose as we move through winter.
27. Data from the Omicron outbreak in New Zealand to date shows that hospitalisations and deaths have been higher in the groups recommended by CV-TAG to receive a fourth (second booster) dose. The highest mortality rates have been among those aged 65 years and over. Additionally, we know that Māori and Pacific peoples have been disproportionately affected in the current outbreak to date and are at greater risk of hospitalisation and severe disease from COVID-19, having respectively 2.5-fold and 3-fold higher odds of being hospitalised compared with non-Māori/non-Pacific peoples, and Māori are likely to spend 4.9 days longer in hospital.
28. Immunocompromised people and those with chronic conditions are also at increased risk of severe outcomes from COVID-19 and are more likely to be hospitalised.
29. The goal of the COVID-19 vaccination programme offering a fourth dose in New Zealand is to maintain the population protection already gained through COVID-19 vaccination and prevent severe disease cause by COVID-19. Fourth doses are critical now as we manage the additional risk of seasonal winter respiratory illnesses alongside the likely

further COVID-19 spread throughout winter, and with modelling forecasting a second peak of cases during winter or early spring.

30. The BA.4 and BA.5 Omicron subvariants are now emerging in New Zealand and have a clear transmission advantage over the currently dominant BA.2. We therefore expect that as these new subvariants, which also exhibit significant immune escape, will add to case numbers and hospital admissions over winter.
31. Demand is already placing significant pressure on the health system, including both primary care and hospitals. COVID-19 and influenza are both contributing markedly to the overall burden, for example 50 percent of district health boards (DHBs) experienced inpatient occupancy of over 90 percent in recent weeks.
32. Despite the impact of other respiratory illnesses on the health system, COVID-19 continues to require targeted measures due to its substantially higher mortality rate compared to seasonal illnesses such as influenza, and the greater potential severity of its symptoms

Eligibility for the fourth dose

33. CV TAG have considered the safety profile of fourth doses of the Pfizer vaccine. 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.
34. 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.
35. This data is contributing to studies such as a nationwide study undertaken by the University Hospital Southampton in the UK, published last month, that found fourth doses of the Pfizer COVID-19 vaccine are proving to be both safe and even more effective than third doses at boosting immunity against COVID-19.
36. CV TAG has recommended the following groups to receive a fourth dose:
 - a. people aged 65 years and over
 - b. Māori and Pacific peoples aged 50 years and over
 - c. residents of aged care and disability care facilities [of any age]
 - d. 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)
 - e. people aged 16 years and over who have a medical condition that increases the risk of severe breakthrough COVID-19 illness
 - f. disabled people aged 16 years and over with significant or complex health needs or multiple comorbidities that increase the risk of poor outcomes from COVID-19.

Māori and Pacific peoples aged 50 years and over

37. There are a number of equity considerations. CV TAG have identified the groups that will most benefit from a fourth COVID-19 vaccination. These groups include Māori and Pacific peoples over 50 years of age.

38. Data from both the Delta and Omicron outbreaks have shown that Māori and Pacific peoples are at greater risk of COVID-19 hospitalisation and severe disease compared to non-Māori and are likely to spend 4.9 days longer in hospital. Māori and Pacific peoples are also more likely to live in multigenerational families housing in overcrowded conditions, increasing the risk of transmission.
39. Delivery of fourth doses will increase protection from COVID-19 for Māori and Pacific peoples over 50 and has the potential to significantly reduce the number of hospitalisations and deaths in the recommended groups, including for Māori and Pacific peoples, and to help manage the additional pressure on the health system during the winter season.

Older people over the age of 65 years old, residents living in aged care and disability care facilities, and those severely immunocompromised

40. An early study from the delivery of fourth doses in Israel has shown that the risk of infection and severe illness appears to significantly reduce after a fourth dose (approximately 2 to 4 times less likely). The study has shown those aged 60 to 100 years old who have received a fourth dose of Pfizer, have had a 78 percent lower mortality rate from COVID-19 than those who only received a third dose.

People identified by CV TAG as being at increased risk of severe outcomes from COVID-19 infection

41. People aged over 16 years with medical conditions that increases the risk of severe breakthrough COVID-19 illness and those who live with disability with significant or complex health needs or multiple comorbidities have also been recommended to receive a fourth dose, as there is potential to significantly benefit from a boost to immunity through the winter months.
42. These changes are consistent with Australia's eligible groups.

Additional aspects for consideration

43. The Director-General has considered the CV TAG advice and reviewed the summary of evidence in that advice. He also reviewed the latest data on New Zealand's Omicron Outbreak, including cases, hospitalisations and deaths and the trends in these; modelling which projects a further surge in cases through winter; WGS data showing the presence and growing contribution of the BA4 and BA5 Omicron subvariants; and the positions and recommendations of other jurisdictions, including the US CDC.
44. To capitalise on the strength of the protection afforded by a fourth dose (therapeutic value), making the vaccine available to additional at-risk groups would benefit both the individual and public from the risks of COVID-19:
45. **People aged over 50 years.** Māori and Pacific people have a lower life expectancy and are disproportionately impacted by COVID-19, including poorer outcomes from a COVID-19 infection, so it is appropriate to recommend the vaccine for these groups and to strongly target vaccination delivery to them and other priority groups. In this case, ethnicity is being used as a marker of higher risk (just as age is for over 65s). Many people without pre-existing conditions in the age group 50 to 64 will be of similar risk. We note that the US CDC has now recommended a fourth dose for all people over 50 years, and a

number of other countries also do (including South Africa, Chile – both in the Southern Hemisphere – and Denmark).

46. **Healthcare workers.** Currently healthcare workers are experiencing higher rates of infection of COVID-19 infection (1.6%) than border workers (1.1%) who are used as a proxy for the prevalence rate in the general population. This group works in an environment where they are in contact with at-risk people. A fourth dose will provide protection to healthcare workers and help to preserve health service delivery during this high demand period. Also of note is that the evidence shows a reduction in likelihood of being infected with COVID-19 for at least a few weeks after a second booster dose, and some residual protection from infection beyond that. This will help to reduce the likelihood of health care workers becoming infected and potentially infecting vulnerable people in their care through winter. Due to the higher rates of myocarditis and pericarditis for individuals under 30 years following first and second Pfizer doses, it is not recommended health care workers under 30 years of age, who are not also in the other recommended groups, receive a fourth dose until further evidence emerges.
47. The Director-General will include the following groups, in addition to those groups recommended by CV-TAG, to be eligible for a fourth dose of COVID-19 vaccine:
- All people over 50 years
 - Healthcare workers 30 years and over
48. In order to ensure that groups at the highest risk of an adverse outcome, and thus most likely to benefit from a second booster dose, the COVID-19 Vaccination Programme should strongly target efforts towards the population groups recommended by CV-TAG, whilst making it available to all people over age 50 and healthcare workers over 30 years of age.

Timing of receiving the fourth dose

49. CV-TAG recommends that the fourth dose should be offered six months after the third dose.
50. This means a number of people in the target groups would already be eligible for and due a fourth dose, and many more will be due throughout July and into August and September 2022.
51. A fourth dose, if due, should be postponed for three months after COVID-19 infection. Clinical discretion can be applied when considering vaccination prior to three months after infection.

Available COVID-19 Vaccine stock

52. There is adequate Pfizer COVID-19 vaccine in stock to vaccinate the cohorts, with current supply sitting at around two million doses.

Reduced interval for third doses

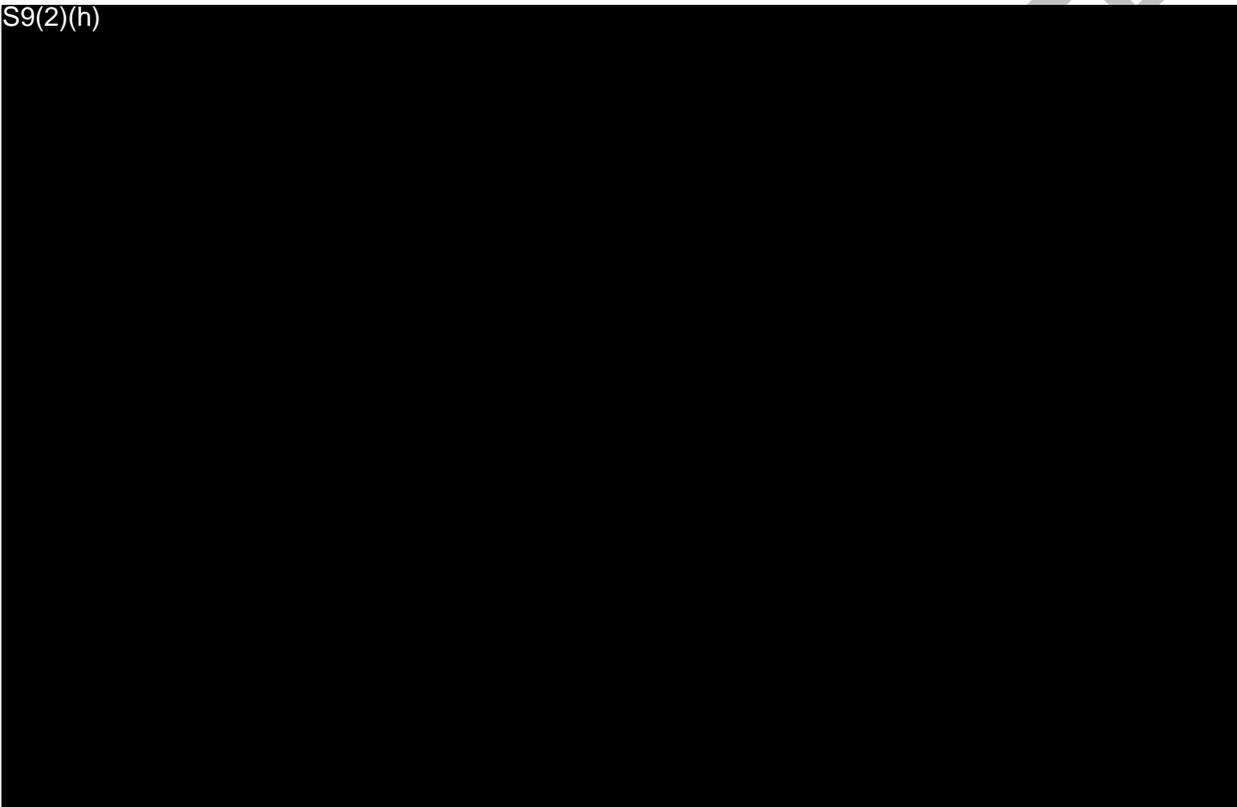
53. Alongside authorising fourth doses for the recommended groups at a 6-month dose interval (between third and fourth doses) the Director-General also needs to issue a notice to

authorise the ongoing reduced dose interval for third (or booster) doses at 3-months since completion of a primary COVID-19 vaccine course.

54. Third (booster) doses (at the reduced three-month dose interval) were previously provided for under the Epidemic Preparedness (COVID-19 – Medicines Act 1981) Immediate Modification Order (IMO) which has been revoked now the Act is in force.
55. The Ministry continues to advise that any vaccine dose that people are eligible for and due, be received 3 months after any infection with COVID-19, and guidance on this is set out on the Ministry website.

Crown Law Advice (*legally privileged*)

S9(2)(h)



Human Rights

60. Delivery of fourth doses of the Pfizer vaccine to the recommended groups will be on a voluntary uptake basis. Fourth doses will not be tied to any government vaccination order and will not be required to access any services or sites.
61. Delivery of fourth doses to the recommended groups does not raise any Human Rights issues for the recommended groups, however there are potential discrimination issues raised, due to the fact that all of the New Zealand population will not be able to access a fourth dose at this stage.
62. The Ministry considers that targeting the recommend groups is justified due to their vulnerability to serious outcomes from COVID-19 or high risk of exposure, and considering the data from the current outbreak that clearly shows those who are developing severe

illness, and those who are dying from COVID-19, are for the most part in the recommended groups. Therefore, the preferential availability of fourth doses for those groups is justified.

63. This does not exclude the option of rolling out fourth doses for the broader population in the near future, should the scientific evidence support this. The Director General is able to consider other population groups based on the best evidence available at the time as the pandemic evolves. It is important to note that with very widespread Omicron in the community for several months now, a level of natural immunity across the population will have developed, and this will also need to be taken into account when considering the timing of any further doses for the broader population.

Equity

64. A key factor to support equitable outcomes for all population groups is providing access to those who are most vulnerable or most at risk of exposure to COVID-19.
65. CV TAG have identified the groups that will most benefit from a fourth COVID-19 vaccination. These groups include Māori and Pacific peoples over 50 years of age.
66. Our experience in the delivery of the COVID-19 vaccination programme so far has taught us that additional levers are required for Māori and Pacific peoples to achieve the same vaccination targets as non-Māori and non-Pacific people.
67. We know that the rate of third (booster) dose vaccination is lower for Māori and Pacific peoples than non-Māori, non-Pacific. We will need to prioritise third (booster) doses for these groups alongside the roll out of fourth doses. Ease of access at trusted localities and from trusted providers is key to achieving high uptake for both third and fourth doses.
68. Providing broader access to fourth doses (beyond GP administration) via this Bill will be crucial to ensure we can achieve improved outcomes for all the groups who will be eligible for fourth doses.

Te Tiriti o Waitangi implications

69. In considering fourth dose requirements, we need to be clear about how we would be protecting Māori to honour our Te Tiriti o Waitangi (Te Tiriti) obligations. We can use the Te Tiriti principals to guide this work.
 - a. **Tino rangatiratanga** – providing broad access to fourth doses, including via Māori health providers, helps to empower Māori to self-determine their collective and individual health response to COVID-19
 - b. working in **partnership** with iwi and Māori health stakeholders particularly as they have insights into issues and improvements for vaccine uptake for Māori
 - c. The roll out of fourth doses to the recommended groups, including targeting Māori over 50 years of age, will support health system resilience, and help minimise the impacts of the Omicron outbreak. This is critical to minimising and addressing existing inequities and is consistent with Te Tiriti principle of **active protection**.
 - d. **Equity** by ensuring that delivery options do not negatively impact on the existing gains made to achieve equitable vaccine uptake for Māori.

70. As COVID-19 has disproportionate effects on Māori, it is important that there is targeted support for Māori to prioritise ongoing uptake of third (booster) doses, as well fourth doses.

Next steps

71. The Director-General has issued a notice on 23 June 2022 under section 34A of the Act to authorise the ongoing delivery of third (or booster) doses of the Pfizer COVID-19 vaccine at the reduced 3-months dose interval since completion of a primary COVID-19 vaccine course.
72. A further Notice will be issued on Monday 27 June 2022 that sets out the authorisation for fourth doses of COVID-19 vaccines to the listed recommended groups, with roll out to commence on the 28 June 2022

ENDS.

PROACTIVELY RELEASED