Booster Vaccination Policy Statement

COVID-19
Vaccine and Immunisation Programme
Aotearoa New Zealand

Version 4

New Zealand Government

MINISTRY OF HEALTH
MANATŪ HAUORA

Table of Contents

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.

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 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).

Purpose

To provide a policy statement on the use of COVID-19 vaccine booster doses in Aotearoa New Zealand.

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.

Policy Statement

The Ministry recommends a booster dose for those who meet the eligibility criteria.

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

A Pfizer vaccine booster dose may be administered to people aged 18 years and older from **three months** following completion of the primary course without a prescription as it is covered under the Epidemic Preparedness (Medicines Act 1981 – COVID-19) Immediate Modification Order 2021 made under section 14 of the Epidemic Preparedness Act 2006, which modifies the requirements imposed by the Medicines Act 1981 to enable effective management of COVID-19 or its effects.

A Pfizer vaccine 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.

A prescription from an authorised prescriber is required when using the AstraZeneca vaccine as a booster dose or a second primary dose (i.e., following a non-AstraZeneca COVID-19 vaccine for dose 1), in accordance with Section 25 of The Medicines Act 1981, as it is considered off-label use and is not covered under an Order in Council.

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

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

The Programme particularly recommends a Pfizer vaccine booster dose for people aged 16-17 years who are at higher risk of COVID-19 severe disease and hospitalisation, including Māori and Pacific adolescents and those who are household contacts of persons who are severely immunocompromised.

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:

1. Use of a Vaccine Booster
2. Planning of Delivery
3. Logistics
4. Correct Procedures
5. Reporting and Monitoring
6. Quality and Performance

Use of a Vaccine Booster

1. Use of vaccine booster doses			
		Who can administer?	**Administration requirements**
1.1	**Pfizer as a 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 Epidemic Preparedness (Medicines Act 1981 – COVID-19) Immediate Modification Order 2021. If consumer is aged 16 or 17 years: • No prescription required if given from 6 months following completion of the primary course. If consumer is aged 12 -15 years of age: • 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	**AstraZeneca as a 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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