Booster Vaccination Policy Statement

National Immunisation Programme Aotearoa New Zealand

Version 5.0

New Zealand Government

MINISTRY OF HEALTH
MANATŪ HAUORA

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Definitions

The following definitions and abbreviations apply to this document, unless otherwise stated.

Word or phrase	Definition
Consumer	A consumer can also be a client, patient, or resident. It is the person who uses or receives health and disability services, or their representative.
Contraindication	Anything (including a symptom or medical condition) that is a reason for a person to not receive a particular treatment because it may be harmful. For the purposes of this document, contraindications refer to those documented on the relevant New Zealand data sheet.
Medsafe	Medsafe is the New Zealand Medicines and Medical Devices Safety Authority. It is a business unit of the Ministry of Health and is the authority responsible for the regulation of therapeutic products in New Zealand.
Medsafe Approval of a Clinical Trial under section 30 of the Medicines Act	Medsafe administers the application and approval process for clinical trials under an authority delegated from the Director-General of Health. Medsafe receives and processes applications, liaises with the relevant Health Research Council committee and the applicant, and issues approval letters.
Medsafe Vaccine Evaluation and Approval Process	Medsafe evaluates applications for all new medicines, including vaccines, to ensure they comply with international standards and local requirements for quality, safety and efficacy. Once Medsafe have completed the evaluation process and international agreed criteria for safety and efficacy are met, consent can be granted either full consent under section 20, or provisional consent under section 23 of the Medicines Act 1981.

Introduction

COVID-19 vaccines are being rolled out in Aotearoa New Zealand through the National Immunisation Programme (the Programme) overseen by the Ministry of Health (the Ministry). This is the country's largest ever immunisation programme.

The Programme offers free COVID-19 vaccinations to everyone within the approved age range. To ensure that the Programme aligns with international evidence, the COVID-19 Vaccine Technical Advisory Group (CV TAG) continuously reviews evidence and provides advice to the Programme.

This policy statement is specific to the COVID-19 **Adult** Pfizer/BioNTech COVID-19 Comirnaty vaccine (**Pfizer**) for eligible consumers (outlined in the eligibility criteria in this policy statement).

Background and context

The Ministry recommends vaccination to everyone of eligible age in Aotearoa New Zealand. As with any vaccine, the Pfizer/BioNTech COVID-19 (Pfizer vaccine) may not fully protect everyone who receives it. However, it has demonstrated its safety and effectiveness against contracting the virus, becoming seriously ill or transmitting the virus to others.

The COVID-19 vaccine's effectiveness may reduce over time and may become less effective at preventing infection or symptomatic illness. While two doses are likely to provide a good degree of protection against severe disease from Delta and Omicron COVID-19 variants for some time, a first booster dose is likely to offer greater protection.

Similarly, there is evidence that protection after the first booster dose reduces faster for some population groups (eg, the elderly) and a second booster dose is likely to offer greater protection.

The Pfizer vaccine is the preferred booster for New Zealand. For clarity, the booster dose is not the third primary dose for severely immunocompromised or any other primary course dose (e.g., extension or replacement dose in the context of a dosing error). Please refer to the third primary dose for the severely immunocompromised Policy Statement.

Purpose

To provide a policy statement on the use of COVID-19 vaccine booster doses in Aotearoa New Zealand. The policy statement and objectives in this document align with the recommendations from the CV TAG.

This policy statement should be used alongside the Immunisation Handbook 2020, the COVID-19 Vaccine and Immunisation Programme Operating Guidelines, and the COVID-19 Vaccine Immunisation Programme Service Standards.

This document should also be used alongside other relevant policy statements available on the Ministry of Health's website.

Policy Statement

The Ministry recommends a first and second booster dose for those aged 16 years and above who meet the eligibility criteria. The first line vaccine and first line booster in Aotearoa New Zealand is the Pfizer vaccine.

First booster dose

AstraZeneca is the second line vaccine and may be used as an alternative first booster dose in specified situations only and if the eligibility criteria in the Programme's AstraZeneca policy statement are met.

A Pfizer first booster dose may be administered to people aged 18 years and older from **three months** following completion of the primary course without a prescription.

A Pfizer first booster dose may be administered to people aged 16 and 17 years of age from **six months** following completion of the primary course without a prescription as approved by Medsafe.

Second booster dose

A Pfizer second booster may be offered to people aged 16 years and older who fulfil the eligibility criteria, at an interval of not less than six months since their last dose of a COVID-19 vaccine. Those who are eligible can have the vaccine without a prescription.

Prescription and Informed Consent

All consumers must be fully informed of the benefits and risks of the vaccine (in their circumstances). This consent may be verbal unless specified below.

A prescription from an authorised prescriber is required when a vaccine is being administered off-label in accordance with Section 25 of The Medicines Act 1981 (that is, when a Medsafe approved medicine is being used for an un-approved use), and the administration is not authorised under section 34A Medicines Amendment Act (No 2) 2022, that empowers the Director-General of Health to authorise, by Notice, the use of a consented COVID-19 vaccine otherwise than in accordance with the approved data sheet.

This includes using the AstraZeneca vaccine as a booster dose.

Written consent is required by the Programme for all consumers receiving a dose of the AstraZeneca vaccine. This Programme requirement will be regularly reviewed.

Eligibility criteria

Covid-19 Infection

A vaccine dose, if due, should be postponed for three months after a COVID-19 infection. Clinical discretion can be applied when considering vaccination prior to three months after infection.

First booster dose

A Pfizer first booster dose is available to people aged 18 years and older who have completed their full primary vaccination course **three** or more months prior, including pregnant people, and the severely immunocompromised who received a 3-dose primary course.

A Pfizer first booster dose is available to people aged 16 and 17 years who have completed their full primary vaccination course **six** or more months prior.

Second booster dose

A Pfizer second booster dose is recommended for:

- All people aged 65 years and above.
- Māori and Pacific peoples aged 50 years and over.
- Residents of aged care and disability care facilities from aged 16 years and above.
- Severely immunocompromised people (aged 16 years and above) who received a three-dose primary course and a fourth dose as a first booster. **Note:** this is a fifth dose overall for these people.
- People aged 16 years or older, who have a medical condition that increases the risk of severe breakthrough COVID-19 illness.[1]

[1] COVID-19 vaccine: Boosters | Ministry of Health NZ

- People aged 16 years and over who live with disability with significant or complex health needs or multiple comorbidities.

A second booster is also available for:

- All people aged over 50 years
- Health, aged care, and disability workers aged over 30 years

A Pfizer second booster can be offered from **six months** since their last dose of a COVID-19 vaccine.

Individual clinical advice is available from IMAC on 0800 466 863.

For clarity, at this time there is insufficient evidence of additional benefit to support recommending a second booster to:

- Young people (particularly those aged under 30 years) without comorbidities and
- Healthy pregnant women

Policy Statement Objectives

The following section outlines the Programme objectives for the different elements of the policy statement related to the COVID-19 vaccine booster dose:

- Use of a Vaccine Booster
- Planning of Delivery
- Logistics
- Correct Procedures
- Reporting and Monitoring
- Quality and Performance

Use of a Vaccine Booster

1. Use of vaccine booster doses			
		Who can administer?	**Administration requirements**
1.1	**Pfizer as a first booster dose**	Fully authorised Vaccinators or provisionally authorised Vaccinators or COVID-19 Vaccinators working under supervision	If consumer is aged 18 years or older: • No prescription required if given from 3 months following completion of the primary course, as covered in the authorised under section 34A Medicines Amendment Act (No 2) 2022, that empowers the Director-General of Health to authorise, by Notice, the use of a consented COVID-19 vaccine otherwise than in accordance with the approved data sheet. If consumer is aged 16 or 17 years: • No prescription is required if given from 6 months following completion of the primary course. Standard informed consent procedures as per the COVID-19 Vaccine and Immunisation Programme Operating Guidelines apply to all ages.
		Fully authorised or provisionally authorised Vaccinators (this includes Pharmacist Vaccinators but not COVID-19 Vaccinators working under supervision).	If consumer is aged 12 -15 years of age if they are high risk for severe health outcomes from COVID-19: • Administration is considered off-label use and requires a prescription by an authorised prescriber, in accordance with Section 25 of the Medicines Act 1981, following a conversation about the risks and benefits. • There is guidance on those considered high risk of severe health outcomes from COVID-19 in this age group in the Immunisation Handbook or from IMAC. Standard informed consent procedures as per the COVID-19 Vaccine and Immunisation Programme Operating Guidelines apply to all ages.

1.2	**Pfizer as a second booster dose**	Fully authorised Vaccinators (this includes Pharmacist vaccinators) or provisionally authorised Vaccinators or COVID-19 Vaccinators working under supervision	For those 16 years and above who meet the eligibility criteria: • A Pfizer second booster can be offered at an interval of not less than six months since their last dose of a COVID-19 vaccine.
1.3	**AstraZeneca as a first booster dose**	Fully authorised or provisionally authorised Vaccinators (this includes Pharmacist Vaccinators but not COVID-19 Vaccinators working under supervision).	• Consumer is aged 18 years or over • Pfizer is the recommended and first-line vaccine for boosters. If consumers meet the criteria for AstraZeneca in the Policy Statement, they may receive it as a booster a minimum of 3 months following completion of a primary course. • The administration of the AstraZeneca vaccine as a booster dose is considered off-label use and requires a prescription by an authorised prescriber, in accordance with Section 25 of The Medicines Act 1981. • Written consent is a Programme requirement for all consumers receiving a dose of the AstraZeneca vaccine. • CVIP AstraZeneca Vaccine Policy Statement Clinical Criteria and Guidance.

Planning of Delivery

2. Planning of delivery	
2.1	The Programme will plan and anticipate vaccine booster doses and ensure it is accounted for in the planning phase of the Programme.
2.2	The Programme will forecast demand for a vaccine booster dose according to the DHB.
2.3	The Programme and providers will plan for the likelihood of vaccine booster doses and have processes and procedures to control any risk associated with them.

2.4	A Provider will use the same delivery processes for the vaccine booster doses as with their usual processes for other COVID-19 primary vaccination doses.

Logistics

3. Logistics	
3.1	The Programme will ensure that the distribution of vaccines will follow the programme requirements on handling and cold chain management of the vaccine.
3.2	The Programme will ensure there is adequate reporting and monitoring mechanisms with assigned responsibilities to ensure vaccines are transported and delivered safely and any potential cold chain breaches or exceptions are managed accordingly.
3.3	The Programme will verify conformance to relevant standards and recommended practice.
3.4	A Provider will ensure that the handling of vaccines will follow cold chain management of the vaccine.
3.5	A Provider will ensure that vaccine is planned, ordered, receipted and consumed through the CIR Inventory system.
3.6	A Provider will ensure that good inventory management practices are followed.

Correct Procedures

4. Correct Procedures	
4.1	A Provider will ensure they meet the National Standards for Vaccine Storage and Transportation for Immunisation Providers (2017), including any relevant addendums.
4.2	The Programme will make available COVID-19 Service Standards and the COVID-19 Vaccine and Immunisation Programme Operating Guidelines with updated booster resources.
4.3	The Programme and providers will verify conformance to relevant standards and recommended practice is followed.

4.4	A Provider will ensure the correct safety requirements are met for the vaccine booster doses.
4.5	A Provider will establish a standard operating procedure/s for vaccine booster dose use.
4.6	A Provider will ensure informed consent for the Pfizer vaccine is recorded through the standard procedures as per the COVID-19 Vaccine and Immunisation Programme Operating Guidelines.
4.7	A Provider will ensure written consent for the AstraZeneca vaccine is recorded.
4.8	A Provider will ensure all vaccine booster doses are correctly recorded in the CIR.

Reporting and Monitoring

5. Reporting and Monitoring	
5.1	The Programme will provide the same reporting and monitoring channels for the vaccine booster dose.
5.2	A Provider will report vaccine booster doses to allow accuracy of waste reporting.
5.3	The Programme will monitor levels of vaccine booster dose use.
5.4	The Programme will report levels of vaccine product waste.

Quality and Performance

6. Quality and Performance	
6.1	The Programme's 'line of sight' on vaccine use will be enabled by an efficient programme-wide reporting and monitoring system.
6.2	The Programme recognises there will be vaccine waste due to warranted system and process factors such as human factors.

6.3	A Provider will report any Adverse Event Following Immunisation (AEFI) as per the COVID-19 Vaccine and Immunisation Programme Operating Guidelines.
6.4	A Provider will support that all known vaccine booster dose adverse events will be reported to the Centre for Adverse Reactions Monitoring (CARM).

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