

# Request for Advice (RfA)

This form contains the details relevant to the questions posed to the Science and Technical Advisory (STA). STA will respond to the request using this form which will also be stored in STA content management system for future reference.

This form, or parts of it, may also be forwarded to other relevant parties as appropriate.

|                  |   |                |            |
|------------------|---|----------------|------------|
| Title            | Rapid review of current data on extended dosing intervals for the Pfizer/BioNTech COVID-19 vaccine.   |                |            |
| Subject          | Vaccines  |                |            |
| Reference No.    | 274   | Date Received  | 29/07/2021 |
| Requestor        | Ashley Bloomfield (DG), CV TAG  | Date Due       | 3/08/2021  |
| Advisor          | s 9(2)(a)   | Date Completed | 5/08/2021  |
| Peer reviewed by | s 9(2)(a)   |                |            |
| Advice issued to | CV TAG  |                |            |
| Approved by      | Ian Town  |                |            |
| Deliverables     | RfA, Memo on recommendations for dosing interval for Pfizer/BioNTech COVID-19 vaccine   |                |            |
| Request Outline  | <p><b>Background/Context</b></p> <ul style="list-style-type: none"> <li>The DG requested a brief update on the emerging concept that we should have a longer interval between doses for everyone, as part of our recommendation on myocarditis for a longer interval for the under 30 year-olds.</li> <li>A recommendation of a longer interval for the whole population might have several advantages if evidence suggests that a longer interval (than the current 3 week interval) has no deleterious impact on safety or efficacy. If a change to a longer interval is recommended for a subgroup of the population, then recommending this to the whole population may be easier to communicate.</li> <li>Many countries have a longer interval than 3 weeks for the Pfizer/BioNTech COVID-19 vaccine as standard, including the UK, Canada, and several European countries, with intervals ranging from, approximately, 8 to 16 weeks.</li> <li>The initial reasons for extending the dosing interval were practical (e.g., covering more of population with at least one dose quickly in an active pandemic situation) and scientific (e.g., prior scientific consensus and basic principles of vaccinology and immunology suggested that, in general, intervals longer than 3 weeks are usually required between the prime and booster doses in order to maximise the immune response). However, it remains true that only</li> </ul> |                |            |

|  |  |
|--|--|
|  | <p>the 3 week interval has been evaluated in a Phase 3 clinical trial for safety and efficacy.</p> <ul style="list-style-type: none"> <li>• This short briefing reviews the recent data from the UK; covers the potential benefits and rollout experiences; and includes a summary of immunogenicity and reactogenicity data.</li> </ul> <p><b>Questions</b></p> <ol style="list-style-type: none"> <li>1. What is the evidence for efficacy/effectiveness and safety of mRNA COVID-19 vaccines when using a shorter versus a longer interval between first and second doses? This can include immunological, epidemiological, and other evidence.</li> </ol> <p><b>Intended application of advice</b></p> <ul style="list-style-type: none"> <li>• RfA to CV TAG for their consideration of the appropriate dosing interval for the Pfizer/BioNTech COVID-19 vaccine</li> </ul> <p><b>Timeline</b></p> <ul style="list-style-type: none"> <li>• Draft report to send to CV TAG 02 August 2021 for their review, ahead of the CV TAG meeting 03 August 2021</li> </ul> |
| <p>What are the implications and considerations of this advice on Te Tiriti o Waitangi and equity?</p> | <ul style="list-style-type: none"> <li>• Data on vaccine efficacy/effectiveness, immunological response, and other data with regard to ethnic differences will be reviewed.</li> <li>• Data on the impact of extending the dosing interval on the immunisation program and vaccine coverage in Māori and Pacific Peoples will be reviewed.</li> </ul>  |

## Response to Request for Advice

### Key Points

- Data is very limited on extended dosing intervals for the Pfizer/BioNTech COVID-19 vaccine and the impact efficacy and safety. However, emerging data suggests that the immune response is likely improved somewhat by extending the dosing interval. One study that found improved immunogenicity for the longer interval compared a median interval of 3.4 weeks to a median of 10 weeks.[1]
- This is consistent with basic principles of vaccinology and immunology, that suggests that immune responses are generally better with longer intervals.
- Several countries have been using extended intervals, ranging from approximately 6-16 weeks for the Pfizer vaccine for their general populations, including England, Canada, and several countries in Europe. Population data from those countries suggest that the vaccine effectiveness for

Pfizer/BioNTech is high (e.g., 85%-88% for symptomatic disease against the Delta variant). The reported safety profiles appear similar to countries with shorter intervals, such as the US (the US recommends 3 weeks, but allows for up to 6 weeks if 3 weeks is not possible).

- Although the data outside of clinical trials is promising for longer intervals, the efficacy and safety for longer dosing intervals have not been evaluated in large phase 3 clinical trials, and STA is unaware of any clinical trial data that is expected to become available.

## Summary of data from extended dosing intervals

- In December 2020, the UK chose to extend the recommended Pfizer dosing regimen of 3 weeks to about 12 weeks to avert deaths and prevent hospitalisation due to severe COVID-19, in the context of an active pandemic in the UK. This facilitated the rapid roll-out of one dose of SARS-CoV-2 vaccine providing a degree of cover as quickly as possible to reduce severe disease in a large proportion of higher-risk groups.
- In a summary of the evidence behind this decision in the British Medical Journal in January 2021, authors acknowledged that there were no clinical trial data evaluating the extended dosing interval for the Pfizer vaccine.[2] However, there are data on AstraZeneca for extended dose, and this is sometimes cited to show that extended intervals may maintain or improve effectiveness for COVID-19 vaccines in general, based on general immunological principles. A post-hoc analysis of the clinical trials for the AstraZeneca COVID-19 vaccine, found that vaccine efficacy 14 days after a second dose appeared to be higher in the group that had more than six weeks between the two doses (65.4%, 95%CI: 41.1-79.6%) than in the group that had less than six weeks between doses (53.4%, 95%CI: -2.5-78.8%).[3] The authors noted that there was limited data on mRNA COVID-19 vaccines specifically, but, quoting Andrew Pollard (head of the Oxford Vaccine Group and chief investigator in the AstraZeneca trial), commented that “*Generally, a longer gap between vaccine doses leads to a better immune response...*” and that, broadly speaking, the underlying biology is similar across vaccines: “*...the immune system remembers the first dose and will respond whether the later dose is at three weeks or three months.*”.
- A UK study published as a pre-print in May 2021 showed that elderly (over 80 years) participants vaccinated with a 12 week interval of Pfizer had a 3.5-fold higher peak spike-specific antibody response, but a 3.6-fold lower peak T-cell response compared to those vaccinated with the recommended 3 week interval.[4] Neutralising antibodies (NAbs) were not measured but spike-specific antibody and neutralising antibody responses have been highly correlated in previous studies of the Pfizer vaccine.
- Another non-peer reviewed UK study published as a pre-print on 23 July 2021 assessed immunogenicity after short (2-5 weeks) and long (6-14 weeks) dosing intervals of Pfizer in healthcare workers (21-71 years).[1] The median interval in the long interval group was 10 weeks. Following the first dose, there was limited detection of neutralizing antibodies (Nabs) against the Beta (B.1.351) and Delta (B.1.167.2) variants, but NAbs were observed against Gamma (P.1) and the original Victoria strain. Antibody levels (binding and neutralising) decreased markedly during the

extended dosing interval but were boosted following the second dose. In addition, higher binding and NAb titers were observed in infection-naïve individuals vaccinated using the long interval regimen, with a 2-4 fold increase in titer, depending on the variant tested. In contrast to antibody responses, spike-specific T cell responses were maintained during the 10 weeks following the first dose, with responses further boosted by the second dose in those who were infection-naïve. However, the longer dosing interval led to a modestly lower T cell response compared to the shorter interval. Overall, T cell data indicated that a shorter dosing interval in infection-naïve individuals led to a modestly higher effector T cell response and the longer interval a deeper T cell memory response, but the overall clinical impact of this result is currently unclear.

- In general, it is not known how these antibody and cellular responses impact the effectiveness and duration of protection provided by the vaccine. However, these preliminary immunogenicity data following are encouraging and are in line with results from several UK studies that report high effectiveness of the Pfizer vaccine following the extension of dosing interval in December 2020.
- Extending the dosing interval means that more people will have only received one dose for an extended period of time. Vaccine effectiveness against symptomatic disease for Pfizer, particularly against the prevalent Delta variant, is low after one dose: Delta 35.6% (95% CI: 22.7-46.4%), Alpha 47.5% (95% CI: 41.6–52.8).[5] After two doses, the vaccine effectiveness was 88.0% (95%CI: 85.3-90.1%) for the Delta variant, and 93.7% (95% CI: 91.6–95.3%) for the Alpha variant. With regard to severe disease, vaccine effectiveness remained very high: vaccine effectiveness against hospitalisation was estimated in the same data to be 96% (95%CI: 86-99) with Delta. However, the risk from COVID-19 is lower in low-prevalence country, but remains an issue for an outbreak situation. Note that these estimates are based on data from the UK, where a 12-week interval for the Pfizer-BioNTech COVID-19 vaccine was used (with peaks in these data occurring and 10, 11 and 12 weeks).
- Estimates for effectiveness of a single dose of Pfizer vaccine covering time points beyond the 3-week dosing interval are between 48.6%-70% for all PCR confirmed infection/symptomatic COVID-19,[6-10] and 81-93% for severe disease/hospitalisation.[8, 11, 12] The effectiveness was calculated over a period that varied between studies but extended to a maximum of 90 days after a single dose. One study indicated that effectiveness might peak at 28-34 days after a first dose of vaccine and then plateau.[11]

### **International recommendations for dosing interval for Pfizer/BioNTech COVID-19 vaccine**

- On 14 May 2021, the the Joint Committee on Vaccination and Immunisation (JCVI) in the UK recommended that the second dose interval be reduced from 12 to 8 weeks for people in priority cohorts 1-9 who have yet to receive their second dose.[13]
- Priority groups in England as of 23 April 2021 are given in Figure 1 (see <https://www.gov.uk/government/publications/covid-19-vaccination-care-home-and-healthcare-settings-posters/covid-19-vaccination-first-phase-priority-groups> ). The clinical conditions that are

part of group 6, include conditions such as blood cancer, diabetes, dementia, and cardiovascular conditions.

| Priority | Risk group  |
|----------|---|
| 1        | Residents in a care home for older adults and staff working in care homes for older adults  |
| 2        | All those 80 years of age and over and frontline health and social care workers   |
| 3        | All those 75 years of age and over  |
| 4        | All those 70 years of age and over and <a href="#">clinically extremely vulnerable</a> individuals (not including pregnant women and those under 16 years of age) |
| 5        | All those 65 years of age and over  |
| 6        | Adults aged 16 to 65 years in an at-risk group (see clinical conditions below) <a href="#">[footnote 1]</a>   |
| 7        | All those 60 years of age and over  |
| 8        | All those 55 years of age and over  |
| 9        | All those 50 years of age and over  |
| 10       | Rest of the population (to be determined)   |

Figure 1 Priority groups for COVID-19 vaccination from Public Health England as of 23 April 2021

- The main exception to the 8 week lower interval are those about to commence immunosuppressive treatment. In these individuals, the NHS recommends that “...minimal intervals (21 days for Pfizer BioNTech vaccine or 28 days for Moderna and AstraZeneca vaccines) may be followed to ensure that the vaccine is given whilst their immune system is better able to respond”. [14].
- The vaccine effectiveness observed in England using the 12-week dosing interval for Pfizer/BioNTech COVID-19 vaccine has been high, even against variants of concern: vaccine effectiveness against symptomatic disease was 93.7% (95% CI: 91.6 - 95.3%) among persons with the alpha variant and 88.0% (95% CI: 85.3 - 90.1%) among those with the delta variant.[5] With regard to safety, broadly speaking, the safety profile for the Pfizer/BioNTech COVID-19 vaccine that has been observed in England is consistent with that observed globally.[15]
- In Europe, the EMA recommends an interval of 3 weeks for the Pfizer/BioNTech COVID-19 vaccine, but allows up to 42 days: the product information states that the participants in the phase 3 trial received their second dose within 19 to 42 days after their first dose, with the majority (93.1%) of the participants receiving the second dose 19 to 23 days after the first dose.[16] Several countries in Europe have employed extended dosing intervals for Pfizer, such as Denmark and Norway, with the recommended intervals ranging between 6 and 12 weeks, although recommendations in different countries have changed over time in response to the changing pandemic situation.
- The United States has consistently recommended an interval of 3 weeks, allowing up to 6 weeks if the 3 week interval is not possible.[17] However, in general, the safety profiles and efficacy data as described by the Summary of Product Characteristics[16] in Europe (EMA) and in the Fact Sheet for

Healthcare Providers Administering Vaccine (Pfizer-BioNTech COVID-19 vaccine) in the US (FDA)[18] are similar.

- In Canada, in early March 2021, the immunisation schedule for the Pfizer COVID-19 vaccine extended the interval from 3-4 weeks to an interval of up to 16 weeks (4 months).[19] The National Advisory Committee on Immunization (NACI) rationale for extending the dosing interval is consistent with those cited by JCVI and others, namely that extending the dosing interval provides some protection to more of the population quickly, while likely ultimately improving the immune response: *“Extending the interval to the second dose of a COVID-19 vaccine maximizes vaccine supply to immunize the largest number of people as quickly as possible. Principles of immunology indicate that a longer interval between priming and boosting doses of a vaccine series results in a better, more durable response”*. Effectiveness in Canada also appears to be high even against the Delta variant, with vaccine effectiveness of 85% (95% CI: 59 - 94%) from 14 days after two doses.[20]
- ATAGI recommends that the second dose of the Pfizer/BioNTech COVID-19 vaccine be administered within 3 to 6 weeks after the first.[21]
- There are no data on dosing interval for the Pfizer/BioNTech vaccine stratified by ethnicity. However, generally speaking, any approach associated with increasing the immune response, may provide greater protection in people with pre-existing conditions, such as obesity or diabetes, that are associated with lower vaccine efficacy; these conditions also tend to have a greater prevalence in Māori and Pacific Peoples in Aotearoa New Zealand.

### Other considerations

- Arguably, extending the dosing interval for the general population, instead of only for those in the 16-29 year-old age group, could remove the potential for concerns and vaccine hesitancy in the younger age group, while potentially maintaining, or even improving, the overall effectiveness for the general population. However, ultimately the impact on vaccine hesitancy or acceptance is unknown.
- With regard to practical considerations, an extension of the dosing interval for all groups may also be more efficient to co-ordinate, compared to restricting the extension of the dosing interval to people under 30 years. However, changing the dosing interval for everyone may impact the completion of the rollout, and may mean a delay in delivering full protection to high-risk populations, such as the elderly and those with comorbidities.

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| Next Steps   | Draft memo, including noting considerations for extended dosing interval |  |
| In the development of this work, the following parties have been consulted with: | CV TAG for final review  |  |
| Resources used:  |  |  |
| Ministry of Health Policies and Procedures                                       | <input type="checkbox"/> Yes<br><input type="checkbox"/> No              |  |
| External Health Scientific organisations   | <input type="checkbox"/> Yes<br><input type="checkbox"/> No              |  |
| Existing database of RFAs  | <input type="checkbox"/> Yes<br><input type="checkbox"/> No              |  |
| Internal Ministry of Health Advice   | <input type="checkbox"/> Yes<br><input type="checkbox"/> No              |  |
| External Expert Advice   | <input type="checkbox"/> Yes<br><input type="checkbox"/> No              |  |
| Literature Review  | <input type="checkbox"/> Yes<br><input type="checkbox"/> No              |  |

## References

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*outbreak setting*. 2021 13 July 2021 [cited 2021 01 August 2021]; Available from: <https://www.health.gov.au/news/atagi-statement-on-use-of-covid-19-vaccines-in-an-outbreak-setting>.

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

**Minutes: COVID-19 Vaccine Technical Advisory Group (3 August 2021)**Excerpt:

|            |   |
|------------|---|
| <b>6.0</b> | <p><b>Dosing interval for Pfizer</b></p> <ul style="list-style-type: none"> <li>• The Request for Advice (RfA) on this topic was reviewed.</li> <li>• The data on improved immune responses with a delayed interval was noted as promising.</li> <li>• It was noted that, in the event of an outbreak, there would be reduced protection for those who have only had one dose. CV-TAG therefore encouraged surge capacity to be built into the programme in case of an outbreak.</li> <li>• Exceptions to the longer intervals among immunosuppressed people (e.g., with solid tumours) was discussed, and the Science and Technical Advisory team will progress consultation and discussion on these exceptions.</li> <li>• The RfA on evidence on the dosing intervals will be shared with the Director-General.</li> </ul> |
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**Minutes: COVID-19 Vaccine Technical Advisory Group (5 October 2021)**Excerpt:

|            |   |
|------------|---|
| <b>2.0</b> | <p><b>Vaccine Rollout</b></p> <p>The Chair provided an update on the vaccine rollout:</p> <ul style="list-style-type: none"> <li>• It has been agreed that the default booking rules change back to a three-week interval, due to the changing context of the Delta outbreak and the increased potential for circulating virus, there is an increased need to get second doses administered</li> <li>• The shift of resources to administering second doses was seen as anti-equity as it may divert focus from outreach to Māori and Pasifika who have not yet had first doses, however it was noted there is no shortage of vaccines or appointments to do both.</li> <li>• There was some discussion on whether a longer interval should be kept for adolescents and young people &lt;30 due to wanting more data on the connection between intervals and side effects.</li> <li>• A shift back to three-week intervals would likely see an increase in people receiving their second dose before the minimum of 21 days, and therefore continued communication on the minimum interval between doses was needed.</li> </ul> |
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# Memorandum

## Decision to increase the Pfizer/BioNTech COVID-19 vaccine interval to six weeks

**Date due to MO:** 6 August 2021      **Action required by:** 6 August 2021

**Security level:** IN CONFIDENCE      **Health Report number:** 20211788

**To:** Vaccine Ministers

### Contact for telephone discussion

| Name                 | Position                   | Telephone |
|----------------------|----------------------------|-----------|
| Dr Ashley Bloomfield | Director General of Health | § 9(2)(a) |

### Action for Private Secretaries

N/A

**Date dispatched to MO:**

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

# Decision to increase the Pfizer/BioNTech COVID-19 vaccine interval to six weeks

## Purpose of report

1. This memo seeks your approval to increase the Pfizer/BioNTech COVID-19 vaccine interval from three to six weeks for the majority of people.

## Background and context

2. In February 2021, Medsafe approved the use of the Pfizer/BioNTech COVID-19 vaccine in New Zealand. This approval required the vaccine to be administered in two doses with a minimum duration of 21 days between each dose.
3. The vaccination roll-out philosophy adopted by the programme to date has been to fully vaccinate individuals as soon as possible, once they become eligible, within the regulatory approval set by Medsafe. This approach was underpinned by the sequencing framework which sought to achieve high efficacy for individuals that were most vulnerable, or most likely to contract COVID-19 due to their occupations, particularly within supply constraints early in the rollout.
4. The Director-General of Health recently requested an update from CV TAG on the emerging information regarding a longer interval between doses for everyone (attached), as part of the original recommendation for a longer interval for people under 30 years of age based on risk of myocarditis. The opportunity to shift approach was initially signalled to Vaccine Ministers on Friday 31 August 2021.

## Rationale for the change

5. Internationally the COVID-19 pandemic remains a huge challenge. This has been particularly evident in the recent outbreaks and community transmission in Australia and the spread of the Delta variant across the world.
6. Many countries have a longer interval than three weeks for the Pfizer/BioNTech COVID-19 vaccine as standard. This includes the UK, Canada, and several European countries, with intervals ranging from around eight to 16 weeks.
7. Internationally, the initial reasons for having a longer dose interval were:
  - a. practical (e.g. covering more of population with at least one dose quickly in an active outbreak); and
  - b. scientific (e.g. prior scientific consensus and basic principles of vaccinology and immunology that, in general, intervals longer than three weeks are typical between the prime and booster doses in order to maximise the immune response).
8. Given the emergence of Delta, and potentially other variants, we consider there is merit in increasing the recommended dose interval. This would allow more people to receive their first dose sooner, lowering the population risk in the case of an outbreak and community transmission. In addition, we consider this would provide a potential upside

of potentially stronger immune response based on emerging evidence, with no negative impact on safety across the population.

9. As a result of new and emerging information, the Ministry recommends increasing the standard interval between doses from current three week minimum to a six week minimum for most consumers. The increased interval advice is consistent with CTAG advice re. myocarditis associated in younger people.
10. No additional Medsafe approval is required in order to implement the recommended change.

## Implementation approach

11. In order to increase the interval between vaccinations the following changes would be implemented:
  - a. a national communications campaign to reinforce the rationale of the change and reassure consumers who have been vaccinated under the current settings that they are still appropriately protected against COVID-19. This would be released in line with any public announcement
  - b. a technology change to the booking system to provide second appointments at a minimum of six-week interval, unless the consumer chooses to be vaccinated sooner (but no less than 21 days) or there is a clear reason for it to be shorter eg. Cancer patients ahead of treatment, border workers (to ensure they are fully protected as soon as possible)
  - c. enable the national call centre support to respond to questions and assist consumers who wish to alter their existing booking to increase the duration between their current appointments
  - d. continuing to work with DHBs to ensure their forward capacity supports the increased interval between vaccinations
  - e. an update to operational procedures and service standards to align these documents to the change in approach.

### *Timeframe for implementation*

12. The earliest that the technology change could be implemented and released is Wednesday 11 August. It is therefore recommended that the change be implemented as effective from this date.
13. Once the technology has been implemented, it is expected that most consumers would book new appointments with at least six weeks between the first and second dose.
14. Individuals with existing bookings would not be automatically rescheduled to increase the interval between doses. Both the national booking system and the national call centre would enable individuals to reschedule their second appointment should they wish to do so.
15. A number of primary care providers are using their own practice management systems to manage bookings. We will work with primary care providers to ensure a consistent approach is implemented across providers in relation to the change in dose interval.

## Impacts of the change

16. There are several issues arising from the implementation of this change that need to be acknowledged prior to implementing this approach.

### *Consumer Confidence in the Programme*

- a. Increasing the duration between vaccinations for all future bookings may lead to questions about vaccine effectiveness for consumers who have either had both of their vaccines or are booked with a duration of less than six weeks between their vaccinations.
- b. Effective public communications will be needed to inform fully vaccinated people who attend their existing appointments, that they are still appropriately protected against COVID-19. This will also mitigate the risk of this change generating hesitancy for un-vaccinated people.

### *Consumer experience*

- c. Individuals who are currently booked to receive their vaccinations within the newly recommended interval would have the opportunity to rebook their second appointment should they choose to do so. People would be encouraged to make these changes online, or by ringing the national call centre.
- d. Those individuals opting for vaccination at their primary care provider and booking on those providers local systems would also have the opportunity to rebook their second appointment directly with their provider if they choose to do so.
- e. It is difficult to predict the number of consumers who may want to change their existing booking, or the method that they will use to achieve this, as we have no previous relevant use cases to reference.
- f. To ensure that consumers can be assisted in changing their bookings, the national call centre would scale to anticipate a higher volume of calls when the change is implemented. As it is difficult to assess the magnitude of this demand, a high initial response may result in extended call times. This would be closely monitored.

### *DHBs production plans*

- g. If a high number of existing appointments are moved into the future, this will result in a lower level of bookings for the weeks immediately after the announcement of the change. A degree of loss of productivity could occur, if the capacity created by consumers moving their second appointment into the future is not fully replaced by a new cohort wishing to book their first appointment.
- h. To mitigate against unused capacity, it is proposed that the next Group 4 age cohort (50–54 years) would also be released on Wednesday 11 August. DHBs would also be encouraged to accept walk-ins to further minimise this impact.

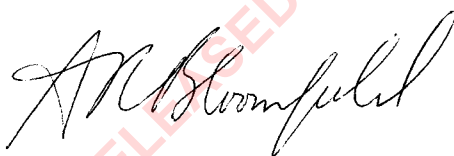
### Vaccination capacity

- i. To support the longer duration between vaccinations, the Ministry is working with DHBs to ensure that enough vaccination capacity is available to allow consumers to select an appointment for both vaccinations. Should this not occur, consumers would potentially become frustrated and disengaged due to not being able to book both appointments, when availability for their first appointment existed.

## Recommendations

It is recommended that you:

|    |              |  |               |
|----|--------------|--|---------------|
| 1. | <b>note</b>  | The rationale for increasing the standard interval between Pfizer/BioNTech COVID-19 vaccination doses for the vaccination programme from three weeks to six weeks.   |               |
| 2. | <b>note</b>  | That an effective communications approach is critical to supporting this change and to maintaining public confidence in the COVID-19 vaccination and immunisation programme.   |               |
| 3. | <b>note</b>  | The recommended approach to implementing the six-week interval between vaccinations, including leaving all existing bookings unchanged to avoid an immediate slow-down of the programme (can be changed by individual consumer). |               |
| 4. | <b>note</b>  | The potential impacts resulting from the implementation of this change and proposed mitigations.   |               |
| 5. | <b>agree</b> | To implement a change to the standard interval between Pfizer/BioNTech COVID-19 vaccine doses for the vaccination programme from three to six weeks for all people booking a vaccination from Wednesday 11 of August 2021.       | <b>Yes/No</b> |



Dr Ashley Bloomfield

**Te Tumu Whakarae mō te Hauora**

Director-General of Health

Date: 5 August 2021

# Memo

## The use of COVID-19 vaccines during an outbreak: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations for prioritisation of first doses nationwide

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**Date:** 20 August 2021

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**To:** Joanne Gibbs, Director of National Operations, COVID Vaccine and Immunisation Programme

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**From:** Dr Ian Town, Chief Science Advisor

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**For your:** Consideration

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### Purpose of report

1. To summarise the COVID-19 Vaccine Technical Advisory Group's recommendations on the use of COVID-19 vaccines during an outbreak, endorsing the prioritisation of vaccination capacity nationwide to allow the maximum number of people to receive at least a single dose of the Pfizer COVID-19 vaccine.

### Context

2. On 19 May 2021, CV TAG provided advice on the use of the Pfizer/BioNTech (Comirnaty) COVID-19 vaccine in an outbreak. The recommendations were:
  - *The characteristics of the Pfizer/BioNTech (Comirnaty) COVID-19 vaccine mean that it cannot be used in the traditional sense of ring vaccination. However, targeted vaccination can be used to encourage 'community confidence' and increased uptake of the vaccine.*
  - *Any targeted vaccination should be implemented alongside other public health measures and not as a standalone measure. A protocol should be developed and ready for implementation if we have an outbreak.*
  - *There is no international data on using the COVID-19 vaccine for targeted vaccination to inform what the trigger point would be for deploying this strategy. The situation in New Zealand means that there may be an opportunity to gain some experience should it be necessary to deploy such a measure.*
  - *There will be communities with low vaccine coverage, and we will need a protocol to ensure increased coverage while maintaining equity in an outbreak setting. The process of progressively relaxing controls at the border may lead to potential outbreaks in some communities.*
3. Currently, New Zealand is at Alert Level 4, indicating COVID-19 is not contained, with a significant number of cases of community transmission in Auckland. Cases have also emerged in Wellington, linked to the Auckland cluster.



4. Demand for vaccinations is high, and there are concerns that at risk groups – such as essential workers – may not be able to access vaccination in a timely manner.
5. There are also concerns that the ability to access vaccinations may be disproportionately difficult for some members of the population, and that this may worsen existing inequities in vaccine coverage, with consequences for the risk of transmission and infection in some communities.
6. The COVID-19 Vaccine and Immunisation Programme (CVIP) sought clinical and scientific advice from CV TAG on the use of the Pfizer COVID-19 vaccine in an outbreak.

## Recommendations

7. CV TAG noted that:
  - a. One dose of the Pfizer COVID-19 vaccine provides good protection against severe disease and hospitalisation.
  - b. Two doses of the Pfizer COVID-19 vaccine are needed to fully protect against infection, and vaccine efficacy is lower in immunocompromised groups. Therefore it is important that immunocompromised groups and those in groups 1, 2 and 3 receive two doses.
  - c. There is growing evidence that longer intervals between doses are not inferior, and may provide a better immune response, further supporting decisions to delay second doses.
8. CV-TAG endorses the following approach for the Pfizer COVID-19 vaccine:
  - a. All capacity nationwide is used to prioritise:
    - i. The two-dose course for Groups 1, 2 and 3 of the sequencing framework, including children 12 years of age and
    - ii. A single dose for Group 4 including children 12 years of age and over.
  - b. Māori and Pacific peoples should be urgently prioritised within all groups due to increased risk of infection, severe disease, and low current vaccination coverage.
9. This approach will apply for this current outbreak and will be kept under regular review or on request from CVIP.

Ian G Town

Dr Ian Town  
Chief Science Advisor  
Chair, CV TAG

# Science Overview of Pfizer COVID-19 Vaccine

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## 1. Prior COVID-19 infection

At least eight small studies have shown that those with previous COVID-19 disease produce a strong antibody response after a single dose of vaccine.[1-6] This response is similar in magnitude to that seen after two doses in those without prior COVID-19 disease. One of these studies also found that the SARS-CoV-2 infection also led to increased numbers of double negative B memory cells, which might be a “dysfunctional B cell subset”. [1] One study has also shown that a single dose of Pfizer vaccination after infection with “original strain” virus substantially enhances neutralising antibody responses against variants including the Beta variant [7]. Overall it has been suggested that vaccination following infection results in a broader and greater magnitude neutralising antibody response than vaccination in SARS-CoV-2 naïve individuals.[8]

Prior infection may also increase the durability of immunity. A Spanish study comparing antibody titres in previously infected and infection naïve healthcare workers found that at two months post-vaccination, the previously infected group had higher antibody titres.[9]

## 2. Immunogenicity

### 2.1. General

This vaccine is immunogenic. In 18-55 year olds, neutralising antibody levels were 3.8 times that in convalescent plasma 1 week after the second dose and in 65-85 year olds 1.6 times, with all vaccine recipients in both age groups producing detectable neutralising antibody titres.[10] Data from a phase 3 trial in adolescents (12-15 years of age) showed a strong neutralising antibody response to vaccination.[11]

In a (non-peer reviewed) observational study, uniformly robust IgG responses across all vaccinees were only seen after the second dose was administered.[12]

When comparing Pfizer vaccination with natural infection, a (non-peer reviewed) study found that vaccination generated lower levels of original antigenic sin-like antibodies and higher levels of SARS-CoV2 specific antibodies.[13] The implications of the cellular response to Pfizer are under-researched. However, a (non-peer reviewed) study monitoring cellular responses to vaccination in the 6-months after the second dose found CD4+ and CD8+ lymphocytes display features of polyfunctionality and longevity.[14]

### 2.2. Single-dose schedule

The neutralising antibody titres generated by one dose are significantly less than those generated after two doses. Furthermore, in the interdose period during an extended interval, neutralising antibody responses have been seen to wane following a peak at around 4 weeks, however the T cell response has been seen to persist. As with post two doses, there is variability seen in the magnitude of the antibody response after the first dose, with it generally higher in healthy younger adults, however there is limited data on whether the kinetics of the response are similar over the extended intervals.[15-20]

### 2.3. Extended interval two-dose schedule

Studies have found that extended intervals between the first and second dose produce higher peak spike-specific antibody responses (3.5-fold higher among 172 80+ participants with a 12-week interval,[21] and ~2-fold among 280 infection-naïve healthcare workers with a 6-14 week interval[16]). However, longer intervals were associated with lower peak T-cell responses when compared to the 3-week interval (3.6 fold in the 80+ group,[21] and 1.59-fold among healthcare workers[16]). Yet among the healthcare workers, the longer interval saw a greater proportion of the T cell response comprised by CD4+ cells and was suggestive of a more developed memory cell phenotype. There were no significant differences between the intervals for 223 previously infected healthcare workers in this study.[16] A Canadian (non-peer reviewed) study has also that found while delaying the second-dose reduced spike-specific CD4+ T-cell responses (>2-fold reduction in median T-cell frequency), anti-RBD binding titres were significantly elevated (3.3-fold increase).[22]

A UK (non-peer reviewed) study, in ages 50+, found that anti-S IgG titres were ~10x fold higher in those with a 65-84 day interval vs the regular 19-29 day interval.[23] Another UK study compared immunogenicity in adults after they received standard or extended-interval schedules of the Pfizer vaccine. They found that the extended interval was associated with higher neutralising antibody levels and an enrichment of CD4+ T cells expressing IL2.[24]

Some evidence suggests that the longer schedule may have a limited effect on the duration of immune response. A (non-peer reviewed) study of antibody responses following the second dose of Pfizer found that while shorter intervals were associated with a lower antibody response at day 21, however by day 42 they were similar to longer intervals. When analyses were limited to the <70 age group, there was no difference between short and extended intervals.[25]

A Canadian (non-peer reviewed) study found that a 16-week interval generated a similar neutralising antibody response to those who had been previously infected and received one dose.[26]

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# Memo

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**Date:** 17 December 2021

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**To:** Dr Ashley Bloomfield, Director-General of Health

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**Copy:** Astrid Koornneef, Director of National Immunisation Programme  
Allison Bennett, Manager, System Enablers, System Strategy and Policy  
Dr Caroline McElnay, Director of Public Health

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**From:** Dr Ian Town, Chief Science Advisor

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**Subject:** COVID-19 booster vaccinations in specific situations: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations

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**For your:** Consideration

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Noted  
AB 19/12/21

## Purpose

1. To summarise the COVID-19 Vaccine Technical Advisory Group's (CV TAG) recommendations about booster doses of the Pfizer vaccine.

## 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. CV TAG has previously made recommendation about 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 (Appendix 1).
4. The COVID Vaccine Immunisation Programme (CVIP) has asked for further information and clarification on CV TAG's recommendations in specific situations:
  - a) Use of booster doses at less than 6 months after the completion of the primary vaccination course.
  - b) Use of booster doses for those under the age of 18 years who are at high risk of exposure to SARS-CoV-2.
  - c) Booster doses for pregnant people.
5. *Antibody waning:* Current evidence shows that antibody levels against SARS-CoV-2 wane over time following the second dose of the Pfizer COVID-19 vaccine. There is a reduction in protection against infection, particularly from 6 months after a primary vaccination course.[1-3] The reduction in protection is similar for Delta and other virus variants.[2, 4] Protection against transmission from vaccinated individuals who are infected also appears to wane over time.[5] However, evidence suggests that protection against severe disease remains high, including for the Delta variant, though follow-up times varied between studies.[1-4, 6-8]

6. *Reactogenicity of a Pfizer booster dose:* Amongst 306 participants aged 18-55 years old receiving a third dose in Pfizer's phase III trial, reactogenicity was largely in line with findings after the second dose, with the exception of lymphadenopathy which occurred at a rate of 5.2% compared to 0.4% post-second dose.[9] Other studies also suggest that the common mild and transient side effects after booster doses are comparable to those following primary vaccine doses.[10-14]
7. *Safety of a Pfizer booster dose:* Data from Israel shows that after more than 2.8 million administered third doses, 19 serious adverse events have been reported, of which 2 have been confirmed as linked, though there is likely underreporting in this data.[15] Only one case of myocarditis has been reported and is under investigation, in a male older than 30 years, however most younger individuals have had limited follow up time.[15] Israeli data suggests that the risk of myocarditis with the booster dose is not increased when compared with the risk after second doses of vaccine.[16] However, there remain limited data on the incidence of myocarditis after second doses of the mRNA vaccines in younger people.[16-22]
8. *Immunogenicity and effectiveness of a Pfizer booster dose:* A COVID-19 vaccine booster dose administered at 6 months or more after completion of the primary vaccine course has been demonstrated to boost the immune response (e.g. neutralising antibody) and is expected to increase protection against infection and disease, particularly in older people where waning appears more marked.[9-12] Data from Israel, where Pfizer booster doses have been administered to large numbers of people, show reductions in all eligible age groups in the rate of infection, as well as severe disease in those aged  $\geq 40$  years, and deaths in those  $\geq 60$  years, after the booster dose.[16, 23, 24]

*Use of booster doses at less than 6 months after the completion of the primary vaccination course*

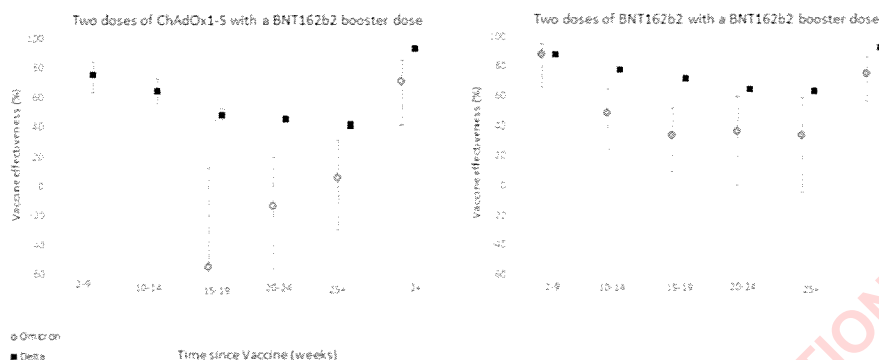
9. Potential reasons to consider early booster doses include:
  - a) to provide potentially higher protection against COVID-19 caused by new variants
  - b) to protect people who are close to 6 months post-primary vaccination course who are at risk of severe COVID-19 and/or SARS-CoV-2 exposure.
10. It is not yet clear if Omicron can evade vaccine-induced immunity. The laboratory data on Omicron from antibody neutralisation studies to date is very limited and preliminary [25-27], and cannot be used to infer an impact on vaccine protection in real world settings at this stage. Additional information about these studies is presented in Appendix 2.
11. Very early data about vaccine effectiveness (VE) against **symptomatic** disease caused by Omicron and Delta variants was released by the UK Health Security Agency (UKHSA) on 10<sup>th</sup> December 2021.[28] This analysis included data from 56,439 Delta cases including 581 Omicron cases. Results are shown in Figure 1 (Figure 7 in original document), below. Data about VE of a Pfizer primary series (weeks "2-9" to "25+") and booster dose (week "2+") against Delta and Omicron variants are shown in the right-hand panel of Figure 1. Confidence intervals for VE estimates for Omicron are extremely wide. However, they do not appear to overlap with confidence intervals for Delta at any point from 9 weeks after the primary course (including after the booster dose). This suggests a lower VE for Omicron than for Delta, but it remains unclear to what extent. The point estimate for VE against Omicron increased to ~76% at >2 weeks after a Pfizer booster dose, from ~35% at 15 to >25 weeks after the Pfizer primary course.



Figure 1: Early UKHSA data on vaccine effectiveness for Delta and Omicron (right panel show Pfizer primary course and booster, with lower effectiveness against Omicron)

**Figure 7: Vaccine effectiveness against symptomatic diseases by period after dose 1 and dose 2 for Delta (black squares) and Omicron (grey circles) for (A) recipients of 2 doses of AstraZeneca vaccine as the primary course and a Pfizer as a booster<sup>1</sup> and (B) recipients of 2 doses of Pfizer vaccine as the primary course and a Pfizer as a booster**

Supplementary data are not available for this figure.



<sup>1</sup> The early observations for 2 doses of AstraZeneca are particularly likely to be unreliable as they are based on relative small numbers and are likely to reflect an older population and a population with more co-morbidities than those given the Pfizer vaccine, and this may explain the negative point estimates.

12. A press release with data from South Africa during the Omicron wave states that two doses of Pfizer has a VE of **70% against hospitalisation**, and **33% against COVID-19 infection**, though the data does not mention time since vaccination.[29]
13. Other data from South Africa shows that the risk of reinfection has increased in the era of Omicron. [30] This suggests that Omicron could have increased evasion of immunity following prior infection.
14. The Australian Technical Advisory Group on Immunisation (ATAGI) advised on 3<sup>rd</sup> December 2021 in a statement about SARS-CoV-2 Omicron variant and COVID-19 booster doses, that at that time there was no evidence to suggest that earlier booster doses of current COVID-19 vaccines will augment protection against the Omicron variant. However, ATAGI also said in this statement that in certain circumstances, the routine six-month interval for booster doses may be shortened to five months for logistical reasons, for example:
  - a) for patients with a greater risk of severe COVID-19 in outbreak settings;
  - b) if an individual is travelling overseas and will be away when their booster dose is due; or
  - c) in outreach vaccination programs where access is limited.
15. On 12<sup>th</sup> December, ATAGI updated their statement to recommend **COVID-19 booster vaccination for anyone aged 18 and older who completed their primary course of COVID-19 vaccination 5 or more months ago**.
16. The UK's Joint Committee on Vaccination and Immunisation (JCVI) have reduced the minimum interval between completion of the primary course and the booster to 3 months, stating that "it may be that higher levels of antibody induced by vaccines directed at the original 'wild type' variant will provide better protection against the Omicron variant, as has been demonstrated in laboratory studies with respect to other variants", and "additional data regarding the Omicron variant will take some time to accrue. Waiting for such data before taking some actions risks a suboptimal delayed response".

*Use of booster doses in those under the age of 18 years who are at high risk of exposure to SARS-CoV-2*

17. In those under 18 years of age, severe COVID-19 is uncommon, and the primary course of COVID-19 vaccines generates a strong immune response. Therefore, the benefit from additional doses of vaccine is thought to be small. In addition, there are currently only very limited data on the safety of repeated mRNA vaccine doses in this age group.
18. On 9<sup>th</sup> December 2021, the U.S. Food and Drug Administration (FDA) amended the emergency use authorization for the Pfizer vaccine, allowing the use of a booster in individuals 16 and 17 years of age at least six months after completion of primary vaccination with Pfizer vaccine.
19. ATAGI does not currently recommended boosters for those aged <18 years.

*Booster doses for pregnant people*

20. CV TAG recommendations from 10<sup>th</sup> November (Appendix 1) excluded pregnant people who received a primary course earlier in pregnancy from priority groups, but there was no specific recommendation given about booster vaccination in pregnancy outside of a prioritisation framework. Specifically, there is concern that messaging that those vaccinated in early pregnancy should not receive a booster dose while still pregnant is raising unintended concerns about the safety of vaccination with COVID-19 vaccines while pregnant (both primary and booster doses).
21. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) states that "a booster dose can be considered if you are 18 years or older and had your initial COVID-19 vaccine course (called the primary course)  $\geq$  6 months ago. Pfizer is the preferred brand for booster doses for all people, including in pregnancy, regardless of the brand used initially". RANZCOG argue "mRNA vaccines are safe and effective for those trying to conceive, pregnant and breastfeeding women. Booster doses have not yet been studied in those who are pregnant but have been shown to be safe and effective in non-pregnant adults. We do know that COVID-19 infection in pregnancy poses a significant risk for mothers and their babies, and RANZCOG recommends that pregnant women receive booster vaccinations in line with the recommendations for the non-pregnant adult population".[31]

## **Recommendations**

22. CV TAG met on 14 December 2021 to consider recommendations regarding COVID-19 booster vaccinations in specific situations.
23. **CV TAG noted that:**
  - a) Data are still accumulating about whether early booster doses offer any advantages in protection against the Omicron variant.
  - b) There are no long term data available about the safety of early booster doses but short term side effects appear to be modest.
  - c) There is insufficient data on the safety profile for booster doses in pregnant people.
  - d) Medsafe has authorised boosters only from six months after completion of the primary dose.
24. **CV TAG recommends that:**
  - a) A Pfizer booster dose should be offered to adults 18 years or over, 5 months after the completion of the primary vaccination course.

- b) Priority should be given to those at high risk of severe disease or exposure to SARS-CoV-2, including:
    - i. those aged 65 years and over
    - ii. those with comorbidities that put them at higher risk of severe COVID-19
    - iii. Māori and Pacific peoples
    - iv. health care workers and workers in other settings at high-risk of SARS-CoV-2 exposure eg Border Workers and MIQ staff.
  - c) The COVID-19 Vaccine and Immunisation Programme (CVIP) of the Ministry of Health will need to work with Medsafe to manage access to boosters for the shorter 5-month interval.
  - d) Booster doses for 16- and 17-year-olds are not currently recommended (including for those working in settings that place them at higher risk of exposure to SARS-CoV-2), in line with the Medsafe authorisation of booster doses.
  - e) Boosters can 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.
25. CV TAG will continue to monitor all relevant information (including vaccine efficacy data against emerging variants of concern and emerging evidence on the duration of immunity) and will update their recommendations as further evidence becomes available.

Ian G Town

**Dr Ian Town**

Chief Science Advisor

Chair, CV TAG

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## Appendix 1

**Priority groups for COVID-19 booster vaccinations: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations**

Memo dated 10 November 2021

**Recommendations**

26. CV TAG met on 2 and 9 November 2021 to consider recommendations regarding priority groups for COVID-19 booster vaccinations.

**27. CV TAG noted that:**

- a) Data are still accumulating about waning of protective vaccination effects after primary vaccination and the benefits of a booster dose.
- b) The goal of offering booster doses in New Zealand is to prevent severe disease caused by SARS-CoV-2, to reduce burden on hospitals and other healthcare providers, and to protect those at high occupational risk of exposure.
- c) The current situation in New Zealand is different to the situation at the start of vaccine roll-out (starting in late February 2021, priority groups listed in Appendix 1). There is now greater availability of Pfizer vaccine and effective infrastructure for administering the vaccine, but there is also a higher risk of healthcare workers being exposed to SARS-CoV-2 with the virus now in the community in New Zealand, especially in Auckland.
- d) There is limited data on the safety profile for booster doses in people younger than 30 years of age from the published trials. Concern was noted around vaccine mandates requiring booster doses in this age group before further data are available
- e) There is insufficient data on the safety profile for booster doses in pregnant people.
- f) Māori and Pacific People are at an increased risk of severe disease and hospitalisation,[32] and therefore having a universal age-criteria for prioritisation is inequitable. A lower age band for Māori and Pacific People would be needed to provide equitable protection.
- g) It is now approximately 8 months since the first doses of COVID-19 vaccine were administered in New Zealand.

**28. CV TAG recommends that:**

- a) Increasing the vaccination coverage of first and second doses, particularly for Māori and Pacific People, should remain the first priority of the COVID-19 vaccination programme in New Zealand.
- b) The Pfizer vaccine is recommended as a single booster dose.
- c) COVID-19 vaccine booster doses should be offered to those 18 years of age and older, who have completed their full primary vaccination course 6 or more months prior.
- d) 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).

- e) Any future vaccine mandates should not require booster doses in younger age groups (<30 years) until further data are available.
- f) When considering prioritisation, priority groups for a booster dose (at least 6 months after completion of the primary course) are those most at risk of exposure to SARS-CoV-2, and those most at risk from serious COVID-19 disease. In particular, these are:
  - i. Frontline healthcare workers, particularly in regions where there is COVID-19 in the community (or regions that are at high risk of further spread of COVID-19),
  - ii. All those who are aged 65 years or over,
  - iii. Māori and Pacific People aged 50 years and over,
  - iv. Anyone over the age of 18 with comorbidities, as specified in Group 3 listed below, with the exception of pregnant people, who completed a full primary course of vaccination in early pregnancy.
- g) AstraZeneca can also be used as a booster dose if available for specific situations including if an individual has had a significant adverse reaction after a previous Pfizer vaccine dose (e.g., anaphylaxis, myocarditis), and if AstraZeneca is not contraindicated.

29. CV TAG will continue to monitor all relevant information (including vaccine efficacy data against emerging variants of concern and emerging evidence on the duration of immunity) and will update their recommendations as further evidence becomes available.

#### Groups for initial vaccine rollout (for reference)

##### Group 1

Group 1 includes people working at the border or in MIQ, and the people they live with (household contacts).

##### Group 2

The Government is expanding the list of Alert Level 4 workers who can get early access to a COVID-19 vaccination. These people will be included in Group 2.

Group 2 will now also include frontline staff who interact with customers and transport and logistic services directly supporting the vaccination programme.

You are also in Group 2 if you:

- are a high-risk frontline healthcare worker (public or private)
- work in a long-term residential environment
- live in long-term residential care and are 12 or over
- are an older Māori or Pacific person being cared for by whānau
- live with or care for an older Māori or Pacific person
- live in the Counties Manukau DHB area and are 65 or over, have an underlying health condition or disability, are pregnant, or are in a custodial setting.

##### Group 3

People who are at risk of getting very sick from COVID-19. You are in this group if you:

- are aged 65 or over
- are eligible for a publicly funded influenza vaccine
- are pregnant
- are disabled, or are caring for a person with a disability
- are severely obese (defined as a BMI  $\geq 40$ )
- have high blood pressure requiring 2 or more medications for control
- are an adult in a custodial setting
- have been diagnosed with a severe mental illness (which includes schizophrenia, major depressive disorder, bipolar disorder or schizoaffective disorder, and adults currently accessing secondary and tertiary mental health and addiction services).

Group 4

Everyone aged 12 and over

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## Appendix 2

**Effectiveness of Booster doses of Pfizer Vaccine against Omicron variant**

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|                  |  |
|------------------|--|
| <b>Date:</b>     | 09 December 2021   |
| <b>To:</b>       | Ashley Bloomfield, Director General, Ministry of Health  |
| <b>Copy to:</b>  | Ian Town, Chief Science Advisor, Ministry of Health  |
| <b>From:</b>     | Fiona Callaghan, Lead Science Advisor, Ministry of Health<br>Jeremy Tuohy, Principal Advisor, Ministry of Health |
| <b>For your:</b> | Information  |

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**Purpose of report**

1. This report provides a rapid update about the effect of booster doses on the vaccine efficacy of the Pfizer BioNTech COVID-19 vaccine against the Omicron variant.

**Background and context**

2. The Omicron variant contains multiple mutations in coding for the spike protein which may result in decreased vaccine efficacy.
3. Rapid analysis of *in vitro* immunology studies has been undertaken by Pfizer BioNTech.

**Results**

4. Pfizer has reported that based on a series of in-vitro antibody neutralisation studies, the third 'booster' shot, or previous infection plus vaccination would be predicted to offer good levels of protection against Omicron.[33]
5. Similar levels of antibody neutralisation were achieved in the lab for Delta and Omicron after 3 doses (Figure 1). As has been demonstrated in several clinical and 'real-world' studies, the Pfizer vaccine offers good clinical protection against Delta (mild and severe disease). The antibody neutralisation data are a good early indication that a third dose of Pfizer may offer similar protection against Omicron. It should be noted that data is available as a media release only, and not in a peer-reviewed publication, as of 09 December 2021.
6. In addition, as with all laboratory studies, it remains to be seen how this will translate into clinical protection and vaccine effectiveness. However, strong laboratory data is promising and there is evidence that neutralising antibody data does correlate with protection from symptomatic disease [34].

## Three doses of BNT162b2 neutralize Omicron

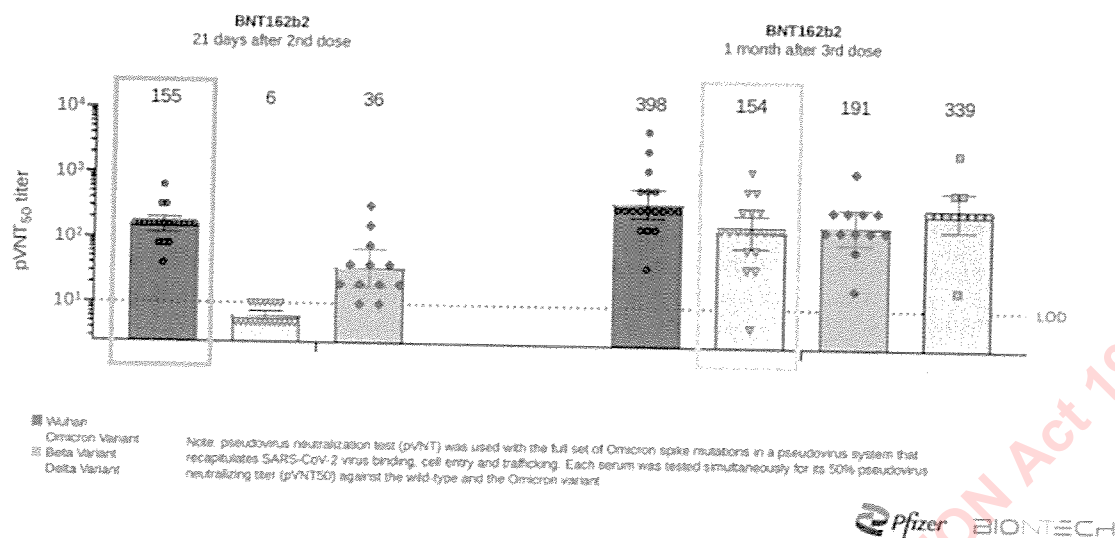


Figure 2 The neutralisation after 2 and 3 doses of Pfizer, of the early 'Wuhan' strain (green); Omicron (purple); the variant that had previously demonstrated the greatest degree of immune escape, Beta (red); and Delta (blue). Omicron shows substantial reduction in neutralisation after 2 doses compared to Beta and Wuhan; however, Omicron has similar neutralisation to other variants after 3 doses.

7. In addition to neutralising antibodies, Pfizer also considered how another arm of the immune response, the cellular response (memory T-cells), performed against Omicron. T-cell responses appeared to be largely unaffected by Omicron.
8. Pfizer also presented neutralisation data on the 'variant-specific' vaccines that they have been developing to date. The lab data for the Pfizer 'Alpha'- and 'Delta'-specific vaccines suggests that those vaccines could offer even better protection against Omicron, because they are able to neutralise Omicron more effectively than the original Pfizer vaccine.
9. In addition, there have been three other preliminary neutralisation studies that have were reported on 08 and 09 December 2021. [35-37]
10. A Swedish study of sera from healthcare workers and blood donors, all of whom had had previous infection, found that the neutralisation of the Omicron variant by Pfizer sera was similar to Delta (both in people with prior infection and as a result of vaccination).[37] Vaccination plus prior infection provided the greatest benefit.
11. Studies from South Africa and Germany found similar results: there was a substantial reduction in neutralisation by Pfizer with Omicron compared to an earlier strain and Delta, but potentially greater protection for people who were vaccinated and had prior infection.[35, 36]

## Disease Severity

12. With respect to disease severity for Omicron, there is currently no evidence that the Omicron variant causes more severe disease. Evidence on disease severity takes time to emerge.
13. The media has reported on the "stealth Omicron variant", which is a variant (sub-lineage) that is missing one of the mutations usually found on Omicron, which gives a different

result with some diagnostic tests. This does not have any practical significance for the testing undertaken in New Zealand as all positive COVID-19 samples will be analysed using whole genome sequencing (see <https://www.theguardian.com/world/2021/dec/07/scientists-find-stealth-version-of-omicron-not-identifiable-with-pcr-test-covid-variant>)

### Comment

14. This emerging data is reassuring for our COVID-19 vaccine programme, and potentially highlights the importance of the booster rollout.
15. The potential vaccine efficacy of Pfizer against Omicron will be discussed at CV TAG on 14 December 2021.
16. It should be emphasised that the data is preliminary, and all studies are based on small sample sizes. This data needs to be confirmed by larger, peer-reviewed, clinical or real-world studies in order to determine the impact on clinical outcomes.

### References

(see reference list, above)

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# Aide-Mémoire

## Cabinet Oral Item: Changing intervals for COVID-19 booster doses with the emergence of the Omicron variant

|                        |   |                              |          |
|------------------------|---|------------------------------|----------|
| <b>Date due to MO:</b> | 19 December 2021                                  | <b>Action required by:</b>   | N/A      |
| <b>Security level:</b> | IN CONFIDENCE                                     | <b>Health Report number:</b> | 20212767 |
| <b>To:</b>             | Hon Chris Hipkins, Minister for COVID-19 Response |                              |          |
| <b>Copy to:</b>        | Hon Andrew Little, Minister of Health             |                              |          |

### Contact for telephone discussion

| Name                        | Position  | Telephone |
|-----------------------------|---|-----------|
| <b>Dr Ashley Bloomfield</b> | Te Tumu Whakarae mō te Hauora<br>Director General of Health | s 9(2)(a) |
| <b>Maree Roberts</b>        | Deputy Director-General, Systems Strategy<br>and Policy     | s 9(2)(a) |

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# Aide-Mémoire

## Cabinet Oral Item: Changing intervals for COVID-19 booster doses

**Date due:** 19 December 2021

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**To:** Hon Chris Hipkins, Minister for COVID-19 Response

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**Security level:** IN CONFIDENCE      **Health Report number:** 20212767

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**Details of meeting:** 20 December 2021

**Cabinet Committee:** Cabinet

**Purpose of proposal:** This Aide-Memoire provides you with talking points for an oral item you are taking to Cabinet on the Director-General of Health's advice to:

- shorten the COVID-19 booster dosing interval from six months to four months to ensure maximum immunity when exposed to COVID-19 variants, and
- seek an in-principle agreement to require COVID-19 booster doses for certain workers under the COVID-19 Public Health Response (Vaccinations) Order 2021.

**Comment:**

- On 17 December 2021, Vaccine Ministers agreed to an oral item on the Director-General of Health's proposal to reduce the approved COVID-19 booster dose interval from 6 months to 4 months for Cabinet to consider on 20 December 2021.
- The oral item is for urgent consideration due to the emergence of the highly infectious COVID-19 Omicron variant.
- Vaccine Ministers also discussed requiring Managed Isolation and Quarantine facilities (MIF and MIQ) and border workers and workers in the health and disability sector, currently captured under the COVID-19 Public Health Response (Vaccinations) Order 2021, to also receive their booster dose.

Dr Ashley Bloomfield

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

# Talking points on changing intervals for booster doses for Minister Hipkins

- I am presenting this oral item to discuss the proposal to shorten the booster dosing interval period and to require certain workers under the Vaccination Order to receive a Pfizer booster dose.
- Evidence is suggesting that waning immunity begins around four months after the second dose of the Pfizer vaccine, but remains sufficiently high at six months to provide good protection against the Delta (and earlier) variants.
- For this reason, Government commenced the roll out of the Pfizer booster programme in November for those over the age of 18 year who have received a primary course (2 doses) of the COVID-19 vaccine at least 6 months prior. This is consistent with Medsafe approval (based on the application received from Pfizer) and with the approach in Australia.
- The recent emergence of the new highly infectious Omicron variant that leads to a significant number of 'breakthrough' infections presents new risks, particularly to those who are currently eligible for a booster, as their immunity against COVID-19 is likely to be waning.
- These are people who were predominately in Groups 1, 2 and 3 of the Sequencing Framework - border workers, health care workers and those most at risk of severe health outcomes and with underlying conditions.
- A significant proportion of these groups are now eligible for a booster dose - 71% of active border workers had their last primary dose six months ago. To date, 55% of these eligible border workers, equating to 39% of all border workers, have had a booster dose.
- Recent advice from the COVID-19 Vaccination Technical Advisory Group (CV TAG) notes emerging evidence increasingly suggests that a third dose of the Pfizer vaccine provides better protection against COVID-19 and its variants, and may in fact be essential to achieve a high level of protection against the Omicron variant.
- With the global presence of the Omicron variant, providing a booster will increase population protection and ensure that immunity levels are at their maximum in New Zealand – ideally with most of the population having received their booster dose ahead of winter 2022.
- Internationally, Australia has adopted a five-month booster interval, in part in response to active community transmission of the Omicron variant. The UK is delivering booster doses at a three-month interval, to help combat high and increasing rates of Omicron in the middle of the winter season, on the background of already high infection rates from the Delta variant.
- With the emergence of the highly infectious Omicron variant and the importance of ensuring a high proportion of people have their booster dose ahead of winter 2022, the Director-General of Health has considered the advice from the CV-TAG and proposes the interval between the completion of the primary course and the booster dose be reduced from six to four months, to maintain the high level of protection.
- Reducing the interval to four months also ensures that Māori, a significant proportion of whom have been vaccinated only in the past two months, can receive a booster before the winter months.
- I support the Director-General's proposal that the interval could be shortened to four months.

- In order to deliver a booster programme with a four month interval and assuming 100% uptake there may be a shortfall in supply of the Pfizer vaccine. Officials are working through options to manage the potential gap, including working with Pfizer to move deliveries forward. Further advice will be provided to Vaccine Ministers, to manage the potential gap in provision, in the New Year.

### Legal risk

9(2)(h)



### Requiring booster doses for those undertaking work in roles at a higher risk of exposure to COVID-19

- The COVID-19 Public Health Response (Vaccinations) Order 2021 (the Order) requires that specified work only be undertaken by workers who have been vaccinated to safeguard them against the risk of COVID-19.
- These settings include specified work at MIF, MIQ and the border as well as high risk work in the health and disability sector.
- MIF, MIQ and Border workers were the first group required to be vaccinated and the majority are now eligible for the Pfizer booster dose. Many health workers were in the second group of the Sequencing Framework (as well as now being required to be vaccinated under the Order) and are also eligible for a booster if they completed their primary course in accordance with the framework.
- As mentioned above, 45% of current eligible border workers (3,421 workers) have yet to receive their booster dose.
- With the emergence of the new Omicron variant, these groups remain at a higher risk of exposure and transmission.



- I am therefore of the view that requiring workers in these settings to receive a Pfizer booster dose will be in line with the intention of the Vaccination Order and continue to ensure population protection.
- While amending the Order to require workers to have the booster dose is desirable, confirming the booster interval is needed before we can make any further amendments.
- Any amendments to the Order needs to clearly state the interval period and the dates by which relevant workers must have received the booster. As the Order has also been subject to a number of legal challenges, it is also important to ensure future amendments are legally robust.
- The drafting of these amendments is likely to be complex, especially to address certain issues such as managing boosters received abroad, those workers under the age of 18 years and also the intersection with the COVID-19 Protection Framework and COVID-19 Vaccination Certificates.
- I am therefore seeking an in-principle agreement to amend the Order to require booster doses for MIF, MIQ, border and health and disability workers, pending confirmation of the booster interval. The application of the booster to the remaining workers covered under the Order will be reviewed accordingly.
- Officials aim to enact this amendment at pace (allowing for the expected complexities) and would follow the usual Orders process. It may need to be undertaken by Ministers with the power to act over the summer break.

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# DG Memorandum

## Implementation and delivery of COVID-19 booster doses at shorter interval with the emergence of the Omicron variant

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|                  |  |
|------------------|--|
| <b>To:</b>       | Dr Ashley Bloomfield, Director-General of Health   |
| <b>Copy to:</b>  | Astrid Koornneef, Director of National Immunisation Programme<br>Allison Bennett, Manager, System Enablers, System Strategy and Policy |
| <b>From:</b>     | Maree Roberts, Deputy Director-General, Systems Strategy and Policy  |
| <b>Date:</b>     | 21 December 2021   |
| <b>For your:</b> | Decision   |

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### Purpose

1. Following Cabinet consideration of your advice on Monday 20 December, this memo provides you with more detailed advice on the legal and practical considerations of the booster interval change in response to the Omicron variant.

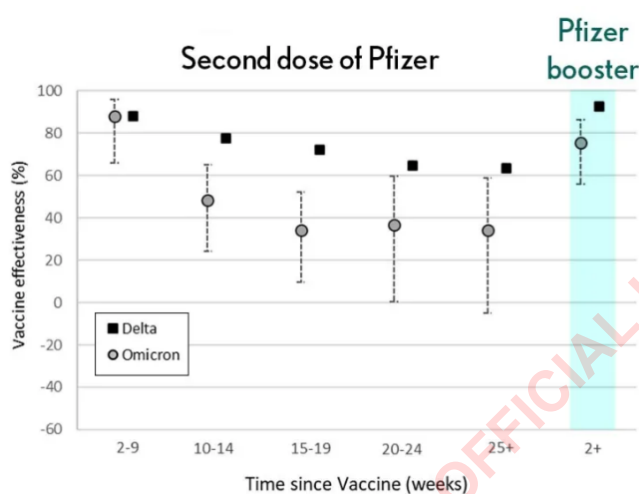
### Context

2. On 17 December 2021, Vaccine Ministers agreed to an oral item on the Director-General of Health's proposal to reduce the approved COVID-19 booster dose interval from six months to four months for Cabinet to consider on 20 December 2021.
3. Cabinet agreed to reduce the booster interval to four months, as per our advice, commencing 5 January 2022.
4. Evidence suggests that immunity gained from COVID-19 vaccinations begins to wane from at least four months, and potentially earlier.
5. The COVID-19 Vaccination and Immunisation Programme (the Programme) has recommended reducing the dosing interval for booster doses as the highly transmissible Omicron variant is posing a greater public health risk and becoming widespread internationally.
6. Delivering booster doses at a shorter interval has legal, operational and technical implications and risks that are outlined in this memo. The memo further outlines the implementation and delivery plan to deliver boosters at a shorter dosing interval.
7. This memo has been prepared in consultation with Health Legal and Crown Law. The legal advice contained in this memo is protected by legal professional privilege.

**The emergence of the Omicron variant and international response indicates the need to shorten the booster dosing interval**

8. Evidence of COVID-19 vaccine effectiveness against the Omicron variant and the need for booster doses is still emerging. Current data indicating that boosters increase effectiveness is looking promising. In a recent UK study<sup>1</sup> (yet to be peer reviewed), the effectiveness of two doses of the Pfizer or AstraZeneca vaccines in preventing COVID-19 symptoms from Omicron waned after four months to about 40 percent. There was a lesser decline in the effectiveness of the Pfizer vaccine against Delta, but vaccine effectiveness still waned to around 60 percent after six months
9. The same study has shown a booster dose of the Pfizer vaccine substantially raised vaccine effectiveness to around 80 percent against Omicron (over 90 percent for Delta).

*Figure 1: Vaccine effectiveness against Omicron variant*



10. Other preliminary studies from South Africa<sup>2</sup>, Israel<sup>3</sup>, and France<sup>4</sup> also show declines in the ability of antibodies to neutralise the Omicron variant in people vaccinated with two doses of the Pfizer vaccine. A US study reported this month<sup>5</sup> shows protection against COVID-19 infection begins to decline three months after the second vaccine dose and accelerates after four months.
11. However, these studies also indicate a booster dose of the COVID-19 vaccines significantly increase antibody levels and should be effective against the Omicron variant.
12. These studies are preliminary and further research is required, but they do provide important initial evidence in a rapidly evolving situation with the Omicron variant spreading around the world. It is now becoming the dominant strain in the UK as it

<sup>1</sup> <https://khub.net/documents/135939561/430986542/Effectiveness+of+COVID-19+vaccines+against+Omicron+variant+of+concern.pdf/f423c9f4-91cb-0274-c8c5-70e8fad50074>  
<sup>2</sup> <https://www.medrxiv.org/content/10.1101/2021.12.08.21267417v3>  
<sup>3</sup> <https://www.medrxiv.org/content/10.1101/2021.12.13.21267670v1>  
<sup>4</sup> <https://www.biorxiv.org/content/10.1101/2021.12.14.472630v1>  
<sup>5</sup> [https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2787183?utm\\_campaign=articlePDF&utm\\_medium=articlePDFlink&utm\\_source=articlePDF&utm\\_content=jamanetworkopen.2021.38975](https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2787183?utm_campaign=articlePDF&utm_medium=articlePDFlink&utm_source=articlePDF&utm_content=jamanetworkopen.2021.38975)

spreads across regions, with four out of five cases tested in London last week being Omicron.

13. Other studies have previously confirmed the safety of booster doses<sup>6</sup>, however most have been based on a six month plus interval after the second dose. While there is limited data on safety issues associated with shortened booster dose intervals, other countries have moved quickly to roll-out booster doses earlier, for example the UK are now recommending boosters after three months, and Australia after five months. There is currently no evidence to suggest the safety of booster doses is materially altered by shortening the dose interval. We will continue to monitor international evidence regarding safety as it emerges.

## **The impacts of bringing forward COVID-19 booster eligibility as a result of the Omicron variant**

14. The Programme has provided Vaccine Ministers with initial advice on the supply and operational impacts of a potential change in timing for booster eligibility. The advice considered emerging evidence on new variants and the impact of waning vaccination protection beyond six months.
15. Based on science advice, supply and operational impacts, the Programme recommended reducing the dosing interval between primary course and boosters to five months starting from 17 January 2022 (HR20212751 refers). This recommendation was in line with the recommendation from the COVID-19 Vaccination and Immunisation Technical Advisory Group (CV TAG) that a Pfizer booster dose should be offered to adults 18 years or over, five months after the completion of the primary vaccination course.
16. With the emergence of the highly infectious Omicron variant and the importance of ensuring a high proportion of people have their booster dose ahead of winter 2022, you have considered the advice from the CV TAG and proposed that the interval between the completion of the primary course and the booster dose be reduced from six to four months, to maintain the high level of protection. This dosing interval has also been supported by Cabinet.
17. Reducing the interval to four months will help ensure that Māori, a significant proportion of whom have been vaccinated only in the past two months, can receive a booster before the winter months.
18. The Programme is preparing a plan to ensure it can deliver the potential booster programme with a four-month dosing interval.

### *Supply considerations to note with bringing eligibility forward*

19. The Pfizer COVID-19 vaccine is the Programme's primary vaccine. At present, there is a potential supply gap in planned delivery schedules from Pfizer to meet demand for the current six-month dosing interval. The Programme has been working to resolve this, but any further acceleration of the booster rollout will exacerbate this supply pressure.
20. To ensure we have sufficient supply of the Pfizer vaccine to deliver on the potential booster programme at a four-month interval, we are progressing two key options:

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<sup>6</sup> For example see: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)02717-3/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02717-3/fulltext)

- a. accelerating the delivery of the contracted vaccine supply with Pfizer, and
  - b. purchasing additional doses of the Pfizer vaccine.
21. If we are unsuccessful in securing additional volumes of the Pfizer vaccine, further options will be considered such as:
- a. the use of other vaccines for boosters, or
  - b. an option to purchase other available vaccines
22. You will receive further advice on the options to ensure we have access to sufficient volumes of vaccine to deliver the booster programme, early in the new year.
23. Current "Book my Vaccine" data indicates that 62,000 doses have been scheduled, of which the majority are for booster doses. There are 853 first doses scheduled (of which 232 are doses for AstraZeneca) and 13,613 second doses scheduled (of which 1,745 are for AstraZeneca).
24. There are sufficient vaccines available for the summer period based on current eligibility status across New Zealand. However, due scheduling because of the summer break vaccinator capacity will be reduced from the pre-summer period baseline.
25. The expected number of those currently eligible for the six months booster doses is 480,000 by 5 January 2022. Should the dosing interval be shortened to four months then we expect 1.19 million would be eligible for their booster dose by 5 January 2022.

### **Legal options for shorter booster dose interval (*legally privileged*)**

9(2)(h)

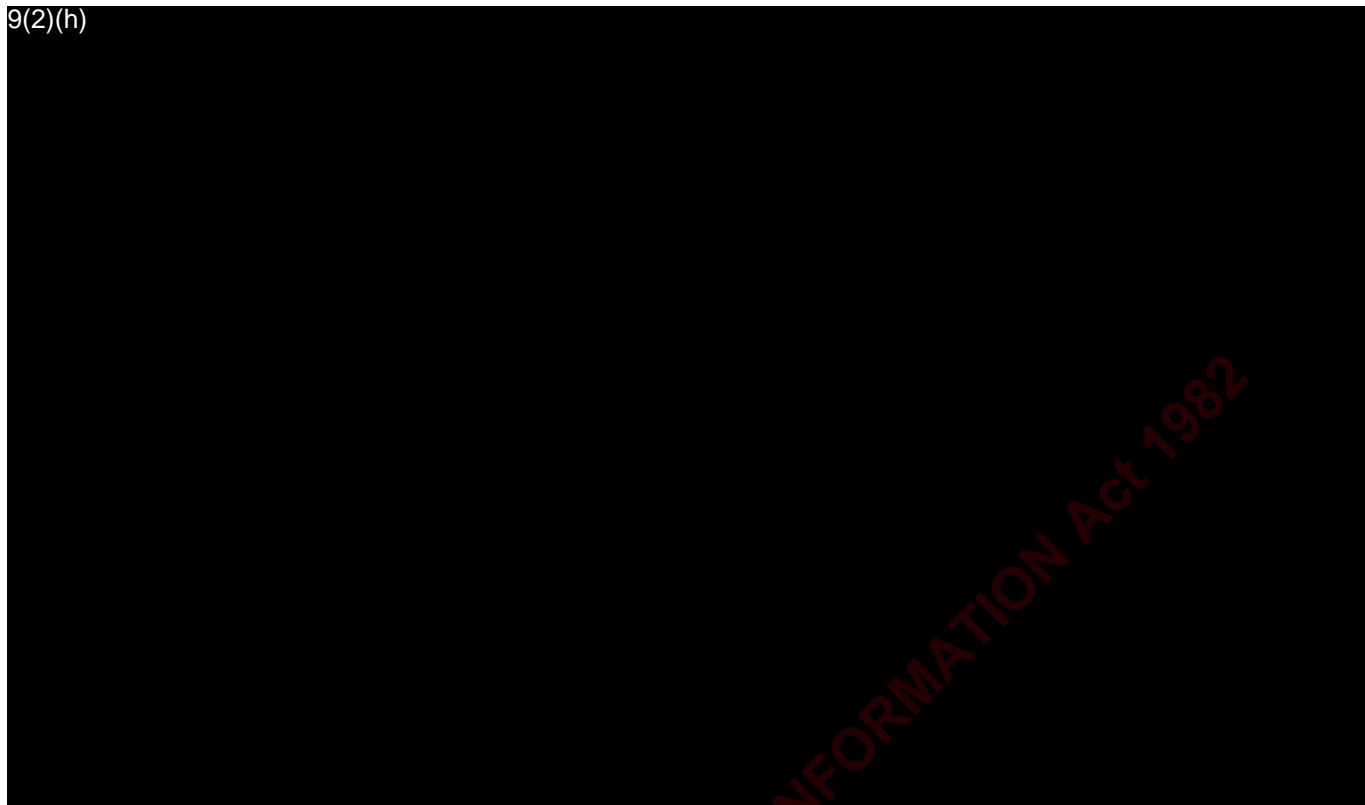
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9(2)(h)



### Operationalising and implementing a shorter booster dosing interval

55. We understand that Minister's want this proposal to be implemented by 5 January 2022. Further operational guidance will be needed to allow for implementation over the summer holiday break and the complexities involved. The Programme is operationally capable of delivering the required COVID-19 booster doses at the reduced dosing intervals of four months, subject to supply.
56. Rapid communications and engagement with District Health Boards (DHBs), vaccination providers, primary care (general practice and pharmacy) as well as with key workforces (border/MIQ/health and disability sector) will be needed. Consideration needs to be given to other immunisation priorities across DHBs and providers as the overall capacity could exceed what has been previously utilised.
57. Providers have demonstrated capacity to safely and quickly scale operations to meet operational demand, as we saw during the emergence of the Delta variant in New Zealand. Existing workforce, processes, systems and logistics across the sector can be leveraged in order to deliver the COVID-19 booster programme.
58. Further operational implications require updating the Immunisation Advisory Centre (IMAC), operating guidelines, the website, and Whakarongorau and Health Pathways information. Safe delivery of immunisations will continue to be the priority throughout this campaign.
59. We recommend allowing for booster doses to be available within a four-month interval to commence "walk-ins" for COVID-19 booster doses from 5 January 2022. The potential roll-out of the COVID-19 vaccination for children aged 5 to 11 years old will also need to be taken into consideration to allow for the whānau based approach to delivering vaccinations and boosters. Additionally, the efficiency impact of concomitant



administration with other vaccines is not yet fully understood but does provide an additional opportunity.

60. There are other technical and operational implications that the Programme will work to manage, such as changes to the booking system.

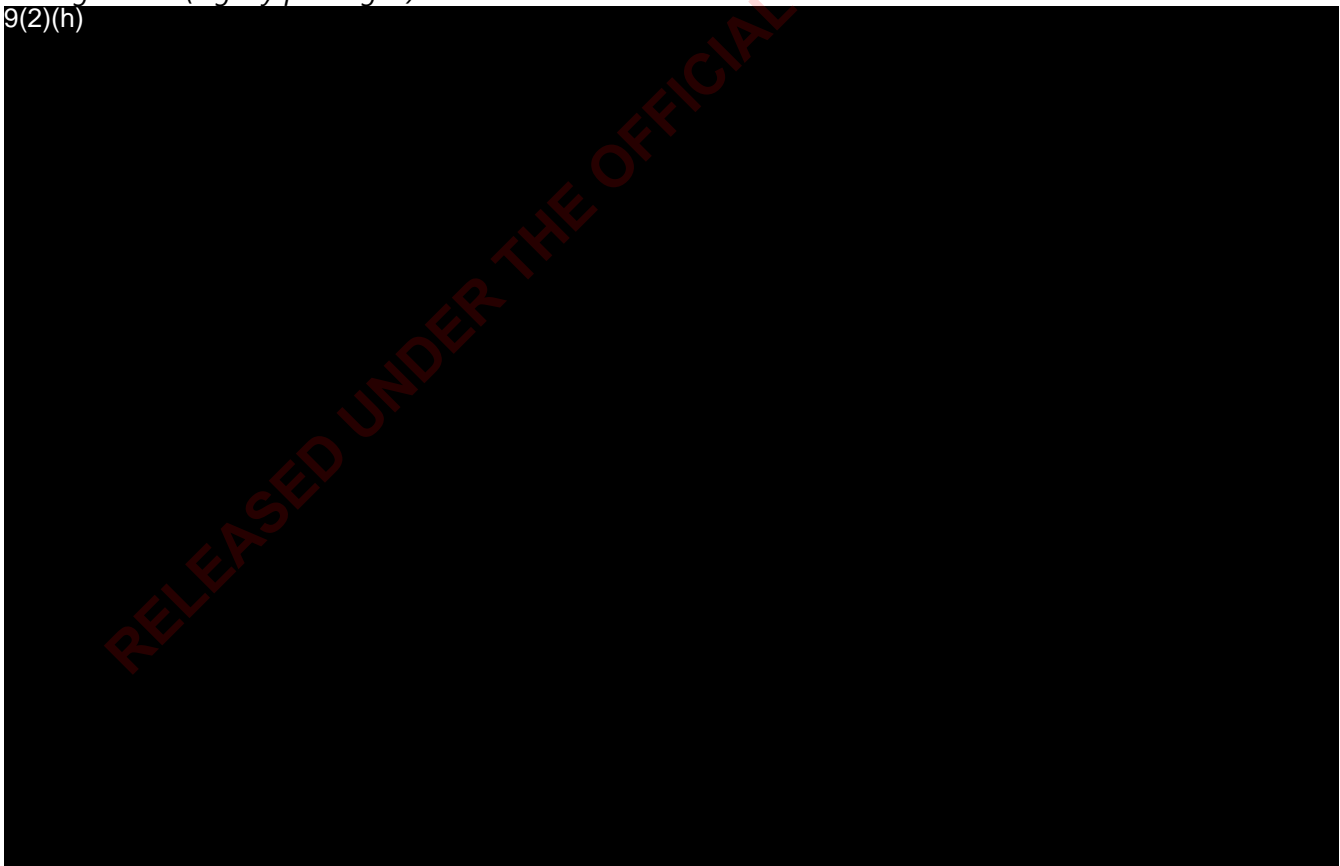
### Communications strategy

61. A clear communication strategy is needed to efficiently delivery the booster doses at a shorter interval. The communication should indicate the availability of boosters to all eligible at a shorter four-month dosing interval from 5 January 2022.
62. Although Pfizer's submission on booster doses was based on a six-month interval, communications should provide that the public will be allowed to receive the booster with a four-month dose interval. This follows similar guidance issued on the three-week interval which was communicated for the primary course.
63. The rationale for the communications messaging should focus on the delivery of booster being in line with the management of the new Omicron variant. This may also assist in driving demand for first and second doses in areas which currently still have low vaccination rates.

### Risks and issues

*Legal risks (legally privileged)*

9(2)(h)



### Next steps

68. Currently a booster dose is not required to be 'fully vaccinated' or to get a vaccine pass or certificate. The definition of 'fully vaccinated' will need to be confirmed and work is underway to provide this advice in January 2022.

69. A paper is being prepared for the Minister for COVID-19 Response on mandating booster doses for MIF, MIQ, border workers, and workers in the health and disability sector. The decision on booster dosing intervals will inform the COVID-19 Public health Response (Vaccination) Order 2021 amendments.

## Recommendations

It is recommended that you:

- a) **Note** the waning immunity after six months of COVID-19 vaccinations and that the Omicron variant is taking hold internationally
- b) **Note** that many New Zealanders are currently eligible for their booster around the start of winter 2022
- c) **Note** that this has led to a proposal of changing the booster vaccine interval from six months to four months
- d) **Agree** that the COVID-19 vaccine booster dose interval be shortened to a four month interval in light of the emergence of the Omicron variant **Yes**

9(2)(h)

- h) **Note** that there are operational and technical issues that will be managed
- i) **Agree** that the availability of booster doses at a four month interval commence on 5 January 2022 **Yes**

- j) **Note** that a separate paper is being prepared for the Minister for COVID-19 Response on mandating booster doses for MIF, MIQ, and border workers.
- k) **Agree** that the booster dosing intervals for the COVID-19 Public Health Response (Vaccination) Order 2021 amendments remain at a six month dosing interval until such time the relevant legislative amendments have been affected to allow for a four-month interval **Yes**
- l) **Agree** to provide advice to the Minister of Health and the Minister for COVID-19 Response on Option five above **Yes**



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

21/12/2021

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