MANATŪ HAUORA
MINISTRY OF HEALTH

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15 December 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2022014350

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 Manatū Hauora (the Ministry of Health) on 11 October 2022 for information regarding section 34A of the Medicines Act 1981. You requested:

> *"1) advice to the DG and the Director-General's reasons for each of his decisions under s34A of the Medicines Act including decisions gazetted on 23 June 2022 and 13 July 2022*
>
> *2) any other correspondence or advice sent or received by the DG from Medsafe, CARM, Pfizer, any Minister about the wisdom or otherwise of these decisions and any risks associated with these decisions*
>
> *3) any other internal advice to the DG about these decisions under s34A including and assessor advice of the risks associated with these decisions and the reason for the July gazette notice*
>
> *4) any risk benefit analysis of the use of s34A of the Medicines Act generally and/or on each occasion it was used*
>
> *5) any other information why the DG was approving additional injunctions of Covid vaccines when the regulator Medsafe had given only conditional Provisional Consent for the use of the Covid vaccines and had not approved and further injections and and risks associated with this*

Nine documents have been identified within scope of the abovementioned parts of your request. These are itemised in Appendix 1 and copies of the documents are enclosed. 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.

The relevant advice provided by the COVID Vaccine Technical Advisory Group (CV TAG) and considered by Director-General of Health is publicly available on the Manatū Hauora website at: www.health.govt.nz/about-ministry/leadership-ministry/expert-groups/covid-19-vaccine-technical-advisory-group-cv-tag.

6) information about how the use of s34A would be communicated to the public including internal or external advice and communication with any Minister, Cabinet and/ or DPMC. Please include any correspondence, analysis, advice or other information on this and any draft and final press releases or other statements."

Manatū Hauora does not hold any information within scope of this part of your request. As such, this part of your request is refused under section 18(g)(i) as the information requested is not held by Manatū Hauora and there are no grounds for believing it is held by another agency subject to the Act.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

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

Nāku noa, nā

Andrew Forsyth
Acting Group Manager, Public Health Strategy
Public Health Agency | Te Pou Hauora Tūmatanui

Appendix 1: List of documents for release

#	Date	Document details	Decision on release
1	23 June 2022	DG Memorandum: New Notice under section 34A of the Medicines Act 1981 authorising off-label administration of COVID-19 vaccines	Publicly available at: www.health.govt.nz/system/files/documents/pages/dg-memo-notice-under-s34a-for-fourth-dose1.pdf.
2	23 June 2022	Briefing: Updated eligibility criteria for fourth doses of Pfizer COVID-19 vaccine	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.
3	11 July 2022	DG Memorandum: New Notice under section 34A of the Medicines Act 1981 authorising off-label administration of COVID-19 vaccines – Nuvaxovid as a fourth dose	Both documents are released in full.
4	13 July 2022	DG Memorandum: New Notice under section 34A of the Medicines Act 1981 authorising off-label administration of the Novavax COVID-19 vaccine – Correction	
5	13 July 2022 - 6 September 2022	Email Correspondence: Request for information re providing for over 30s 2nd Booster access	Some information withheld under section 9(2)(a) of the Act.
6	6 September 2022	Email Correspondence: Action: Eligibility for fourth dose	Some information withheld under the following sections of the Act: • Section 9(2)(a); and • Section 9(2)(h). Information deemed out of scope of the request has been excluded.
7	1 April 2022	Attachment to Document 6: CV TAG Memo: Fourth dose (second booster): COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations	Released in full.
8	22 June 2022	Attachment to Document 6: CV TAG Memo: Second booster update: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations	Publicly available at: www.health.govt.nz/system/files/documents/pages/cv_tag_second_boosters_update.pdf.
9	2 February 2022	Attachment to Document 6: Briefing: Further reduction in COVID-19 vaccine booster dose interval to three months	Withheld in full as deemed out of scope.

Document 2

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, Minster 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:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

Document 2

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

Security level:	IN CONFIDENCE	**Date:**	23 June 2022
To:	Hon Dr Ayesha Verrall, Minster 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: 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	**Noted**
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: • all people aged over 50 years • healthcare workers aged over 30 years	**Noted**
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

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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 circumstan es 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 disproportionally 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 Pacifi 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.

Document 3

DG Memorandum

New Notice under section 34A of the Medicines Act 1981 authorising off-label administration of COVID-19 vaccines – Nuvaxovid as a fourth dose

Date:	11 July 2022
To:	Dr Ashley Bloomfield, Director-General of Health
Copy to:	Graham Cameron, Acting Deputy Director-General, Public Health Agency
From:	Jane Chambers, Group Manager, Public Health Policy and Regulation
For your:	Decision

Purpose of report

1. This memo seeks your agreement and signing of a notice, pursuant to section 34A of the Medicines Act 1981, authorising administration of the Novavax COVID-19 vaccine Nuvaxovid (Nuvaxovid vaccine) as a fourth dose (or second booster).

2. This would authorise the administration of a fourth dose of the Nuvaxovid vaccine on the same basis as the Pfizer/BioNTech COVID-19 vaccine (the "Pfizer vaccine"), to broaden access to booster doses for groups at greater risk from COVID-19 and thereby helping to manage the risks associated with the outbreak and spread of COVID-19.

Background

3. On 29 June, you signed a Director-General Notice that would allow for off-label administration of the Pfizer vaccine as a fourth dose, to provide widespread access to the recommended at-risk groups (detailed below at paragraphs 14 and 17).

4. This followed an amendment to the Medicines Act 1981 enabling 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, by issuing a notice under section 34A of the Act.

5. The 29 June 2022 Notice, accompanying memo and CV-TAG advice is attached as Appendix One. The CV-TAG advice accompanying that memo recommended all COVID-19 vaccines approved by Medsafe could be used as a fourth dose.

Fourth doses will help to maintain population protection during the winter months and in face of another Omicron peak

6. 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.

7. The rationale for authorising fourth doses of a COVID-19 vaccine to manage the risks associated with the outbreak and spread of COVID-19 is discussed in the 23 June 2022 memorandum. Fourth doses will help to manage the likely further COVID-19 spread throughout winter, and with modelling forecasting a second peak of cases during winter or early spring.

8. The latest figures from the week ending 3 July 2022 suggest that COVID 19 infection rates are getting worse:

   a. There has been a 43% increase in case rates from 7 per 1000 to 10 per 1000 over the last two weeks.

   b. Case rates have increased across all regions compared to last week, with an R number effective of 1.4, indicating cases will increase substantially in the coming weeks.

   c. Cases rates in those who are 65 years and older have also increased by 67% over the last two weeks, with a 38% increase for Māori and a 5% increase for Pacific People.

9. The figures also suggest that the new COVID-19 variants (BA.4 and BA.5) are becoming more widespread and are on track to dominate by mid-July. There is no evidence that these variants are more severe than the BA.1 and BA.2 variants, however they are likely to spread faster because they can evade immunity from previous Omicron infections and vaccinations more easily:

   a. There has been a 33 percent increase in detections of these variants in wastewater.

   b. In the last two weeks, the national hospital occupancy has increased 10% and the in-patient test positivity for COVID-19 in tertiary hospitals has increased by 40%.

The Medicines Act 1981 allows the Director-General of Health to authorise the administration of COVID-19 vaccines otherwise than in accordance with the approved data sheet

10. The recent amendment to the Medicines Act 1981 (the Medicines Act) 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.

11. As the Director-General, you 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 Medicines Act. In doing this, you also must:

   a. 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, and

b. 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.

12. The Director General may specify by notice published in accordance with the Legislation Act 2019:

a. who may receive the vaccine

b. the recommended number and frequency of doses

c. the recommended manner of administration; and

d. any other circumstances in which the vaccine may be administered.

13. Any person or class of persons permitted by the Medicines 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 current y administering COVID-19 vaccines as part of the COVID-19 Immunisation Programme are able to administer any vaccines authorised by notice under section 34A.

The Director-General Notice for the Pfizer fourth dose

14. Following initial advice in April 2022, CV-TAG provided further advice in June 2022 on the science rationale, safety and peak body guidance on the use of a fourth dose in certain population groups. They recommended that the following groups receive a fourth dose following an interval of six months after 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)

e. people aged 16 years and over who have a medical condition that increases the risk of severe breakthrough COVID-19 illness (see Table 1 in appendix 3 in attached CV-TAG advice for expanded groups)

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.

15. CV-TAG noted that data on increased benefits from healthcare workers receiving a fourth dose remains marginal and that there is no evidence within the available New Zealand data to suggest healthcare workers (particularly if young and without comorbidities), have a higher risk of acquiring and transmitting infection at their place of work. CV-TAG deferred any specific recommendation related to healthcare workers who do not otherwise fall within the groups recommended above.

16. CV-TAG did not make a general recommendation on whether all people aged 50 years and over be given access to a fourth dose of a COVID-19 vaccine. CV-TAG's recommendation was focused solely on Māori and Pacific peoples aged 50 years and over.

17. During your consideration of the Notice, you agreed a fourth dose should be available to all of the groups recommended by CV TAG and also that a fourth dose should also be *available* for all people aged 50 and over and healthcare workers aged 30 years and over, should they choose to receive it.

18. The Director-General Notice authorising Pfizer vaccine fourth doses came into force on 29 June 2022.

The Nuvaxovid vaccine is recommended to be authorised as a fourth dose

19. It is proposed that you authorise the use of the Nuvaxovid vaccine as a fourth dose for the same population groups as authorised for the Pfizer vaccine, under section 34A of the Medicines Act.

20. New Zealand's COVID-19 Immunisation Programme has predominantly relied on the Pfizer vaccine. However, once the rollout of the vaccine programme became more advanced and access to other vaccines became possible, Vaccine Ministers agreed to purchase alternatives for those who were either unable or unwilling to be vaccinated with the Pfizer vaccine.

21. In March 2022, the Nuvaxovid vaccine was given consent by Medsafe, recommended by CV-TAG, and approved by Ministers for use in New Zealand, and was adopted into the COVID-19 Immunisation Programme. On 17 June, Medsafe approved the Nuvaxovid vaccine to be administered as a booster, however at 27 June 2022 it was still being considered by Vaccine Ministers for inclusion as a booster in the COVID-19 Immunisation Programme and therefore was not considered alongside the Pfizer vaccine for inclusion in the Pfizer vaccine fourth dose notice.

22. On 4 July 2022, the Nuvaxovid vaccine was incorporated into the programme as a booster, but is not yet approved by Medsafe for use as a fourth dose. In order for people to receive the Nuvaxovid vaccine as a fourth dose, they must first seek prescription from an authorised prescriber, resulting in the same access issues as the Pfizer vaccine outlined in the memorandum in Appendix 1.

AstraZeneca COVID-19 vaccine, the only other COVID-19 vaccine currently available in New Zealand, is not being proposed to be made available as a fourth dose at this time.

23. The Astra Zeneca COVID-19 vaccine was also included in the updated CV-TAG advice as a vaccine that could be used as a fourth dose, however as we are seeking Ministerial approval to remove Astra Zeneca from our portfolio of vaccines, we do not propose its further use as a fourth dose at this time.

Approving the Nuvaxovid vaccine meets the criteria for you to exercise your power to act

24. In order to authorise off-label administration of a COVID-19 vaccine, pursuant to section 34A of the Medicines Act you must have regard to the therapeutic value of that off-label administration and the likelihood of that off-label administration injuriously affecting the health of any person and be satisfied that authorising the off-label administration is an appropriate measure in managing the risks associated with the outbreak or spread of COVID-19.

Therapeutic value and safety of Nuvaxovid as a fourth dose

25. 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 of a COVID-19 vaccine. 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.

26. The decision to introduce Nuvaxovid into the COVID-19 Immunisation Programme was informed on the available evidence, and its continued safety and efficacy, supported by studies such as the UK COV-BOOST study. This evidence has been a contributing factor to subsequent decisions for it to be used as a third (or booster) dose.

27. There is limited evidence available that specifically relates to the use of Nuvaxovid as a fourth dose, however it is considered that the Director-General can reasonably be satisfied that a fourth dose is safe and has a similar favourable risk benefit profile to a primary course and booster dose of the Nuvaxovid (vaccine efficiency after a primary dose was around 90% against symptomatic COVID-19 and was maintained over 6 months; immune responses were enhanced with a third (booster) dose; similar frequencies of adverse effects for third dose as primary dose).

28. This is also based on the principles of vaccinology and experience that subsequent vaccinations after primary doses have high safety and efficacy profiles, and adverse reactions are less common. Nuvaxovid is a protein-based vaccine that are the more traditional form of vaccines and are known to have good safety profiles. Multi-dose protein-based vaccines have excellent safety and efficacy profiles.

29. CV TAG, in their advice on fourth doses (Appendix 1), support all COVID-19 vaccinations as a fourth dose, but noted that people younger than 30 years appeared to have adequate immune protection after three doses, and a low baseline risk of severe disease and therefore were not recommended to receive a fourth dose.

Using Nuvaxovid *as a fourth dose is an appropriate measure for managing the risk of an outbreak or spread of COVID-19*

30. The memorandum to you of 23 June 2022 discusses the need for fourth doses of COVID-19 vaccines for the groups listed above in paragraphs 14 and 17 to manage the risks associated with the outbreak or spread of COVID-19.

31. The rationale to enable at-risk groups to have access to a fourth dose of a COVID-19 vaccine to manage the risks associated with the outbreak or spread of COVID-19, remains the same.

32. Evidence indicates that we are likely entering a second Omicron wave, particularly as the new, more transmissible strains of Omicron are beginning to overtake in prevalence and are more likely to reinfect people sooner. As we move into the winter months and seasonal illnesses are increasing in circulation, the health system is coming under significant pressure. While COVID-19 is no longer the leading infectious disease for hospitalisations, it is a contributing factor to the current pressure that is being experienced nationwide.

33. By authorising administration of the Nuvaxovid vaccine under Section 34A as a fourth dose, those who are unable or unwilling to receive the Pfizer vaccine will have an alternative COVID-19 vaccine more easily available to them as a fourth dose). This will remove a barrier

to uptake for this group [and will likely result in a higher uptake of fourth doses amongst the at-risk groups].

Dose interval for Pfizer and Nuvaxovid fourth doses, and clarification of age range for residents of disability care facilities

34. The dose interval between the third and fourth dose of any COVID-19 vaccine is 6 months and should be specified in the Notice.

35. The Director-General Notice authorising Pfizer vaccine fourth doses of 27 June 2022 did not specify the dose interval although the intention was clear from the memorandum signed by you on 23 June 2022. Therefore, for clarification, a new Notice specifying this interval is attached for your signature alongside that of the Nuvaxovid Notice that will revoke the Notice of 29 June 2022.

36. CV TAG has issued a correction for the CVTAG memo sent to the DG on 2nd boosters, as an age group was not specified for residents of aged care and disability care facilities. We have now clarified that this applies to those aged 16 years and over and this applies to both Comirnaty and Nuvaxovid. Therefore, for clarification, this has also been included in both Notices.

Next steps

37. Should you agree to the recommendations below, please sign the attached Notice which authorises the ongoing delivery of the Nuvaxovid vaccine as a fourth dose. Officials will ensure that the Notice is published on the Ministry's website and notified in the *New Zealand Gazette* and the changes will be communicated through the relevant channels in accordance with the Legislation (Publication) Regulations 2021. The Minister is also required to present the Notice to the House of Representatives.

38. The service delivery model used will be reviewed to ensure that it allows the best access to second line vaccines, particularly as such off-label access is more inequitable than the Pfizer off-label access pattern, due to the restricted number of sites that provide the product.

Recommendations

It is recommended that you:

1.	**Note** that under the Medicines Act 1981, the Director-General of Health may authorise the administration of a consented COVID-19 vaccine other than in accordance with the approved data sheet for that vaccine by issuing a notice under section 34A of the Act.	**Noted**

2.	**Note** that in order for the Director-General of Health to do this, the Director-General must: a. 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, and b. 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.	**Noted**
3.	**Note** the 23 June 2022 memorandum to you, attached to this memo, by which you authorised, pursuant to section 34A of the Act, the administration of fourth doses of the Pfizer/BioNTech COVID-19 vaccine to certain groups at an interval of six months since their last dose of a COVID-19 vaccine	**Noted**
4.	**Note** the COVID-19 Vaccine Technical Advisory Group (CV-TAG)'s June 2022 advice, attached to this memo and in particular CV-TAG's recommendation that all available COVID-19 vaccines in New Zealand (Pfizer, Nuvaxovid and AstraZeneca) be available for fourth doses.	**Noted**
5.	**Note** that making the Nuvaxovid COVID-19 vaccine available as a fourth dose is an off-label use but will help to reduce access issues and increase the likelihood of uptake by people (in the at risk groups) who are unwilling or unable to receive a fourth dose of the Pfizer vaccine.	**Noted**
6.	**Agree** you are satisfied that authorising the administration of fourth doses of the Nuvaxovid COVID-19 vaccine to anyone in groups noted above at paragraphs 14 and 17, 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**
7.	**Agree** you are satisfied that the likely therapeutic value of a fourth dose of the Nuvaxovid COVID-19 vaccine to anyone in the groups noted above at paragraphs 14 and 17 outweighs the risk, if any, of a fourth dose injuriously affecting the health of any person in those groups.	**Yes**
8.	**Authorise** pursuant to section 34A of the Medicines Act 1981 the administration of fourth doses of the Nuvaxovid COVID-19 vaccine to anyone in groups noted above at paragraphs 14 and 17, at an interval of not less than six months since their last dose of a COVID-19 vaccine and sign the draft notice attached for that purpose.	**Yes**

9.	**Authorise** pursuant to section 34A of the Medicines Act 1981 the administration of fourth doses of the Pfizer COVID-19 vaccine to anyone in groups noted above at paragraphs 14 and 17, at an interval of not less than six months since their last dose of a COVID-19 vaccine and with clarification that it is for residents of disability care facilities aged 16 years and over; and sign the draft notice attached for that purpose clarifying the dose interval and the age range for residents in disability care facilities that will revoke the Notice of 29 June 2022.	**Yes**
10.	**Note** that upon your signing, this will come into effect immediately and be published on the Ministry website and in the *New Zealand Gazette*.	**Noted**

Signature  Date: 12 July 2022

Dr Ashley Bloomfield
Te Tumu Whakarae mō te Hauora
Director-General of Health

Notice under Section 34A of the Medicines Act 1981 authorising off-label administration of COVID-19 Vaccine Nuvaxovid

Pursuant to section 34A of the Medicines Act 1981, I, Dr Ashley Bloomfield, Director-General of Health, make this Notice.

A fourth dose of Novavax COVID-19 vaccine Nuvaxovid may be administered 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

Dated this 12th day of July 2022.

DR ASHLEY BLOOMFIELD, Director-General of Health.

Notice under Section 34A of the Medicines Act 1981 authorising off-label administration of COVID-19 Vaccine

Pursuant to section 34A of the Medicines Act 1981, I, Dr Ashley Bloomfield, Director-General of Health, make this Notice.

A fourth dose of Pfizer/BioNTech (Comirnaty, Tozinameran, BNT162b2) vaccine may be administered 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

The notice "Notice under Section 34A of the Medicines Act 1981 authorising off-label administration of COVID-19 Vaccine" made on 27 June 2022 is revoked.

Dated this 12th day of July 2022.

DR ASHLEY BLOOMFIELD, Director-General of Health

Document 4

DG Memorandum

New Notice under section 34A of the Medicines Act 1981 authorising off-label administration of the Novavax COVID-19 vaccine - Correction

Date:	13 July 2022
To:	Dr Ashley Bloomfield, Director-General of Health
Copy to:	Phil Knipe, Chief Legal Advisor, Health Legal
From:	Graham Cameron, Acting Deputy Director-General, Public Health Agency
For your:	Decision and signing

Purpose of report

1. This memo notifies you of a change required to the Director-General Notice of 11 July 2022 regarding the age ranges stated for the fourth Novavax Nuvaxovid COVID-19 dose. Advice provided by the COVID-19 Vaccine Technical Advisory Group (CV TAG) in its update memo dated 22 June 2022 implies that the fourth dose of all COVID-19 vaccines could be provided from age 16 and over, and this advice was reflected in the Notice signed by you on 12 July 2022.
2. We seek your agreement to and signing of an updated notice, pursuant to new section 34A of the Medicines Act 1981 with the corrected age group of 18 years and over specified.
3. This memo also clarifies that the fourth dose of Nuvaxovid can be given as a fourth dose of a COVID-19 vaccine schedule, rather than as a fourth dose of Nuvaxovid, and that Vaxzevria (AstraZeneca) will continue to be available (off-label, on prescription) until the decision is made to remove it from the Programme.

Correction of age groups expressed in the memo and the Notice

4. On 22 June 2022, you received a memo from CV TAG (attached) outlining the groups who are eligible for a fourth dose of a COVID-19 vaccine. That memo included recommendations regarding the age range for the availability of the vaccines for some groups.
5. CV TAG recommended:
    a. Maximising efforts to ensure that at-risk populations receive their first booster dose, as this remains the priority, as advised on 1 April 2022.
    b. In accordance with ATAGI recommendations, and previously issued advice, a second booster dose be offered to:

- People aged 65 years and over
- Māori and Pacific peoples aged 50 years and over
- Residents of aged care and disability care facilities aged 16 years and over
- Severely immunocompromised people (people aged 12 years and older) who were eligible for and received a three-dose primary course, with the first booster as a fourth dose (noting this is a fifth dose for this group).

c. That additional groups recommended to receive a second booster include people aged 16 years or older, who have:

- A medical condition that increases the risk of severe breakthrough COVID-19 illness
- Disabled people with significant or complex health needs, or multiple comorbidities which increases the risk of poor outcomes from COVID-19

6. CV TAG also noted that the recommendations outlined above should apply to all COVID-19 vaccines currently approved in New Zealand and in use within the National COVID-19 Vaccine and Immunisation Programme i.e. Comirnaty (Pfizer), Nuvaxovid (Novavax) and Vaxzevria (AstraZeneca).

CV TAG advice implies that the Nuvaxovid fourth dose is recommended to be administered to people aged 16 and 17 years

7. The CV TAG memo can be read to imply that the Nuvaxovid as a fourth dose is recommended to include people aged 16 and 17 years. While these recommendations can apply to Comirnaty (Pfizer), the age range of 16 and over should not apply to Nuvaxovid nor Vaxzevria (AstraZeneca). Currently, the Medsafe approvals for Nuvaxovid and Vaxzevria are only for people aged 18 and over as a primary course, and therefore there would be an anomaly between the primary dose and subsequent doses, causing implementation issues and consumer confusion. The age range should be aligned to the approved ages.

8. As currently written, the Notice for Nuvaxovid authorises the vaccine for 16 and 17 year olds.

9. The Science and Technical Advisory Group have advised that the Nuvaxovid Notice should state it is authorised for people aged 18 and over for:

- Residents of aged care and disability care facilities
- Severely immunocompromised people who were eligible for and received a three-dose primary course, with the first booster as a fourth dose (noting this is a fifth dose for this group).
- Those with a medical condition that increases the risk of severe breakthrough COVID-19 illness, and
- Disabled people with significant or complex health needs, or multiple comorbidities which increases the risk of poor outcomes from COVID-19.

10. A new Notice is attached for your signature with the age range of 18 and over explicitly stated.

11. Implementation processes currently have a fail-safe to stop under 18 year olds from receiving Nuvaxovid, so incorrect vaccination is unlikely to occur.

Clarification of the Nuvaxovid fourth dose after mixed primary and booster doses

12. The memo of 12 July 2022 could be interpreted to recommend that the fourth Nuvaxovid dose would be the fourth dose of Nuvaxovid, however, this is not the intention. In order to provide complete clarity, this memo notes that people can receive Nuvaxovid as a fourth dose **after earlier administration of an approved COVID-19 vaccine**.

Clarification of AstraZeneca Vaxzevria COVID-19 vaccine as a fourth dose off-label

13. The memo of 11 July 2022 stated that because Vaxzevria is due to be withdrawn we do not propose it further use as a fourth dose at this time. However, while this decision is imminent, until a decision is made to withdraw AstraZeneca, we will use it as a fourth dose in an off label manner. This means people can access a fourth dose of AstraZeneca for the time being on prescription from an authorised prescriber. Due to its imminent removal we are not proposing to include it in the Notice at this time.

Recommendations

It is recommended that you:

1.	note	that you signed the attached memo of 12 July 2022 approving a fourth off-label dose of the Nuvaxovid COVID-19 vaccine, and that memo had recommendations that specified some age groups based on the CV TAG advice of 22 June 2022.	Noted
2.	note	that the CV TAG advice (attached) incorrectly implies that the age range of 16 years and over can apply to Nuvaxovid, and that its inclusion in the Notice means that it is authorised to give to a 16 – 17 year old.	Noted
3.	note	that this is inconsistent with the approved age range for the primary course of Nuvaxovid and the Science and Technical Advisory Group have advised that Nuvaxovid should only be authorised for people aged over 18 years	Noted
4.	authorise and sign	pursuant to section 34A of the Medicines Act 1981, the Notice attached, which outlines the correct age range, revoking the Notice of 12 July 2022	Yes
5	note	that a dose of Nuvaxovid can be administered after a primary course and third dose of any approved COVID-19 vaccine	Noted
6	note	That AstraZenenca Vaxzevria is currently used as a fourth dose (off-label, prescription required) until a decision is made to withdraw it from the Programme.	Noted

Signature Date: 13 July 2022
Dr Ashley Bloomfield

Director-General of Health
Te Tumu Whakarae mō te Hauora

Notice under Section 34A of the Medicines Act 1981 authorising off-label administration of COVID-19 Vaccine Nuvaxovid

Pursuant to section 34A of the Medicines Act 1981, I, Dr Ashley Bloomfield, Director-General of Health, make this Notice.

A dose of Novavax COVID-19 vaccine Nuvaxovid may be administered as a fourth dose after a primary course and first booster dose of a COVID-19 vaccine to which the Minister has given consent or provisional (a COVID-19 vaccine) to –

a) any person aged 50 years and over;
b) residents of aged care and disability care facilities, aged 18 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), aged 18 years and over;
d) people aged 18 years and over who have a medical condition that increases the risk of severe breakthrough COVID-19 illness;
e) disabled people aged 18 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

The notice “Notice under Section 34A of the Medicines Act 1981 authorising off-label administration of COVID-19 Vaccine Nuvaxovid” made on 12 July 2022 is revoked.

Dated this 13th day of July 2022.

DR ASHLEY BLOOMFIELD, Director-General of Health.

Document 5

Sent By: Alison.Cossar@health.govt.nz on 6/09/2022 4:08:55 pm
To: Daniel.Bernal@health.govt.nz, Astrid.Koornneef@health.govt.nz, Ian.Town@health.govt.nz, John.Harvey@health.govt.nz, COVID-19_Science_Technical@health.govt.nz, David.Henderson@health.govt.nz, Mike.Rankin@health.govt.nz
Copy To: Rachel.Mackay@health.govt.nz, Ashley.Bloomfield@health.govt.nz, Nick.Chamberlain@health.govt.nz, Allison.Bennett@health.govt.nz
Subject: RE: Request for information re providing for over 30s 2nd Booster access

Kia ora Astrid

From a policy point of view, the only point I can see here is the mechanism – which we now have the DG Notice (section 34A of the Medicines Act) for off label use. This is what we have used to authorise the 50 years and over and the healthcare workers 30 years and over, etc. This would be done with reference to CV TAG advice, risks and benefits, and the impact on the management of any outbreak and spread (and operational feasibility) to the satisfaction of the DG.

Ngā mihi

Alison

Alison Cossar (she/her)

Manager

Public Health Policy and Regulatory

S9(2)(a)

alison.cossar@health.govt.nz

Public Health Agency

Manatū Hauora, 133 Molesworth Street

Thorndon, Wellington 6011

MANATŪ HAUORA
MINISTRY OF HEALTH

From: Dan Bernal <Daniel.Bernal@health.govt.nz>
Sent: Thursday, 14 July 2022 9:46 am
To: Astrid Koornneef <Astrid.Koornneef@health.govt.nz>; Ian Town <Ian.Town@health.govt.nz>; Alison Cossar <Alison.Cossar@health.govt.nz>; John Harvey <John.Harvey@health.govt.nz>; COVID-19 Science Technical <COVID-19_Science_Technical@health.govt.nz>; Dave Henderson <David.Henderson@health.govt.nz>; Mike Rankin <Mike.Rankin@health.govt.nz>
Cc: Rachel Mackay <Rachel.Mackay@health.govt.nz>; Ashley Bloomfield <Ashley.Bloomfield@health.govt.nz>; Nick Chamberlain <Nick.Chamberlain@health.govt.nz>; Allison Bennett <Allison.Bennett@health.govt.nz>
Subject: RE: Request for information re providing for over 30s 2nd Booster access

Kia ora Astrid,

There is not a CV TAG question that I can see here and they're not meeting until coming Tuesday. This is currently not on the agenda, either and too late to be added at this stage.

I can see a question around stats here wrt hospitalisation rates between 30 and 50 y.o.'s here. I've added Dave and Mike to the chain as I believe it is between them to establish which area has any data to support this. I've seen/heard there's work in action to start predicting likely waning effectiveness but not sure how progressed this is.

Regards

Dan

From: Dan Bernal <Daniel.Bernal@health.govt.nz>
Sent: Wednesday, 13 July 2022 8:40 pm
To: Astrid Koornneef <Astrid.Koornneef@health.govt.nz>; Ian Town <Ian.Town@health.govt.nz>; Alison Cossar <Alison.Cossar@health.govt.nz>; John Harvey <John.Harvey@health.govt.nz>; COVID-19 Science Technical <COVID-19_Science_Technical@health.govt.nz>; Dave Henderson <David.Henderson@health.govt.nz>; Mike Rankin <Mike.Rankin@health.govt.nz>
Cc: Rachel Mackay <Rachel.Mackay@health.govt.nz> ; Ashley Bloomfield <Ashley.Bloomfield@health.govt.nz> ; Nick Chamberlain <Nick.Chamberlain@health.govt.nz>; Allison Bennett <Allison.Bennett@health.govt.nz>
Subject: RE: Request for information re providing for over 30s 2nd Booster access

Kia ora koutou

Please note the request from Min Verrall below.

The Programme can coordinate the response and provide the operational view, however additional information is required from a policy and CVTAG perspective.

If we could have your information by the Thursday end of day we can collate the response and circulate for sign out on Friday.

Ngā mihi

Astrid

Document 5

From: S9(2)(a)
Sent: Wednesday, 13 July 2022 9:30 am
To: Astrid Koornneef <Astrid.Koornneef@health.govt.nz>
Cc: Allison Bennett <Allison.Bennett@health.govt.nz>; Health New Zealand Govt Services <hnzgovernmentservices@health.govt.nz>; DG Advisory <dgadvisory@health.govt.nz>
Subject: Request for information re providing for over 30s 2nd Booster access

Kia ora Astrid,

As discussed, the Minister has requested in email format information related to providing for those 30 and over to access 2nd boosters for anyone that wishes to have one.

The Minister is particularly interested in understanding feasibility of introducing/implementing this from an operational perspective, highlighting any potential barriers or impacts and also what the current process is in relation to regular review of second dose criteria. She is also keen to understand from the data (if available) what the current rates of hospitalisation may be for under 50s with COVID.

We are happy to receive this initial information in email format, which can be sent directly to me in the first instance. Could I ask that this be sent through by 10 am Monday 18th July?

Let me know if there are any issues or if you have questions at all.

Ngā mihi

S9(2)(a)

S9(2)(a) ***BHSc Para, MPH***

Health Private Secretary (COVID-19) | Office o Dr Ayesha Verrall

Minister for COVID-19 Response

Minister of Research, Science and Innovation Minister for Seniors

Associate Minister of Health

M: S9(2)(a)

Private Bag 18041, Parliament Buildings, Welling 6160, New Zealand

Document 6

Sent By: Allison.Bennett@health.govt.nz on 6/09/2022 4:18:59 pm
To: Ashley.Bloomfield@health.govt.nz
Copy To: Caroline.Flora@health.govt.nz, Andrew.Bichan@health.govt.nz, Astrid.Koornneef@health.govt.nz, Dawn.Kelly@health.govt.nz, Phil.Knipe@health.govt.nz, Jane.Hubbard@health.govt.nz, Alison.Cossar@health.govt.nz
Subject: ACTION: Eligibility for fourth dose

Hi Ashley,

Out of Scope [redacted]

Thank you for the thorough discussion last night with reference to the eligibility of the fourth dose. The team have been working closely with CL to reflect these points accordingly. Please find attached, the following for your review and action.

1. **HR to Min Verrall** noting the changes in eligibility and the decision you will be making today

1. **Memo** to support you to discharge your decision making rights to utilise the Pfizer vaccine as a fourth dose for specific groups. Also included are the following attachments.

S9(2)(h) [redacted]

The timing is tight – SORRY – as we will need to action by 4pm in order to publish and gazette.

Kind regards,

Allison

Allison Bennett
Acting Group Manager **I** Public Health System Policy **I** System Strategy and Policy **I** Mobile: S9(2)(a) [redacted]

MINISTRY OF HEALTH
MANATŪ HAUORA

(See attached file: CV TAG Memo Second boosters_FINAL signed (003).pdf)(See attached file: 220202-SIGNED-Ardern Rt Hon J-Booster interval.pdf)(See attached file: CV TAG Memo Second boosters_UPDATE_CSAsigned.pdf)(See attached file: DG memo - Notice under s34A for fourth dose final.docx)(See attached file: HR to inform Ministers of expanded eligibility criteria for fourth doses of Pfizer COVID-19 vaccine - Final.docx)(See attached file: put-in-cabinet-data.json)

Document 7

Memo

Fourth dose (second booster): COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations

Date:	1 April 2022
To:	Dr Ashley Bloomfield, Director-General of Health
Copy to:	Astrid Koornneef, Director, National Immunisation Programme (NIP) Allison Bennett, Manager, System Enablers, 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) advice about the waning of immunity after first boosters (third doses) and the need for a second booster (fourth) dose in groups at greater risk of experiencing impacts from COVID-19.

Background and context

2. On 8 November 2021 Medsafe updated the provisional approval for the Pfizer vaccine to state: *"a booster dose of Comirnaty may be administered intramuscularly at least 6 months after completion of the primary course in individuals aged 18 years of age and older.*

3. In November 2021, CV TAG made initial recommendations on booster vaccinations in the memo "Priority groups for COVID-19 booster vaccinations: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations", dated 10 November 2021. In this memo, CV TAG also noted that (emphasis added) "*those aged over 18 who are immunocompromised and have received a third primary dose of a COVID-19 vaccine as described in previous CV TAG recommendations, should only receive a booster dose **6 months** after completion of their primary course (i.e., 6 months after their third dose)*." A six-month interval was also recommended for the general population at this time. At this time CV TAG noted "*there is insufficient data on the safety profile for booster doses in pregnant people*" and therefore the recommendations did not include pregnant people who received a primary course earlier in pregnancy.

4. CV TAG issued updated recommendations in the memo "COVID-19 booster vaccinations in specific situations: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations", dated 17 December 2021. In this memo, CV TAG noted that data was still accumulating about whether early booster doses offer any advantages in protection against the Omicron variant, that there continued to be insufficient data on the safety profile for booster doses in pregnant people, and that Medsafe had authorised boosters only from six months after completion of the primary course. CV TAG recommended that a booster be offered to pregnant people who completed their primary vaccination course more than 6 months prior. Those approaching the full-term of their pregnancy 6 months after completing their primary course can choose to receive their booster after the baby is

born if preferred. No further recommendation was given on boosters in severely immunocompromised people.

5. The Ministry of Health was requested to provide interim advice over the 2021/22 Christmas and New Year period on these two issues. The Science and Technical Advisory noted the updated (24 December 2021) Australian Technical Advisory Group on Immunisation (ATAGI) advice and that of jurisdictions such as the UK and Canada, and recommended that pregnant people and those who are severely immunocompromised be able to access the booster dose at the same dosing interval as the rest of the adult population.

6. In light of emerging evidence on the importance of boosters for protection against infection for Omicron, and updates to guidance in other countries, CV TAG recommended in January 2022 that pregnant people aged 18 and older can receive the Pfizer booster vaccine at any stage of pregnancy, at least 4 months after the second dose, and are encouraged to discuss the timing of their booster with their midwife, obstetrician or general practitioner. They also recommended that immunocompromised people who have received three primary doses should have a booster dose in line with the timing for the general population i.e., a 4-month interval from their primary course (three doses).

7. **In early February 2022, the current recommendation was made by CV TAG, that a booster dose of the COVID-19 vaccine should be given sooner after the primary course to all eligible people aged 18 years and over, including immunocompromised individuals and pregnant persons. Cabinet agreed to give boosters from 3 months.**

8. As cases of COVID-19 climb globally due to outbreaks of the Omicron variant, and evidence has emerged on the waning of protection, some jurisdictions have rolled out second boosters (fourth doses) to their most vulnerable (people with comorbidities, the elderly, and healthcare workers).

9. The Director-General of Health has requested further information on the waning of immunity after a first booster dose and groups in which waning may occur more rapidly. The Director-General of Health has also asked for advice on whether a second booster dose is needed, and if so, the interval at which this should be given and the priority groups for this second booster dose.

Evidence informing advice

Waning of immunity after a first booster dose

10. Data from the United Kingdom and United States show that vaccine effectiveness (VE) against symptomatic infection and severe disease caused by Omicron wanes over time.

    a. A CDC study found the VE for Pfizer against Omicron *hospitalisation* after three doses wanes from 91% (95% CI: 88–93) at ≤2 months to 78% (95% CI: 67–85) at ≥4 months.[1] This trend is broadly in line with the UK Health Security Agency (UKHSA), who found VE after three doses of Pfizer against *hospitalisation* wanes from 85-90% at 2-4 weeks to approximately 75% at 10-14 weeks (~2-3 months).[2]

    b. Data from the UKHSA also shows that 2-4 weeks after a booster dose of the Pfizer vaccine, VE against *symptomatic* COVID-19 caused by Omicron is approximately 65% and declines to around 45% from 10-14 weeks after the booster.[2]

11. *Pace of waning and at-risk groups:* Evidence also shows that protection does not wane at the same pace for everyone, and appears to wane faster for the elderly, and for some people with other health conditions their immune response to the vaccine is lower.

    a. A study of people aged over 80 years found participants to have significantly lower neutralising titres against the wild type and some variants of concern than people aged under 80 years, particularly before receiving a second dose.[3]

b. Similarly, a study of Greek healthcare workers found that although titres did not significantly differ among participants aged 20–49 years, there was a significant decline in the 50-59 years age group and a further decline among those over 60.[4]

c. Another study with a cohort of 83 individuals aged 81-91 years showed that after 1 month, individuals vaccinated with one dose of Pfizer had high enough antibody titres to protect against infection (>141 BAU/ml) while seven months later, this was reduced.[5]

d. A study conducted in Germany found that neutralising antibody titres had waned to a significantly greater extent among the elderly, compared with young healthcare workers, at six months after the first vaccination.[6]

e. Immunogenicity data suggests that cancer, transplant, dialysis patients, and those on immunosuppressant therapy have a reduced response to a first dose of vaccine which can improve with a second dose,[8-15] although it still may not be optimal, with both reduced antibody and T cell responses.[16-24]

f. A (non-peer reviewed) study of antibody responses following the second dose of Pfizer has been conducted using data from the UK's national COVID-19 Infection Survey. This study found that antibody responses can last for over a year, though they declined more rapidly in older people, males, and those with underlying health conditions. The grea est antibody half-life was observed among those previously infected by SARS-CoV-2.[25]

Safety, reactogenicity and efficacy of a second booster dose

12. Data on the reactogenicity, safety, immunogenicity, and efficacy of a second booster dose are currently limited to three studies from Israel.

    a. One study of Israelis aged 60 years and over extracted data for the Omicron-dominated period (15 January through 27 January 2022) from the Israeli Ministry of Health database. It included 1,138,681 persons aged over 60 years, who were eligible for a fourth dose in Israel at the time.[26] The rate of confirmed COVID-19 infections and severe illness was analysed and compared between those who had received a fourth dose at least 12 days prior, those who had received a fourth dose 3-7 days prior, and those who had received only three doses.

    b. Another study of Israeli healthcare workers aged 18 years and over evaluated a fourth dose of Pfizer or Moderna administered after three Pfizer doses. The study population were 1,050 eligible healthcare workers with no known history of SARS-CoV-2 infection, who received the third dose of Pfizer at least 4 months earlier.[27] Of 1050 eligible, 154 and 120 (274 total) were enrolled to receive Pfizer and Moderna, respectively, and compared to 426 age-matched controls. Primary endpoints were safety and immunogenicity. and secondary endpoints were vaccine efficacy in preventing SARS-CoV-2 infections and COVID-19 symptomatic disease.

    c. A preprint retrospective cohort study was also conducted with all members of Clalit Health Services, aged 60 to 100, eligible for the second booster in Israel. Mortality due to COVID-19 among participants who received the second booster was compared with participants who received one booster dose. A Cox proportional-hazards regression model with time-dependent covariates was used to estimate the association between the second booster and death due to COVID-19 while adjusting for demographic factors and coexisting illnesses. A total of 563,465 participants met the eligibility criteria. Of those, 328,597 (58%) received a second-booster dose during the 40-day study period.[28]

13. *Safety and Reactogenicity:* In the trial of healthcare workers, most adverse events (AEs) were reported as mild and resolved within 1.7 days post booster dose. No serious AEs or hospital admissions were reported. Solicited local AEs were common, and for Pfizer 78.6% (95% CI: 71.2-84.8) of second booster dose recipients reported an adverse event. Among Pfizer second booster dose recipients, more were reported by younger participants: 88% (95%CI: 80.6-95.3) compared with

69.6% (95% CI: 59.4-79.7) in those >60 years of age. Solicited systemic AEs were reported by 42.9% (95% CI: 35-50.7) of Pfizer second booster dose recipients. Younger participants reported systemic AEs more commonly than older participants for each of the AEs and in both vaccines, but this effect was small and did not reach statistical significance. Systemic adverse events resolved within 1.3 days. The most common systemic AE reported was fatigue (27.3%, 95% CI: 20.4-35.0% for Pfizer second booster dose), followed by myalgia and headache. Fever was relatively uncommon, with only 7.1% (95% CI 3.1-11.2). Fever resolved within 24-36 hours in either group.[27] The study of Israelis 60 years and over did not report any safety or reactogenicity data.[26]

14. *Breakthrough infection:* In the trial of Israeli healthcare workers, 18.3% of participants that received a Pfizer second booster had breakthrough infection compared with 25.0% of the control group who had only had three doses. In the majority of cases (65-72%) symptoms were mild (without fever of ≥38°C).[27]

15. *Effectiveness:* The study of healthcare workers was not originally designed to assess vaccine effectiveness, which was only a secondary outcome. However, after adjustment for period of exposure and age-group, the second booster dose relative vaccine effectiveness (compared to first booster only) against infection was 30% (95% CI: -9-55) for Pfizer. For symptomatic disease, the relative vaccine effectiveness (compared to first booster only) was 43% (95% CI: 7-65).[27]

16. In the study of Israelis aged over 60 years, the rate of confirmed infection for those who received the fourth dose at least 12 days prior was lower by a factor of 2.0 (95% CI: 2.0-2.1) compared to those who had not received the fourth dose and was lower by a factor of 1.9 (95% CI: 1.8-1.9) compared to those who had received the fourth dose 3-7 days prior (Figure 1). The rate of severe illness for those who received the fourth dose at least 12 days prior was lower by a factor of 4.3 (95% CI: 2.4-7.6) compared to those who had received only three doses, and was lower by a factor of 4.0 (95% CI: 2.2-7.5) compared to those who had received the fourth dose 3-7 days prior (Figure 1).[26]

	Cases (person-days at risk)			Rate Ratio (95% CI)		Adjusted rate difference per 100,000 person-days at risk (95% CI)	
	3rd dose only	3-7 days after 4th dose	12+ days after 4th dose	3rd dose only vs. 12+ days after 4th dose	3-7 vs. 12+ days after 4th dose	3rd dose only vs. 12+ after 4th dose	3-7 vs. 12+ days after 4th dose
Confirmed Infections	42,693 (7,603,132)	5,945 (1,264,767)	9,071 (3,421,826)	2.0 [2.0, 2.1]	1.9 [1.8, 2.0]	279 [271, 287]	234 [219, 247]
Severe illness	195 (4,277,639)	55 (1,023,355)	13 (980,984)	4.3 [2.4, 7.6]	4.0 [2.2, 7.5]	3.8 [2.8, 4.8]	3.5 [2.1, 5.1]

Figure 1: Results of the Poisson regression analysis for confirmed infection and severe illness between the different study groups. [26]

17. Israelis aged 60-100 who received a second booster of Pfizer had a 78% lower mortality rate from the disease than those who only received one booster, a preprint study from Israel has shown from the country's largest healthcare provider, Clalit Health Services. 58% of participants had received a second booster and the remainder had received only one booster (at least 4 months prior). Researchers recorded 92 deaths among the first group and 232 deaths among the second, smaller group, with 40 days follow-up after the second booster. The research excluded people who received Moderna's vaccine and those who had taken oral anti-COVID therapy.[28]

18. *Limitations:* More data is required to understand the relative effectiveness of a second booster against infection and severe disease, as the sample sizes for these studies were small. Participants in both studies were selected based on having low antibody titres, which may overestimate the benefit for general population. If borne out by more data, effectiveness estimates are significantly lower than efficacy against infection post-third (first booster) dose and suggest that current mRNA vaccines may produce a "peak" response after the third dose, but further doses may only recover the immunity lost over time owing to waning. Despite this, the authors note that the second booster dose could be

beneficial for people at higher risk of severe illness, particularly during periods of surge and rising infections, while emphasising the urgency of next generation development.[29]

International recommendations from peak bodies and rollout of second booster doses

19. Given the potential for waning immunity following a first booster, particularly against severe disease (as measured by hospitalisation), some countries have begun recommending the administration of a second booster dose to elderly populations or individuals at increased risk of severe disease or exposure.

    a. *Australia:* The Australian Technical Advisory Group on Immunisation (ATAGI) issued recommendations about fourth doses on 25 March 2022. ATAGI recommended an additional booster dose of COVID-19 vaccine to increase vaccine protection before winter for selected population groups who are at greatest risk of severe illness from COVID-19 and who have received their primary vaccination and first booster dose (link). These groups are:

        i. Adults aged 65 years and older

        ii. Residents of aged care or disability care facilities

        iii. People aged 16 years and older with severe immunocompromise (as defined in the ATAGI statement on the use of a 3rd primary dose of COVID-19 vaccine in individuals who are severely immunocompromised)

        iv. Aboriginal and Torres Strait Islander people aged 50 years and older.

    b. ATAGI have recommended that the additional winter booster dose can be given from 4 months or longer after the person has received their first booster dose, or from 4 months after a confirmed SARS-CoV-2 infection, if infection occurred since the person's first COVID-19 booster dose. ATAGI recommended that the rollout of the additional booster dose for these groups starts from April 2022, coinciding with the rollout of the 2022 influenza vaccination programme. ATAGI state that there is currently insufficient evidence to recommend additional booster doses for other population groups, including people with medical risk factors; individuals with disability and National Disability Insurance Scheme (NDIS) recipients who are not in residential disability care; aged care, disability care and healthcare workers; healthy individuals aged 16 to 64 years, and; Aboriginal and Torres Strait Islander people aged under 50 years.

    c. *Israel*: In January 2022, Israel began administering a fourth dose of the Pfizer vaccine to people aged over 60 years and at-risk populations who had received a third dose at least 4 months earlier. An Israeli hospital is also conducting a trial of the second booster dose in healthcare workers. (link) Early data from Israel's rollout of a second booster dose is presented below. On 22 January 2022, Israel's vaccine advisory committee recommended that those aged 18 and over be offered a fourth vaccine dose at least five months after their third dose or after recovering from the disease. (link)

    d. *UK*: The Joint Committee on Vaccination and Immunisation (JCVI) has advised an additional spring booster dose be given for the most vulnerable individuals in the population. (link) As a precaution, a further booster dose is advised 6 months after the last vaccine dose for adults aged 75 years and over, older residents in a care home, and individuals aged 12 years and over who are immunosuppressed.

    e. *US*: Pfizer applied for authorisation to the US FDA on 15 March 2022 for adults 65 years and over, (link) and the US FDA has been reviewing data to authorise a second booster dose of vaccines from Pfizer and Moderna. (link) On 29 March 2022, the FDA authorised second boosters for peopled aged 50 and over, and immunocompromised people. (link)

f. *Europe:* The European Medical Authority are yet to receive any application for a second booster dose, though the Head of Vaccine Strategy has been reported in the media to say there is not yet enough evidence on its need (link).

g. *Chile*: Media reports have stated that from 7 February 2022, eligibility for a fourth dose will be extended to people aged over 55 years who had a third vaccine dose at least 6 months prior. (link) The fourth vaccine regimen has not been specified.

h. *Hungary*: In January 2022, Hungary made a fourth COVID-19 vaccine shot available to people who ask for it, after a consultation with a doctor, in order to combat growing Omicron infections. (link)

i. *South Korea*: In February 2022, populations that are at increased risk of severe disease (the elderly and immunocompromised) or at increased risk of exposure (healthcare workers) became eligible for a fourth dose, however authorities are not currently considering expanding it more widely. (link)

Recommendations

20. CV TAG met on 1 March and 22 March 2022 to discuss the waning of protection after first booster doses, and the need for second booster doses.

21. CV TAG noted that:

a. There is evidence of waning of protection following the first booster dose. Protection also appears to wane faster in some populations, e.g., the elderly. People with other health conditions or comorbidities are at an increased risk of poor outcomes also, and may have a lower immune response to vaccines, though evidence is still emerging on the need for a further dose.

b. Booster doses began to be administered from 29 November 2021, and therefore some groups are now four months from receiving their first booster dose as we approach winter.

c. The influenza immunisation programme is starting in April, and there is a risk of increased burden on the healthcare system from having both SARS-CoV-2 and influenza circulating. Research from 305,000 people in hospital in the UK with COVID-19 between February 2020 and December 2021 found 6,965 people were also recorded as having another respiratory infection alongside COVID - 227 of which were influenza. The researchers estimated that people with COVID-19 and influenza combined were 2.4 times more likely to die and four times more likely to end up on a ventilator than if they only had COVID.[30]

d. Data on the reactogenicity, safety, immunogenicity, and efficacy of a second Pfizer booster dose is currently limited to three studies from Israel, which studied the immunogenicity and safety among healthcare workers and the elderly. However, a second booster of the Pfizer vaccine appears to be safe and effective at restoring protection against COVID-19, including Omicron. The vaccine is a reactogenic vaccine, with 78.6% (95%CI: 71.2-84.8) of people who received a second booster dose reporting a local adverse event, and 42.9% (95%CI: 35-50.7) reporting systemic adverse events. Most of these were mild and resolved quickly.

e. Some countries have begun rolling out second booster doses, and these have been from four to six months after the first booster dose.

f. The goal of the COVID-19 vaccination programme and offering a second booster dose in New Zealand is to prevent severe disease caused by SARS-CoV-2.

g. There are a number of equity considerations which are important to consider:

i. Māori and Pacific peoples have been disproportionately affected in the current outbreak.

ii. Māori and Pacific peoples are at greater risk of COVID-19 hospitalisation and severe disease, having respectively a 2.5-fold and 3-fold higher odds of being hospitalised compared to non-Māori, and Māori are likely to spend 4.9 days longer in hospital [31, 32].

iii. Māori and Pacific peoples are more likely to live in multigenerational families housing in overcrowded conditions, increasing the risk of transmission [33, 34].

h. Medsafe are yet to approve the use of Pfizer as a second booster dose, and therefore these recommendations are requiring Medsafe approval.

i. Data is limited on the safety and efficacy of a second booster dose in populations younger than 65 years of age, in healthy individuals, in people with medical or social risk factors, and in pregnant people. Young people (aged under 30) appear to produce a strong immune response to three doses and are considered well protected.

22. CV TAG recommended that:

a. a second booster dose be offered to:

i. people aged 65 years and over

ii. Māori and Pacific peoples aged 50 years and over

iii. residents of aged care and disability care facilities

iv. severely immunocompromised people who received a three-dose primary course and a fourth dose as a first booster (noting this is a fifth dose for these people).

b. The second booster dose should be offered from six months after a first booster dose, however consideration should be given to aligning the rollout of second boosters with the influenza immunisation programme. This would require a shorter interval between the first and second booster dose (for example, from 4 months after the first booster dose) to allow it to be given at the same time as influenza vaccine. CV TAG would support an interval of greater than or equal to 4 months for this purpose. Consideration should also be given to bringing the age range eligibility for the funded influenza vaccine down to align with the age ranges recommended for the COVID-19 second booster vaccines.

c. A second booster dose, if due, should be postponed for three months after SARS-CoV-2 infection. 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. The influenza, MMR, HPV, diphtheria/tetanus/pertussis combination vaccine (Boostrix), and other vaccines may be administered before, after, or at the same time as the Pfizer COVID-19 vaccine, without concern for the spacing of the vaccinations. The only exception to this advice is for the live-attenuated shingles vaccine (Zostavax) where a 7-day interval, before or after administering Pfizer COVID-19 vaccine, is advised.

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

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