# Fully Vaccinated against COVID-19 within Aotearoa New Zealand Policy Statement

New Zealand COVID-19 Vaccine and Immunisation Programme

Version 2.0



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# **Definitions**

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

Word of 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 by Medsafe 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 (1981)	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.
Fully vaccinated	Immediately after the last dose of a COVID-19 primary vaccination course as defined in this policy statement.
Fully immunised	Seven or more days after the last dose of an accepted COVID-19 primary vaccination course.

### Introduction

COVID-19 vaccines are being rolled out in Aotearoa New Zealand through the National Immunisation Programme (the Programme) run by the Ministry of Health (the Ministry). This is the country's largest ever immunisation programme and offers free COVID-19 vaccination to everyone within the eligible 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**

As part of Aotearoa New Zealand's public health response, the Government has introduced the COVID-19 Protection Framework whereby those who are fully vaccinated against COVID-19 will have greater access to environments that are at a higher risk for the transmission COVID-19, such as concerts and festivals.

The Ministry has developed a verifiable digital vaccination certificate (My Vaccine Pass) as proof of vaccination for people who are fully vaccinated. This can be utilised to access places that require a vaccination certificate.

The meaning of fully vaccinated is defined in accordance with the national COVID-19 pandemic response within the motu. This policy statement recognises many consumers entering Aotearoa New Zealand from overseas that have been vaccinated abroad against COVID-19 with vaccines other than the Medsafe-approved COVID-19 vaccines.

This policy statement sets out the definition to be fully vaccinated within Aotearoa New Zealand as it relates to the requirements of the COVID-19 Protection Framework.

## **Purpose**

The purpose of this document is to provide a policy statement on the Programme's COVID-19 vaccines and combinations of other approved vaccines, to be deemed fully vaccinated for stated purposes within Aotearoa New Zealand.

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

In scope for this policy statement are:

- 1. Groups of affected persons contained in the Public Health Response (Vaccinations) Order 2021 as specified in Schedule 2 of that Order (vaccination requirements contained in Schedule 3 of that Order)<sup>1</sup>.
- 2. Recognised Seasonal Employer (RSE) workers

Out of scope for this policy statement are:

3. Vaccination requirements for persons crossing over the border into Aotearoa New Zealand. <sup>2</sup>

<sup>&</sup>lt;sup>1</sup> https://www.legislation.govt.nz/regulation/public/2021/0094/latest/LMS573022.html

<sup>&</sup>lt;sup>2</sup> This definition of fully vaccinated will be incorporated into the advice on border entry pathways for COVID-19 management (e.g., MIQ, self-isolation and testing requirements) under the Reconnecting New Zealanders' strategy to be eligible for reduced isolation requirements, where vaccination status is a consideration.

# **Policy Statement**

The Programme's first line vaccine where there are no contraindications is the Pfizer vaccine. The AstraZeneca vaccine is available as second line vaccine for consumers who meet the eligibility criteria.

For the purposes of the COVID-19 Protection Framework there are 10 recognised vaccines included in Aotearoa New Zealand's definition of fully vaccinated against COVID-19.

A fully vaccinated course is the approved number of doses or combination of doses of any of the 10 recognised vaccines administered in accordance with this policy statement. For more information refer to **Appendix 1**.

As of 31 January 2022, there are 10 recognised vaccines in Aotearoa New Zealand, three of these are approved by Medsafe and the Programme offers free vaccination with Pfizer Comirnaty or AstraZeneca Vaxzevria (if age and eligibility criteria are met):

- 1. Pfizer/BioNTech Comirnaty
- 2. AstraZeneca (Oxford) Vaxzevria
- 3. Janssen (Johnson and Johnson)
- 4. Moderna Spikevax
- 5. Bharat Biotech Covaxin
- 6. Novavax Nuvaxovid
- 7. Serum Institute of India (AstraZeneca) Covishield
- 8. Serum Institute of India (Novovax) Covovax
- 9. Sinopharm BBIPB-CorV
- 10. Sinovac (CoronaVac)

**Note:** The definition of fully vaccinated does not stipulate a maximum time since the last dose. However, as booster doses become more common, requirements for booster doses and a maximum time since last vaccination could be added to future definitions. As such the policy statement will be reviewed as new advice is provided.

# Policy Statement Objectives

The following section outlines the Programme objectives for the different elements of the policy statement and must be used alongside **Appendix 1**:

- Combination of COVID-19 vaccines
- 2. Consumers tested positive for COVID-19
- 3. Participants in Registered Vaccine Trials
- 4. Recognised Seasonal Employer (RSE) workers

#### 1. Definition of fully vaccinated for combination of COVID-19 vaccines

- 1.1 Two doses\* of any combination of any of the 10 recognised vaccines in Aotearoa New Zealand. This includes the Medsafe, and the World Health Organization Emergency Use Listing (WHO EUL) approved vaccines as at 31 January 2022.
  - \*Note: A single dose of the Janssen (Johnson and Johnson) vaccine is recognised as fully vaccination in Aotearoa New Zealand.
- A complete primary course of any other <u>COVID-19 vaccines</u> authorised by at least one government or authority **PLUS** a single dose of a Medsafe approved vaccine (the Moderna Spikevax COVID-19 vaccine is also acceptable as an additional dose in the case that it was administered outside of New Zealand).

**Note:** Where an additional dose is given it should be given at least 28 days after the previous COVID-19 vaccine dose. For more information refer to **Appendix 1**.

1.3 A single dose of any of the <u>COVID-19 vaccines authorised by at least one government or authority</u> **PLUS** a single dose of a Medsafe approved vaccine (the Moderna Spikevax COVID-19 vaccine is also acceptable as the additional dose in the case that it was administered outside of New Zealand).

**Note:** Where an additional dose is given it should be given at least 28 days after the previous COVID-19 vaccine dose. For more information refer to **Appendix 1**.

# Consumers previously tested positive for COVID-19 Consumers previously tested positive for COVID-19 must complete their COVID-19 primary vaccination course to be fully vaccinated. Vaccinators should refer to the <a href="mailto:lmmunisationHandbook">lmmunisation Handbook</a> (2020) for clinical guidance.

#### 3. Participants in Registered Vaccine Trials

Those participating in a registered COVID-19 vaccine trial in Aotearoa New Zealand will be able to apply for a temporary vaccine exemption from being fully vaccinated and access this exemption if they meet the temporary vaccine exemption criteria.

#### 4. Recognised Seasonal Employer (RSE) workers

The definition of fully vaccinated does not impact on the vaccination requirement for RSE workers from the Pacific or non-New Zealand citizen arrivals by air introduced on 01 November 2021, which recognises any COVID-19 vaccine approved by at least one government of authority. For more information see **Appendix 2**.

# **Appendix 1**

**Table 1.** Definition of 'fully vaccinated' in Aotearoa New Zealand (including MIQ/Isolation/Testing pathways on arrival to Aotearoa New Zealand, vaccine mandates and vaccine certificates).

Location	Group	Mandatory Vaccination	Approval Body	Vaccine and Course to be Fully Vaccinated against COVID-19 in Aotearoa New Zealand (if age and eligibility criteria are met)	Additional Actions Required
Within NZ  (as at 31 January 2022 there are 10 recognised	(as at 31 January 2022 there are 10 recognised workers (including affected workers World Health Organisation Emergency Use		World Health Organisation	A complete course of any of the following 10 recognised vaccines (number of doses required):  1. Pfizer/BioNTech Comirnaty, Tozinameran, BNT162b2 (2 doses)	
vaccines)	vaccination			2. AstraZeneca Vaxzevria, AZD1222 (2 doses)	
	mandates)	ites)		3. Janssen (Johnson & Johnson), Janssen COVID-19 Vaccine, Ad26.COV2.S, Ad26COVS1, JNJ-78436735 (1 dose*)	*Janssen is a single dose course. It is recommended to offer
				4. Moderna Spikevax, mRNA-1273. (2 doses)	another dose of a vaccine
				5. Bharat Biotech Covaxin, BBV152 (2 doses)	approved by Medsafe for those at high risk of serious disease or
				6. Novavax Nuvaxovid, NVX-CoV2372 (2 doses)	occupational exposure. This is not required to be
				7. Serum Institute of India (AstraZeneca formulation) Covishield (2 doses)	considered fully vaccinated.
					8. Serum Institute of India (Novavax formulation) Covovax
				9. Sinopharm, BBIBP-CorV, Sinopharm COVID-19 vaccine, BIBP vaccine, Covilo (2 doses)	

Location	Group	Mandatory Vaccination	Approval Body	Vaccine and Course to be Fully Vaccinated against COVID-19 in Aotearoa New Zealand (if age and eligibility criteria are met)	Additional Actions Required
				10. Sinovac CoronaVac, Sinovac COVID-19 vaccine, PiCoVacc. (2 doses)	
				Two doses of any combination of the above 10 recognised vaccines are also accepted (heterologous schedules).	
				An incomplete primary course (1 dose, excluding Janssen) of Medsafe or WHO EUL approved vaccines (the 8 recognised vaccines listed above).	Will require an additiona dose of a Medsafe-approved vaccine (currently Pfizer, AstraZeneca, Janssen) or Moderna to be considered fully vaccinated in New Zealand.
					Additional dose should be at least 28 days after the previous COVID-19 vaccine dose (except afte first dose Pfizer which is 21 days).
			Any other COVID-19 vaccine/s authorised by at least one government or authority as listed on the vaccine list (currently 28 vaccines at 09 December 2021).	Complete or partial COVID-19 vaccine course.	Will require an additional dose of a Medsafe-approved vaccine (currently Pfizer, AZ, Janssen) or Moderna to be considered fully vaccinated in New Zealand.  Additional dose should

Location	Group	Mandatory Vaccination	Approval Body	Vaccine and Course to be Fully Vaccinated against COVID-19 in Aotearoa New Zealand (if age and eligibility criteria are met)	Additional Actions Required
					the previous COVID-19 vaccine dose.

**Table 2.** Examples of schedules received outside of New Zealand needing an additional dose in New Zealand (at least 28 days after most recent dose) to become 'fully vaccinated'

Vaccine Combination Example	Reason	Action
2 doses of Gamaleya Research Institute of Epidemiology and Microbiology (Sputnik V, Gam-COVID-Vac)	Not a Medsafe or WHO EUL Vaccine approved vaccine	1 additional dose of Medsafe approved vaccine
1 dose of Gamaleya Research Institute of Epidemiology and Microbiology (Sputnik V, Gam-COVID-Vac)	Not a Medsafe or WHO EUL approved vaccine and an incomplete course	1 additional dose of Medsafe approved vaccine
3 doses of Zydus Cadila (ZyCoV-D), 3 doses is the primary course for this vaccine	Not a Medsafe or WHO EUL Vaccine	1 additional dose of Medsafe approved vaccine
1 or 2 doses of Zydus Cadila (ZyCoV-D), 3 doses is the primary course for this vaccine	Not a Medsafe or WHO EUL vaccine, and an incomplete course	1 additional dose of Medsafe approved vaccine
2 doses of Kazakhstan RIBSP vaccine (QazVac, QazCovid-in)	Not a Medsafe or WHO EUL vaccine	1 additional dose of Medsafe approved vaccine
1 dose of Kazakhstan RIBSP vaccine (QazVac, QazCovid-in)	Not a Medsafe or WHO EUL vaccine, and an incomplete course	1 additional dose of Medsafe approved vaccine
1 dose of Pfizer	An incomplete primary course	1 additional dose of Medsafe or WHO EUL approved vaccine

**Table 3.** Examples of schedules received outside of New Zealand that are 'fully vaccinated'

Vaccine Combination Example	Reason	Action
2 doses Pfizer	Complete primary course of Medsafe or WHO EUL vaccine	None
1 dose of Janssen	Complete primary course of Medsafe or WHO EUL vaccine	Additional dose of Pfizer recommended but not required
1 dose of unspecified COVID-19 vaccine, and second dose Moderna/ Pfizer/ AstraZeneca/ Janssen.  Note: This might be how EU vaccine certificate presents data.	In the "worst case", this is 1 dose of a non-approved Medsafe or WHO-EUL vaccine, and 1 dose of a Medsafe approved vaccine which fits the definition of 'fully vaccinated'.	None

# **Appendix 2**

For RSE workers who have received	Recommendation
2 doses of the Pfizer or 2 doses of the AstraZeneca vaccine	This is a full primary course of vaccination approved by Medsafe. Considered 'fully vaccinated'.
2 doses of the Sinopharm vaccine	This is a full primary course of vaccination approved by WHO EUL. Considered 'fully vaccinated'.
1 dose of the AstraZeneca vaccine  1 dose of the Sinopharm vaccine	These RSE workers should receive one dose of the first or second line Medsafe approved vaccine if age and eligibility criteria are met.

### References

- Ministry of Health. 2020. Immunisation Handbook. Wellington: Ministry of Health. Retrieved from: <a href="https://www.health.govt.nz/publication/immunisation-handbook-2020">https://www.health.govt.nz/publication/immunisation-handbook-2020</a>
- Ministry of Health. 2021. COVID-19 Vaccine Operating Guidelines. Wellington: Ministry of Health. Retrieved from: <a href="https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals/covid-19-vaccine-operating-and-planning-guidelines#operate">https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals/covid-19-vaccine-operating-and-planning-guidelines#operate</a>
- Ministry of Health. 2021. Service Standards. Wellington: Ministry of Health. Retrieved from: <a href="https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals/covid-19-vaccine-policy-statements-and-clinical-guidance#service">https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals/covid-19-vaccine-policy-statements-and-clinical-guidance#service</a>
- World Health Organisation (WHO), "International Clinical Trials Registry Platform," [Online]. Available: <a href="https://trialsearch.who.int/">https://trialsearch.who.int/</a>