In Confidence

Office of the Minister for COVID-19 Response

Office of the Minister of Health

Cabinet Legislation Committee

Medicines Amendment Bill: Approval for Introduction

Proposal

1 This paper seeks:

1.1 Cabinet approval for amendments to the Medicines Act to enable the Director-General of Health to authorise the administration of a consented COVID-19 vaccine otherwise than in accordance with the approved data sheet for that vaccine. It is anticipated that this power may be utilised to enable "off-label" fourth doses of the Pfizer/BioNTech COVID-19 vaccine (Pfizer vaccine) to be administered without a prescription. This will not preclude further ability to enable other COVID-19 vaccines via the usual consenting process under the Act.

1.2 Approval for the introduction of the Medicines Amendment Bill (the Bill) and its progression to move through all stages of the House without urgency, subject to the approval of the business committee.

Policy

2 On 16 May 2022 Vaccine Ministers agreed to progress an amendment to the Medicines Act 1981 (the Act) to provide for the broader roll out of fourth doses of the Pfizer vaccine beyond administration on prescription via General Practitioners (GPs).

3 As the pandemic continues, there may be additional COVID-19 vaccine doses that people (or specific groups) may require, beyond fourth doses. Therefore, Vaccine Ministers agreed to an amendment that would not only provide a basis for administration of a fourth dose, but would also provide:

3.1 a long term solution for the provision of the third (booster) dose at the three month dose interval;

3.2 for future doses of COVID-19 vaccines to be administered if emerging scientific evidence demonstrates this is required.

4 The Bill creates a provision 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. The Director-General must be satisfied that doing so is an appropriate measure to manage the risks associated with an outbreak or spread of COVID-19 and having regard to the likely therapeutic value of the proposed administration of the COVID-19 vaccine and its risk (if any) of injuriously affecting the health of any person. The Director-General will only be able to use this power in relation to COVID-19 vaccines that have consent or provisional consent under section 20 or 23 of the Act.

5 It provides a permanent and future proofed solution to meet future COVID-19 challenges. These may include further vaccine doses, changes to dose intervals, or targeting different population groups in response to future variants, where scientific evidence supports this.

6 Currently the Epidemic Preparedness (COVID-19 – Medicines Act 1981) Immediate Modification Order (IMO) enables the administration of a booster dose of the Pfizer vaccine at a reduce interval of three months (rather than six months as is recommended in the approved data sheet). The IMO is a temporary measure, and once the Epidemic Preparedness Notice expires or is revoked, the IMO will automatically be revoked. It is intended that the IMO will be revoked with the enactment of the Bill and that the reduction of the third (booster) dose interval will be authorised with the new provision.

Rationale for the Amendment Bill

7 On 16 May 2022 Vaccine Ministers agreed to progress the amendment to the Act as indicated above. On 17 May 2022 the Attorney General provided authorisation to issue drafting instructions to the Parliamentary Counsel Office for the proposed amendment.

8 These actions followed the advice to Vaccine Ministers in early May 2022 that set out the policy options to enable the broad roll out of fourth doses of the Pfizer vaccine.

9 In April 2022 the COVID-19 Vaccine Technical Advisory Group (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.

10 The following groups are recommended by CV TAG to receive a fourth dose, at an interval of six months since their previous dose:

10.1 people aged 65 years and over

10.2 Māori and Pacific peoples aged 50 years and over

10.3 residents of aged care and disability care facilities

10.4 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).

11 The Pfizer vaccine is approved by Medsafe based on two primary vaccine doses at least 21 days apart and, for people aged 18 years and older, a third (booster) dose to be given at least six months after the second primary dose (reduced to an interval of 3 months via the current IMO).

12 Engagement with Pfizer New Zealand highlighted they do not intend to apply for consent for fourth doses in New Zealand or in other jurisdictions.

13 As fourth doses are not contemplated in the approved data sheet for the Pfizer vaccine, a fourth dose is considered an "off-label" use and is only available on prescription via General Practitioners (GPs). 'Off-label' vaccination by prescription raises significant equity and access issues as well as operational challenges.

14 Therefore Vaccine Ministers agreed to progress an amendment to the Act to ensure fourth doses are more accessible to the recommended groups and can be rapidly rolled out as we head into the winter months, which will bring the increased risk of COVID-19 infection, alongside other winter respiratory illnesses.

15 The Medicines Amendment Bill will allow for the broader roll out of additional consented COVID-19 vaccine doses to be widely available at COVID-19 vaccination sites, including local pharmacies and via Māori and Pacific Health providers.

16 Despite the proposed changes through the Medicines Amendment Bill, authorised prescribers such as General Practitioners (GPs) will still be able to prescribe an "off-label" vaccination under section 25 of the Medicines Act 1981, following a conversation about the risks and benefits and obtaining the patients' informed consent.

17 We now seek approval for the policy intent as laid out above to address the equity and access issues, alongside the introduction of the Bill.

Omicron and the impact of fourth doses

18 International evidence has shown immunity after third doses wanes at a similar rate as it does after completion of a primary course of COVID-19 vaccination, and waning occurs more quickly in the groups identified by CV TAG. This means some people in the recommended groups will have already passed four to five months since their third (booster) dose and their immunity may have already waned significantly.

19 Additionally, data from the Omicron outbreak in New Zealand to date shows that hospitalisations and deaths have been high among Māori and Pacific peoples, the elderly and all of those in the recommended groups.

20 CV TAG advised that Māori and Pacific peoples have been disproportionately affected in the current outbreak 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 to non-Māori/non-Pacific peoples, and Māori 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.

21 Similar concerns in these high risk groups regarding winter respiratory illnesses such as influenza led to Cabinet agreeing (as part of the Government's COVID-19 response measures) to wider eligibility criteria for free influenza vaccinations, which includes targeting Māori and Pacific peoples.

22 A number of other countries (see Appendix 1) have been delivering fourth doses to their elderly and vulnerable populations, including for example in Australia to Aboriginal and Torres Strait Islander people aged over 50. At this early stage there is limited data and evidence available on the impact of fourth doses. 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 to4 times less likely). The study showed those aged 60-100 years old who have received a fourth dose of the Pfizer vaccine, had a 78 percent lower mortality rate from COVID-19 than those who only received a third dose.

23 CV TAG's early April advice also considered the safety profile of fourth doses of the Pfizer vaccine. Again, whilst data is limited at this stage, 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.

24 Whilst CV TAG have recommended the six month dose interval for fourth doses, for those recently infected with COVID-19, the standard advice to wait three months after infection before receiving further COVID-19 vaccinations will apply.

25 Delivery of fourth doses has the potential to significantly reduce the number of hospitalisations and deaths in the recommended groups, and to help manage the additional pressure on the health system during the winter season.

26 High uptake will be the key to achieving this. Easy and equitable access, alongside trust and confidence in the vaccine and the system are crucial to achieve high uptake. Therefore, providing for fourth doses to be widely available at COVID-19 vaccination sites, (including local pharmacies and via Māori and Pacific Health providers) is critical. Implementation will be supported by clear communications to providers regarding the targeted groups.

27 Of the approximately 834,000 people in the recommended groups, some will have passed the recommended six months dose interval in May, but the bulk will become due for a fourth dose in June and July 2022. The Bill will facilitate

the rapid roll out of fourth doses to be widely available at vaccination sites and able to be administered by all vaccinators. There is also sufficient Pfizer vaccine in stock with current supply sitting at around two million doses.

28 The Director-General has provided advice and we support the recommendation to introduce this Bill to provide for the lawful administration of fourth doses of the Pfizer vaccine to the recommended groups, and to provide a permanent and future proofed solution for any further COVID-19 vaccine dose requirements.

Amendment to the Medicines Act 1981

29 The Bill creates a new provision that enables the Director General to authorise consented COVID-19 vaccines to be procured and administered for an "off-label" use without a prescription, if the Director General is satisfied that this is an appropriate measure in order to manage the risks associated with an outbreak or spread of COVID-19. The Director General must have regard to the likely therapeutic value of the proposed administration of the COVID-19 vaccine and the risk (if any) of that proposed administration injuriously affecting the health of any person. 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.

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

30.1 to whom the vaccine may be administered:

30.2 the recommended dosage and frequency of doses:

30.3 the recommended manner of administration:

30.4 the circumstances in which the vaccine may be administered.

31 The practical effect of the amendment is that the Director-General will be able to authorise the use of a consented COVID-19 vaccine otherwise than in accordance with the approved data sheet for that vaccine.

32 Any person or class of persons permitted by the Act or by regulations made under the Act to administer a COVID-19 vaccine may administer a COVID-19 vaccine in accordance with a notice made by the Director General.

33 All prescription and restricted medicines must have a data sheet. The data sheet contains recommendations relating to the safe and effective use of a COVID-19 vaccine. The data sheet is approved by the Minister of Health (or their delegate) at the time a medicine is given consent or provisional consent. Any subsequent changes to the data sheet can only be instigated by the importer or manufacturer of the medicine and must be approved by the Director-General (or their delegate).

34 The data sheet for the Pfizer vaccine recommends a primary course of two doses at least 21 days apart and, for people aged 16 years and older, a third

(booster) dose to be given at least six months after the second primary dose. A fourth dose is not contemplated in the approved data sheet for the Pfizer vaccine. With this amendment to the Act, the Director-General will be able to authorise the administration of a fourth dose of the Pfizer vaccine without any change to the data sheet (if he is satisfied that doing so is an appropriate measure in order to manage the risks associated with an outbreak or spread of a COVID-19 outbreak).

35 The Director-General's power in this new provision is not limited to authorising fourth doses of the Pfizer vaccine. The Director-General will have the power to authorise the administration of consented COVID-19 vaccines for specified groups, dose intervals or numbers of doses other than those specified in the data sheet.

36 As set out above, the Director General will only be able to exercise this new power in relation to a COVID-19 vaccine that has consent or provisional consent under sections 20 or 23 of the Act, and if he is satisfied it is an appropriate measure to manage the risks associated with the outbreak or spread of COVID-19.

37 Additionally, the Director General must have regard to the therapeutic value of the off-label use weighed against the risks of that use to the health of any person.

38 Ministers will continue to receive advice to support any further decisions relating to the COVID-19 immunisation programme. The Director-General's use of the new provision will be undertaken alongside the usual decision to vaccinate process, allowing Ministers to consider the COVID-19 vaccination options based on the latest scientific and technical advice.

39 The Therapeutic Products Bill will provide regulatory mechanisms to ensure such issues may be more easily dealt with in the future.

Impact Analysis

40 The Treasury's Regulatory Impact Analysis team has determined that the proposal for the Bill to enable a fourth dose of COVID-19 vaccinations over the winter period is exempt from the requirement to provide a full Regulatory Impact Statement (RIS).

41 The exemption is on the grounds that the proposal is intended to mitigate the short-term impacts of the COVID-19 emergency and it is required urgently to be effective. However, the exemption is conditional on the Ministry of Health completing a streamlined RIS, which has not been formally quality assured as per the usual RIA requirements, given the time constraints.

42 The streamlined RIS is attached as Appendix Two.

Compliance

43 The Bill complies with:

43.1 the principles of the Treaty of Waitangi;

43.2 the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 or the Human Rights Act 1993;

43.3 the principles and guidelines set out in the Privacy Act 2020;

43.4 relevant international standards and obligations;

43.5 the Legislation Guidelines (2018 edition), which are maintained by the Legislation Design and Advisory Committee.

Binding on the Crown

44 The Medicines Act 1981 is binding on the Crown.

Creating new agencies or amending law relating to existing agencies

45 No new agency is created by the Bill.

46 The Bill does not amend the law relating to existing agencies.

Allocation of decision making powers

47 The draft legislation does not involve the allocation of decision making powers between the executive, the courts, and tribunals.

Associated regulations

48 No associated regulations will be required.

Other instruments

49 The Bill includes a provision empowering the Director-General of Health to make notices of authorisation. These notices are legislative instruments and disallowable instruments.

Definition of Minister/department

50 The Bill does not contain a definition of Minister, department (or equivalent government agency), or chief executive of a department (or equivalent position).

Commencement of legislation

51 The Bill will come into force on the day after the date of Royal assent.

Parliamentary stages

52 The Bill is intended to be introduced 7 June 2022.

53 The Acting Leader of the House is seeking approval from all parties at Business Committee on Tuesday 31 May for the Bill to move through all stages without urgency, and if not agreed, then under urgency.

Publicity

54 Once the Bill is enacted the amended Act will be made available on the New Zealand legislation website and notified in the New Zealand Gazette.

55 It is anticipated that the new provision may be utilised to enable fourth doses of the Pfizer vaccine to be administered without a prescription but that this will be a decision for the Director-General once the amendment comes into force. Any decisions the Director-General makes in relation to the roll out of fourth doses to the recommended groups will be made public.

Proactive release

56 We intend to proactively release this paper, subject to any redactions, after decisions have been made by Cabinet.

Consultation

57 Limited consultation on this paper has been carried out with the Crown Law Office, the Treasury, Ministry of Justice, the Parliamentary Counsel Office and the Department of Prime Minister and Cabinet.

58 Other political parties have been consulted on the provision of fourth doses and have been informed that an amendment to the Medicines Act 1981 will be progressed.

Recommendations

The Minister of Health and the Associate Minister of Health recommend that the Committee:

1 **Note** the Bill amends the Medicines Act 1981 to enable the Director-General 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 an outbreak or spread of COVID-19.

2 **Note** it is anticipated that the new provision may be utilised to enable fourth doses of the Pfizer/BioNTech COVID-19 vaccine (Pfizer vaccine) to be administered without a prescription but that this will be a decision for the Director-General once the amendment comes into force. This will not preclude further ability to enable other COVID-19 vaccines via the usual consenting process under the Act.

3 **Note** that the Bill gives effect to decisions made by Vaccine Ministers.

4 **Note** this change does not affect the ability for prescribers to continue to be able to give "off-label" doses of COVID-19 vaccines in individual circumstances.

5 **Note** the intention that the Medicines Amendment Bill be introduced 7 June 2022 and not be referred to a Select Committee

6 **Note** that the Acting Leader of the House is seeking approval from all parties at Business Committee on 31 May for the Bill to move through all stages without urgency; if not agreed, it will be passed under urgency.

7 **Note** that the amendments to the Medicines Act 1981 will come into force on the day after Royal Assent.

8 **Note** that once the Medicines Amendment Bill comes into the force the current Epidemic Preparedness (COVID-19 – Medicines Act 1981) Immediate Modification Order will be revoked.

9 **Approve** the policy behind this Bill as set out in this paper to address the equity and access issues to provide fourth COVID-19 doses, noting the amendment to the Act will provide an enduring and secure legal basis for the provision of third and fourth doses, and any further COVID-19 vaccine doses that may be required in the future.

10 **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.

11 **Authorise** the introduction of the Medicines Amendment Bill.

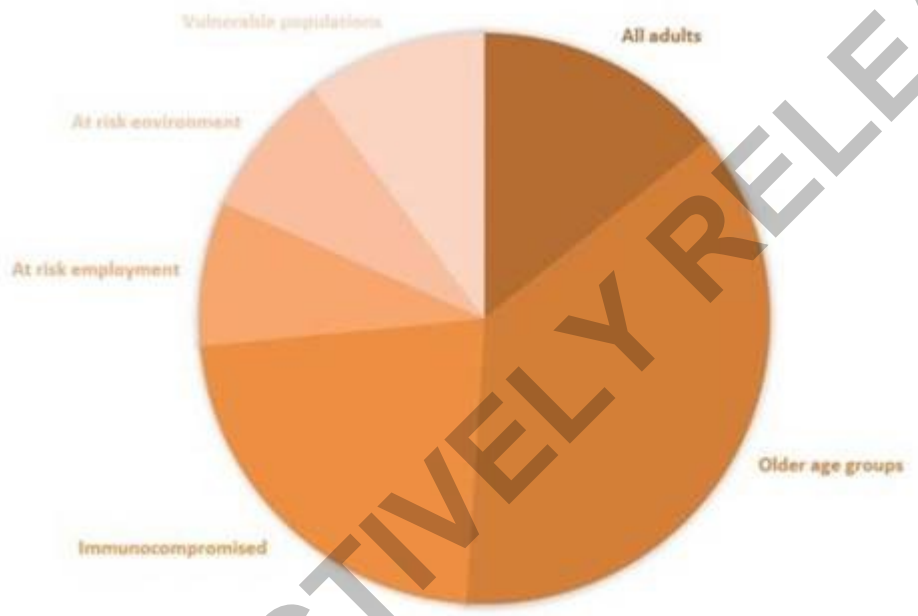
Authorised for lodgement

Hon Dr Ayesha Verrall
Associate Minister for COVID-19 Response

Hon Andrew Little
Minister of Health

Appendix 1:
Updated global COVID-19 vaccination fourth dose situation (provided by MFAT)

- There has been **no change in total number of jurisdictions** (36) that have rolled out fourth doses
- **Uruguay** has now become the seventh jurisdiction to rollout **fourth doses to all adults** (in addition to the six jurisdictions noted in previous report: **Chile, El Salvador, Hungary, Israel, Laos** and **Mongolia**)
- There has been some expansion of priority groups eligible for fourth doses in some jurisdictions (for example, US now recommends fourth doses for immunocompromised, in addition to over 50s). However, overall trend is unchanged with the **majority of jurisdictions prioritising older age groups, immunocompromised and high risk groups** (see chart below).



Also below some recent updates:

Australia (April)
Fourth dose for severely immunocompromised people over 16, adults aged 65 and over, First Nations Australians aged over 50, and residents in aged care and disability settings over 12 years old (Pfizer-BioNTech).

Taiwan 15 May
Recent changes include a second booster shot (fourth dose) is recommended five months after first booster (third dose) for people aged 65 or older, residents of long-term care facilities, and individuals aged 18 or above who are immuno-compromised.

Singapore 1 May)
The Government has made second booster doses available to adults aged 60 and over, and are actively encouraging its uptake among those aged 80+ and with co-morbidities.

United States: 20 May

- Second boosters were approved for older adults at the end of March but, to date, only a quarter have received the additional shot. The CDC is now doubling down on efforts to get more people jabbed for a fourth time.
- In a sign of growing concern among US health officials about the spread of new coronavirus infections, the Centres for Disease Control and Prevention is now saying that all people 50 or older should get a second booster shot if at least four months have passed since their first booster dose.
- Previously, the agency said those 50 and older had the option of the additional shot but only encouraged people older than 65 or with underlying medical conditions to get it.
- The new guidance, issued in a statement on the CDC's website on Thursday (May 19), also extends to anyone 12 and older with certain immune deficiencies.
- The CDC said it was changing its advice because of a steady rise in infections over the past month, coupled with "a steep and substantial increase in hospitalisations for older Americans." see: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html

Canada: 20 May

- **Manitoba** Province is expanding the eligibility for fourth shots of the COVID-19 vaccine to:
  - anyone over the age of 50.
  - Previously, anyone aged 70 and over was eligible. First Nations, Inuit and Métis people aged 30 or older are also now eligible, regardless of where they live.
  - As well, anyone aged 18 to 49 who are moderately to severely immunocompromised can receive their fourth dose of the vaccine.
  - Personal care home residents and elderly people living in congregate settings are also eligible.
- The province also announced that it would shorten the intervals between booster doses. First booster shots can be given four months after someone's initial two vaccines. The second booster can also now be given four months after the first booster shot.
- People can get a booster shot three months after a COVID-19 infection.
- **Nunavut**: Nunavummiut 18 and over, who have gotten their third dose four and a half months ago and over, can now get their fourth dose following an announcement by Nunavut's department of health on 24 May Fourth Covid-19 vaccine now available for Nunavummiut 18 and over (nnsl.com)

Sweden: 24 May

- Sweden is recommending a **fifth COVID-19 vaccine dose** for people with an increased risk of becoming seriously ill, including pregnant women and anyone aged 65 and over.

Appendix 2

Regulatory Impact Statement

Regulatory Impact Statement: Amending the Medicines Act 1981 to allow for off-label use of COVID-19 vaccinations

Coversheet

Purpose of Document	
Decision sought:	*Analysis to support the introduction of an amendment of the Medicines Act 1981 to allow for off label use of COVID-19 vaccinations*
Advising agencies:	*Ministry of Health*
Proposing Ministers:	*Hon Chris Hipkins, Minister for COVID-19 Response, Hon Andrew Little, Minister of Health*
Date finalised:	*27 May 2022*

Problem Definition

Currently, the Medicines Act 1981 does not allow the off-label use of COVID-19 vaccinations without a prescription, as the fourth dose is not approved by Medsafe. When large cohorts are recommended to have further vaccinations within a short timeframe, this can be challenging to implement, including raising significant equity issues. Previously used mechanisms to allow for off-label use (such as reducing the dose period between the second and booster doses from 6 months to 3 months) are no longer appropriate.

Executive Summary

The COVID-19 Technical Advisory Group recommended that people aged over 65 years, Māori and Pacific peoples aged over 50 years, people in aged residential care, and the severely immunocompromised should receive a fourth dose of Cominarty COVID-19 vaccine before winter 2022.

Currently a fourth dose is considered “off-label” as a fourth dose of Comirnaty has not been approved by Medsafe, due to the absence of an application from Pfizer. The only way for the approximately 834,000 at-risk people to access the fourth dose is on prescription via a General Practitioner (GP) on an individualised basis. This raises concerns over the ability to maximise uptake of the vaccine in these groups, due to equity of access, cost and timeliness of implementation.

An alternative to individuals seeking a prescription is to amend the Medicines Act 1981 to include the ability for the Director-General to make decisions regarding the administration and supply of COVID-19 vaccines in the absence of consent under the Act. This would ensure that the Ministry of Health can react quickly to any necessary changes to the vaccine dose or frequency as the pandemic develops. Whilst being outside of the established Medsafe regulations of medicines process, it would provide an enduring and sound legal basis for the provision of any further doses of COVID-19 vaccines, including fourth doses.

Limitations and Constraints on Analysis

This proposal was developed under time pressure due to the approach of winter, when it is expected that the continuing COVID-19 pandemic could increase due to people being indoors and with the increased risk of influenza and other respiratory illnesses.

Additionally, as the Omicron outbreak continues in New Zealand, immunity gained from the primary course and 'booster' doses of COVID-19 vaccines in the targeted groups is waning rapidly.

No application is expected from Pfizer for their Cominarty vaccine to receive approval as a fourth dose, and therefore normal regulatory approval processes are unable to be utilised.

No public consultation was undertaken with this proposal due to the time frame available. However, strong support for a fourth dose is considered likely as this has been consistently raised in the media and by members of the public to the Ministry of Health.

Responsible Manager(s) (completed by relevant manager)
Caroline Flora *Associate Deputy Director-General* *System Strategy and Policy* *Ministry of Health* *27 May 2022*

Quality Assurance (completed by QA panel)	
Reviewing Agency:	
Panel Assessment & Comment:	N/A – waiver obtained from QA assessment

Section 1: Diagnosing the policy problem

What is the context behind the policy problem and how is the status quo expected to develop?

International evidence has shown that immunity gained after a third COVID-19 dose wanes at a similar rate as after completion of a primary course of COVID-19 vaccination, and it wanes more quickly in the elderly and the immunocompromised.

In New Zealand, these groups and Māori and Pacific people are at higher risk of severe outcomes and many received their third COVID-19 vaccination (booster) in December 2021 and January 2022 when they became available. This means some people in these groups will have already passed four months since their booster dose and their immunity may have already waned significantly.

The Omicron outbreak in New Zealand appeared to be on the decline until recently, but case numbers have begun climbing again.. Notably, whilst case numbers in age groups under 50 years old continue to decline, case numbers in the older age groups have been increasing again. Hospitalisations and deaths in New Zealand during the Omicron outbreak have been high among the identified groups. For example, most people reportedly dying *with* COVID-19 have been in the older age groups (approximately 89 percent).

On the basis of this information, the COVID-19 Technical Advisory Group (CV-TAG) have recommended that a fourth (and in some cases fifth) dose of Comirnaty (the Pfizer vaccine) should be given to the following at risk groups:

- people aged 65 years and over,
- Māori and Pacific peoples aged 50 years and over,
- residents of aged care and disability care facilities and
- 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).

These groups cover approximately 834,000 people.

Currently, a fourth dose of Comirnaty has not been consented under the Medicines Act and would therefore be considered an “off-label” administration of the vaccine. That means it can only be accessed on prescription for an individual from an authorised prescriber. In many cases, an authorised prescriber will be a General Practitioner (GP).

Pfizer have not applied for approval of fourth doses in NZ (or other countries) and consider it best for local jurisdictions to find their own approval solutions.

What is the policy problem or opportunity?

At present the only way to implement the CV-TAG recommendation is by way of an off-label approach, requiring a prescription to be issued by an authorised prescriber. This would require over 800,000 New Zealanders to access a prescription in the next few months to ensure that their immunity to COVID-19 was maximised over the winter months. This poses siginificant access and equity issues.

International evidence

A number of other countries have been delivering fourth doses to their elderly and vulnerable populations, but at this early stage there is limited data and evidence available on the impact of fourth doses.

Preliminary data (and an early study) has shown that the risk of infection and severe illness appears to significantly reduce after a fourth dose (approximately 2-4 times less likely), and those aged 60-100 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.

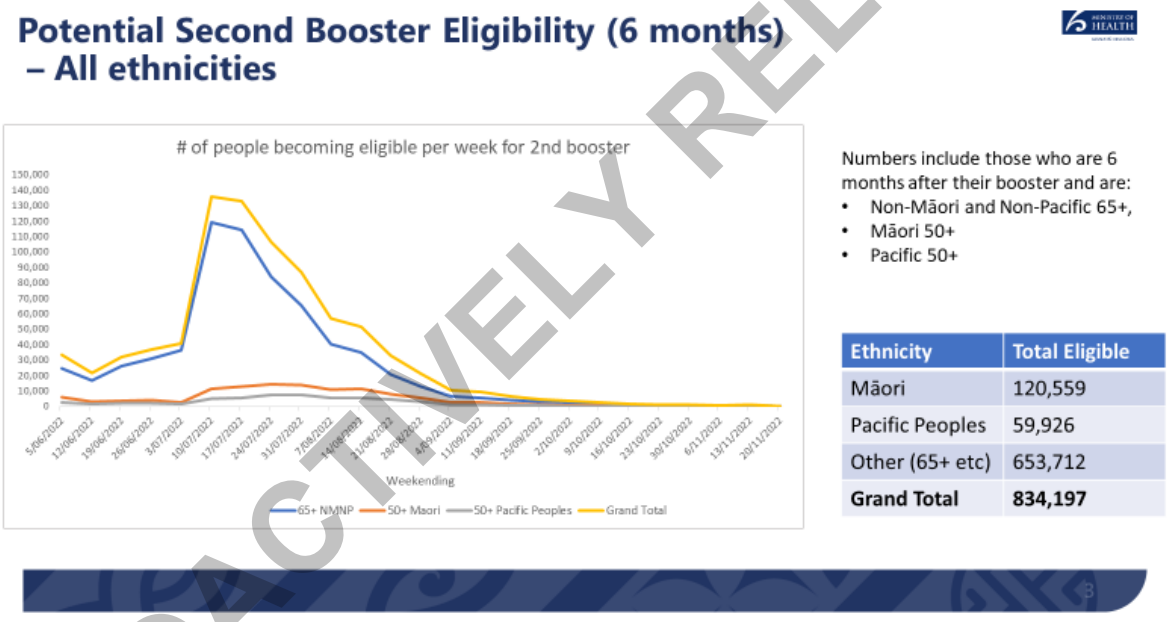
There are at risk groups in New Zealand who would benefit from a fourth dose

The Omicron variant coupled with waning immunity from either vaccinations or previous COVID-19 infection would disproportionately impact on the identified at-risk groups. We know that there is strong support for protecting these groups via vaccination, with vaccination rates especially high in the over-65s and the immunocompromised.

The success of Māori and Pacific health providers to promote vaccination cannot be overstated and it is likely that a fourth dose would also be highly supported and promoted, due to the awareness of the impacts of a COVID-19 infection on these population groups.

There is a time pressure to maximise immunity at a time when winter illnesses are at their peak

The graph below shows that the majority of the at-risk groups would be eligible for a further dose about mid-winter. Providing a fourth dose will maximise immunity for the at-risk groups, particularly when it coincides with the winter season where winter illnesses such as influenza and other respiratory infections cause significant increases in hospitalisations. The groups who are at risk of severe outcomes from COVID-19 are also at-risk of severe outcomes from other respiratory illnesses.



It would be ideal to enable broader delivery of fourth doses by early June 2022 as the majority of the at-risk group will become due for a fourth dose in June and July 2022.

Access can be improved

Off-label vaccination on prescription via GPs favours people who are enrolled with a general practice, have good access to health services, can afford the cost of the service, and knowledge of what they are eligible for and how to access it.

Administration via GPs is a slower, more costly and operationally challenging approach compared to having vaccination available from other community-based clinics, (including local pharmacies and via Māori and Pacific Health providers) where it is able to be administered by all COVID-19 vaccinators. It also places a large atypical workload on the GP network at a time when they are traditionally busy dealing with winter illnesses.

Ministry data shows that of the people in the recommended groups who have received a third (booster) dose, only 24 percent of them accessed this dose at a general practice. A large proportion (48 percent) accessed their third dose at their local pharmacy, and 28

percent accessed via a vaccination centre, pop-up, or mobile delivery clinic, with 5 percent via a marae, hospital, or residential care service. This means that of the approximately 834,000 people in the recommended groups who will become eligible for a fourth dose in the short-term, over 600,000 of them are likely to prefer vaccination somewhere other than a general practice.

COVID-19 vaccinations can be given at the same time as the influenza vaccine and many other vaccinations

Comirnaty is known to be able to be concomitantly administered with other vaccinations, such as the influenza vaccine. As mentioned above, these two viruses have similar at-risk groups and the influenza vaccine is free for these groups and available from pharmacies. Therefore, there is an opportunity to co-administer the vaccinations to maximise uptake and the protection of these groups if a person has not already received their influenza vaccine.

Maintaining trust and confidence in the health system

Experience from the COVID-19 vaccination programme has shown that alongside easy and equitable access to vaccinations, trust and confidence in the system and a good customer experience are also essential to encourage uptake. This includes the ease of booking, multiple available sites, and trustworthy local sites and providers. Through the delivery of the primary course and third (booster) doses, people have come to expect a certain experience. Adding additional steps into the customer journey could undermine the trust and confidence gained.

Futureproofing is required

During the pandemic, the Prime Minister put in place an Epidemic Notice under the Epidemic Preparedness Act. Once this Notice is revoked (expected within the next few months), a number of pathways to achieving COVID-19 health responses (including previous allowances for off-label vaccinations such as reducing the dose interval for third doses to 3 months) will fall away.

It is expected that COVID-19 will not disappear completely but will become an illness that can be managed, probably in a similar way that influenza is managed (regular vaccinations). However, there is the risk that further variants may arise that requires a change in the current vaccinations and their protocols, even if there is no Epidemic Notice in place. This could result in a need for large numbers of New Zealanders to access vaccinations without a prescription over a short period of time. Therefore, a flexible, proportionate and enduring solution is needed.

What objectives are sought in relation to the policy problem?

The desired outcome is for the recommended at-risk groups to get their fourth dose of Comirnaty to ensure that they have maximum immunity against COVID-19 going into winter 2022. The objectives are to:

- reduce hospitalisations and deaths from COVID-19 infection
- reduce the pressure on the health system over the busy winter period
- maximise uptake of the fourth dose in the at-risk groups recommended by CV-TAG
- maintain trust and confidence in the health system
- provide a permanent and future-proofed solution as COVID-19 vaccination activities move into a steady state.

Section 2: Deciding upon an option to address the policy problem

What criteria will be used to compare options to the status quo?

The options have been assessed against the following criteria:

- *Effectiveness*

  The option should provide for reasonable protections against COVID-19 in the at-risk groups and reduce hospitalisations, deaths, and the pressure on the health system

- *Equity*

  Access should be fair, just and proportionate for all in the at-risk groups

- *Simplicity*

  The option should be simple to implement and clear and understandable to those it seeks to engage with. This enhances trust and confidence in the health system

- *Timeliness*

  The option should be able to be initiated and implemented within the desired timeframe

- *Futureproofed*

  The option should be enduring and flexible to be able to be used for other scenarios related to COVID-19 vaccination proposals

What scope will options be considered within?

While a number of other options are available for the administration of a vaccine for the purposes of promoting public health during pandemic conditions, these are determined to be limited to the two options proposed.

For recent off-label changes such as reducing the dose interval from 6 months to 4 months and then to 3 months, an Immediate Modification Order (IMO) under the Epidemic Preparedness Act is currently in place. Consideration was given to replacing the current IMO with one that also allows for the delivery of a fourth dose, but Ministers decided that this was not an option due to its temporary nature and vulnerability of being tied to the temporary Epidemic Notice. An IMO can only be made:

a. while an epidemic notice is in force (one is currently in force for COVID-19);
b. on the recommendation of the Minister of Health;
c. on the written recommendation of the Director-General of Health that the modifications are or are likely to be necessary to enable the effective management of COVID-19 or its effects (or both).

There are two non-legislative options that were taken forward were:

- Pfizer submitting an application for Comirnaty to be approved as a fourth dose. Medsafe cannot procure an application from a company for medicine approvals and as stated, Pfizer has indicated that they are encouraging countries who wish to provide their populations with fourth doses to find their own legal ways of providing this route.
- Standing Orders cannot be made for an unconsented medicine (a “new medicine” under the Act). Treating a fourth dose as other than “new medicine” undermines the scheme and purpose of the Medicines Act and the consent process under the Act.

Additionally, liability for standing orders ultimately sits with the issuer and the person acting in reliance of the standing order.

What options are being considered?

Option One – *Status Quo*

Section 25 of the Medicines Act permits authorised prescribers to administer new medicines and medicines for an off-label use. Option 1 allows anyone to seek a prescription for a fourth dose and obtain maximum immunity against COVID-19.

However, it is known that a number of people in the recommended groups will experience inequities in access to the vaccine if provided only through authorised prescribers on prescription. Some may not be enrolled with a GP (and there is clear evidence that this is especially true in rural areas and certain regions), the cost of seeking a prescription, and if they do have a GP, the ability to receive a timely appointment can be a barrier to seeking what is essentially a recommended course of action. While some elderly and immunocompromised are more likely to have an existing relationship with an authorised prescriber, Māori and Pacific people aged over 50 are likely to find access significantly more difficult. This may mean that some will choose not to get the fourth dose as access is too problematic.

The implementation of Option 1 can be relatively simple if messaging is to seek access through a GP. This is, however, very different from the messaging that has occurred with previous doses of COVID-19 vaccinations and may be confusing for those who fall into the recommended groups, who have expectations of widespread providers and flexible booking times.

GPs are already under pressure, and workload increases over the winter period. Finding available time for a GP appointment can be challenging and therefore a person may not be able to obtain their vaccine in a timely manner.

Section 25 is able to be used for many medicines and is a permanent feature of the Medicines Act, although it is limited in its use to only authorised prescribers. Most of the COVID-19 vaccinating workforce are currently not authorised prescribers so are unable to rely on section 25 to administer an off-label dose.

Option Two – Amendment of the Medicines Act 1981

An amendment to the Medicines Act 1981 would enable the usual rules that restrict administration of medicines to be explicitly overridden in the case of COVID-19 vaccines.

This approach would:

- provide a basis for administration of a fourth dose to protect from serious outcomes from a COVID-19 infection
- provide for equitable access to vaccinations through a range of vaccinators
- provide a vaccination experience similar to that with previous vaccinations, ie using the same technology and at similar venues
- provide a mechanism to more readily enable future doses of COVID-19 vaccines to be administered if emerging scientific evidence demonstrates this is required (such as fourth doses for the wider population).

The key risk with this option is that an amendment such as this would not be in keeping with the scheme of the rest of the Act. It singles out COVID-19 vaccines from a regulatory regime that is intended to set requirements for the safety, quality and efficacy of all medicines.

To mitigate this risk, we need to ensure the amendment is narrowly applied, although not so narrow as to create problems for administering COVID-19 vaccines in future. Finding the right balance between an amendment that is overly broad or overly restrictive will be crucial to ensure we are not restricting any future doses that may be required, such as a fifth dose, or further doses for the broader population. This can be achieved by providing for the Director-General of Health to be satisfied that it is an appropriate measure to manage the risks associated with a COVID-19 outbreak or spread.

To enable the bespoke amendment to be enacted in time for the recommended June 2022 roll out (to align with most of the recommended groups' six-month dose interval, as well as being in time for winter), this option requires Ministers to act under urgency.

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

Option 2 is the preferred approach

An amendment to the Medicines Act is the preferred option as it provides for a permanent and future proofed pathway in case further changes are needed to meet future COVID-19 challenges. These may include further vaccine doses, changes to dose intervals, or targeting different population groups in response to future variants where evidence supports its use. This is similar to the approach taken in the IMO providing for a third (booster) dose (Epidemic Preparedness (Medicines Act 1981—COVID-19) Immediate Modification Order 2022). It provides for the Director-General of Health to specify a class of authorised vaccinators who can administer doses of COVID-19 vaccines contrary to the usual rules, in addition to a number of other conditions not included in the section 20 or section 23 consent processes.

Option 2 is also the preferred option to ensure equitable access for the at-risk groups as the data shows that the majority prefer to receive their vaccinations from a pharmacy or other health provider.

This Option is expected to promote a higher uptake of the fourth dose resulting in better health outcomes of the at-risk groups vulnerable to COVID-19 over the winter period, and reduced pressure on the health system. The higher uptake would also help consume the current supplies of vaccine that otherwise could expire before they are used.

The Therapeutic Products Bill will provide regulatory mechanisms to ensure such issues may be more easily dealt with in the future

Section 3: Delivering an option

How will the new arrangements be implemented?

The preferred option would be given effect through an amendment to the Medicines Act. The Bill would be introduced on 7 June 2022 and passed by mid-June 2022 under urgency. This would result in an additional section of the Medicines Act that only applies to COVID-19 vaccinations and only on the recommendation of the Director-General of Health.

Provision of fourth doses to the CV-TAG recommended groups will be on a voluntary uptake basis and will not have any impacts on other COVID-19 legislation, such as the COVID-19 Public Health Response (Vaccinations) Order 2021.

The Ministry of Health would be responsible for the implementation of the roll out of the fourth dose, utilising all existing delivery settings, processes and technology that have been developed and used for previous COVID-19 vaccination roll outs.

How will the new arrangements be monitored, evaluated, and reviewed?

The Ministry of Health would monitor the impacts of the new arrangements through existing comprehensive data collection processes. The uptake of COVID-19 vaccinations is currently reported publicly and regularly, and therefore the application of the amendment to the fourth dose would be included and be available for analysis.

The amendment is to the Medicines Act 1981, which is currently under review and expected to be replaced with the Therapeutic Products Bill (intended to be introduced later in 2022). It is expected that the Bill will be fit for purpose and be better able to manage situations such as those that required the proposed amendment.

In the meantime, the Ministry will monitor the application of the amendment to ensure its ongoing use does not undermine the usual consenting processes under the Act.

Medicines Amendment Bill (No 2)

Government Bill

Explanatory note

General policy statement

The purpose of this Bill is to amend the Medicines Act 1981 to provide population protection against COVID-19 via vaccination by providing for—

- the lawful administration of fourth doses of COVID-19 vaccines beyond use on prescription via an authorised prescriber other than in accordance with the data sheet (**off-label use**):
- a long-term solution for the provision of the third (booster) dose at the 3-month dose interval:
- any future doses of COVID-19 vaccines to be administered if scientific evidence demonstrates that is recommended.

The Bill meets these objectives by creating a new provision (*new section 34A*) that enables the Director-General of Health (the **Director-General**) to authorise, by notice, the administration of a consented COVID-19 vaccine otherwise than in accordance with the approved data sheet for that vaccine.

This is consistent with the policy intent of the COVID-19 vaccination programme to provide ongoing population protection against COVID-19, and to continue to adapt and respond as the pandemic evolves.

The amendment will enable the Director-General to specify by notice who the vaccine may be administered to, the recommended number of doses and frequency of doses, the recommended manner of administration, and any circumstances in which the vaccine may be administered.

The Director-General must be satisfied that doing so is an appropriate measure to manage the risks associated with the outbreak or spread of COVID-19, having regard to the likely therapeutic value of the proposed administration of the COVID-19 vaccine and the risk (if any) that any proposed administration of the vaccine may injuriously affect the health of any person.

The amendment will only enable the Director-General to use this power in relation to COVID-19 vaccines that have consent or provisional consent under section 20 or 23 of the Act. The amendment does not affect the usual consenting process under the Act.

Departmental disclosure statement

The Ministry of Health is required to prepare a disclosure statement to assist with the scrutiny of this Bill. The disclosure statement provides access to information about the policy development of the Bill and identifies any significant or unusual legislative features of the Bill.

A copy of the statement can be found at [PPU to insert URL and link] (if it has been provided for publication).

Regulatory impact statement

The Ministry of Health produced a regulatory impact statement on 30 May 2022 to help inform the main policy decisions taken by the Government relating to the contents of this Bill.

A copy of this regulatory impact statement can be found at—

- https://www.health.govt.nz/about-ministry/information-releases/regulatory-impact-statements/amending-medicines-act-1981-allow-label-use-covid-19-vaccinations/
- https://treasury.govt.nz/publications/informationreleases/ris

Clause by clause analysis

Clause 1 is the Title clause.

Clause 2 provides that the Bill, when enacted, comes into force on the day after the date on which it receives Royal assent.

Clause 3 provides that the Bill amends the Medicines Act 1981.

Clause 4 inserts *new section 34A* into Part 2 of the Act (which provides for dealings with medicines and medical devices). In summary, *new section 34A*—

- enables the Director-General, by notice, to authorise the administration of a COVID-19 vaccine other than in accordance with the data sheet (**off-label administration**) if the vaccine has consent or provisional consent under section 20 or 23 of the Act:
- enables the Director-General to specify in the notice who the vaccine may be administered to, the recommended number and frequency of doses, the recommended manner of administration, and any circumstances in which the vaccine may be administered:
- requires the Director-General, before making a notice, to be satisfied that the proposed administration of the vaccine is an appropriate measure to manage

the risks associated with the outbreak or spread of COVID-19, having regard to the likely therapeutic value of the proposed administration of the COVID-19 vaccine and the risk (if any) of injuriously affecting the health of any person:

- provides that neither the off-label administration nor the authorisation of the off-label administration of a COVID-19 vaccine makes the vaccine a new medicine for the purpose of section 20:
- provides that any person or class of persons permitted by the Act or regulations to administer a COVID-19 vaccine may administer a dose of the vaccine in accordance with a notice made under *new section 34A*:
- provides that a notice made under *new section 34A* does not limit section 24 (which relates to the distribution of a medicine if a material change is made to the medicine by its manufacturer).

Clause 5 revokes the Epidemic Preparedness (Medicines Act 1981—COVID-19) Immediate Modification Order 2022.

Hon Andrew Little

Medicines Amendment Bill (No 2)

Government Bill

Contents

The Parliament of New Zealand enacts as follows:

1 Title

This Act is the Medicines Amendment Act **2022**.

2 Commencement

This Act comes into force on the day after the date of Royal assent.

3 Principal Act

This Act amends the Medicines Act 1981.

4 New section 34A inserted (Director-General may authorise off-label administration of COVID-19 vaccines)

After section 34, insert:

PCO 24788 v 18.0: 2 June 2022: 12:56 p.m.

COVID-19 vaccines

34A Director-General may authorise off-label administration of COVID-19 vaccines

(1) This section applies if—

(a) the Minister has given consent or provisional consent to a COVID-19 vaccine; and

(b) a data sheet is approved for the vaccine under the regulations.

Notice

(2) The Director-General may, by notice, authorise the administration of the vaccine other than in accordance with the data sheet.

(3) The notice may specify any 1 or more of the following matters in relation to the administration of the vaccine:

(a) who it may be administered to:

(b) the recommended number and frequency of doses:

(c) the recommended manner of administration:

(d) any circumstances in which it may be administered.

(4) Before issuing a notice under this section, the Director-General must—

(a) have regard to the likely therapeutic value of the proposed administration of the vaccine and the risk (if any) that the proposed administration of the vaccine may injuriously affect the health of any person; and

(b) be satisfied that the proposed administration of the vaccine is an appropriate measure to manage the risks associated with the outbreak or spread of COVID-19.

Effect of notice

(5) A COVID-19 vaccine is not a new medicine for the purpose of section 20 by reason only of—

(a) a notice made under this section in relation to the vaccine; or

(b) administration of the vaccine in accordance with the notice.

(6) Any person or class of persons permitted by the Act or by regulations to administer the vaccine may administer the vaccine in accordance with the notice.

(7) Nothing in this section limits section 24.

Status of notice

(8) A notice made under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

PCO 24788 v 18.0: 2 June 2022: 12:56 p.m.

Legislation Act 2019 requirements for secondary legislation made under this section		
Publication	The maker must publish it in accordance with the Legislation (Publication) Regulations 2021	LA19 s 74(1)(aa)
Presentation	The Minister must present it to the House of Representatives	LA19 s 114
Disallowance	It may be disallowed by the House of Representatives	LA19 ss 115, 116

This note is not part of the Act.

Revocation

5 Order revoked

The Epidemic Preparedness (Medicines Act 1981—COVID-19) Immediate Modification Order 2022 (SL 2022/7) is revoked.