Novavax COVID-19 Vaccine Policy Statement Clinical Criteria and Guidance

New Zealand National Immunisation Programme

Version 3.2

Te Whatu Ora
Health New Zealand

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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.
Qualified healthcare professional	For the purposes of this document, a qualified healthcare professional is a registered healthcare professional who is acting within their scope of practice and has completed the required Novavax training to be able to discuss the benefits, risks, and alternatives with the consumer.
Novavax Vaccinators	Only fully authorised, pharmacist or provisionally authorised Vaccinators (but not COVID-19 Vaccinators working under supervision) are authorised to administer the Novavax vaccine. Fully authorised, pharmacist or provisionally authorised vaccinators must complete the required training module prior to administering the Novavax vaccine.

Introduction

COVID-19 vaccines are being rolled out in Aotearoa New Zealand through the National Immunisation Programme (Programme) overseen by the Ministry of Health (Ministry). COVID-19 vaccinations are 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.

1) The Pfizer/BioNTech COVID-19 (Pfizer) vaccine has been the only COVID-19 vaccine available in Aotearoa New Zealand since the first quarter of 2021. The Pfizer vaccine is the first line vaccine where there are no contraindications.
2) The Novavax COVID-19 vaccine (Novavax) was granted provisional approval by Medsafe for use in people aged 18 years and over in Aotearoa New Zealand in February 2022, under section 23 of the Medicines Act. Cabinet has since made the decision to also use the Novavax vaccine as a second line vaccine in Aotearoa New Zealand.

Medsafe, New Zealand's medicines and medical devices safety authority, continues to closely monitor all COVID-19 vaccines for safety through pharmacovigilance activities.

CV TAG have advised the eligibility criteria for the Novavax vaccine as outlined in this policy statement.

Purpose

To provide a policy statement on the use of the Novavax vaccine in Aotearoa New Zealand and provide guidance on its use. The policy statement and objectives in this document align with the recommendation from the CV TAG.

This policy statement should be used alongside the Immunisation Handbook 2020, the COVID-19 Vaccine 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.

Equity

In Aotearoa New Zealand, people have differences in health outcomes that are not only avoidable but unfair and unjust. Equity recognises that different people with various levels of advantage require different approaches and resources to get equitable health outcomes.

Overall, Māori and Pacific peoples are impacted more by communicable diseases as well as the social and economic consequences of serious illness. The differential impact is expected to continue or increase as these communities have lower vaccination rates, higher rates of underlying health conditions and disabilities, and high-contact living conditions.

Whānau-based approaches will provide an opportunity to improve delivery and uptake of the COVID-19 vaccine among Māori and Pacific peoples as well as uptake of the wider National Immunisation Schedule.

Policy Statement

The Ministry recommends vaccination to everyone of eligible age in Aotearoa New Zealand. The first line vaccine where there are no contraindications is the Pfizer vaccine. The Novavax vaccine is available as a second line vaccine for consumers who meet the eligibility criteria.

A **prescription** from an authorised prescriber is required when using the Novavax vaccine as a second primary dose (i.e., following a non-Novavax COVID-19 vaccine for dose 1), in accordance with Section 25 of The Medicines Act 1981, as it is considered off-label use.

The vaccine programme requires written consent for all consumers receiving a second primary dose of the Novavax vaccine following a non-Novavax COVID-19 vaccine

The Pfizer vaccine is the preferred booster vaccine in Aotearoa New Zealand. The Novavax vaccine can be administered **without a prescription** as a first and second booster dose from six months following completion of a primary course of a COVID-19 vaccine.

Eligibility Criteria

1	Consumers who are contraindicated to receive the Pfizer vaccine, OR Consumers who would prefer to receive the Novavax vaccine and are currently under the COVID-19 Public Health Response (Vaccinations) Order 2021, OR Consumers who are unvaccinated or incompletely vaccinated and hesitant about receiving the Pfizer vaccine.
Notes	1. The Novavax vaccine is only approved for individuals aged 18 years and older. 2. Clinician or Healthcare professional support is available through the Immunisation Advisory Centre (IMAC) clinical advice line (**0800 466 863**).

Novavax Contraindications and cautions

Contraindication to receiving the Novavax Vaccine	
1	The contraindications for the Novavax vaccine are anaphylaxis to a previous dose of the Novavax COVID-19 vaccine or to a component of the vaccine, as outlined in the vaccine Data Sheet.

Caution to receiving the Novavax Vaccine	
1	A second or subsequent dose of the Novavax vaccine should not be given to those who have experienced a serious adverse event (such as myocarditis or pericarditis) to the first or subsequent dose of any COVID-19 vaccine without seeking advice from a medical professional.

Timing and combination of doses

Timing and combinations of doses for Novavax	
Novavax primary course	Consumers who have received Novavax for their first dose can get their second dose of Novavax at least 21 days after the first dose was administered.
Novavax as a second dose following other COVID-19 vaccines.	Consumers who have received other COVID-19 vaccines (such as Pfizer), should receive the Novavax vaccine at least 28 days after the most recent dose of another COVID-19 vaccine for the primary series.
Novavax as a booster dose	Pfizer (Comirnaty) is the preferred booster vaccine in New Zealand. However, a consumer who is 18 years and older can receive a Novavax booster dose at a minimum of 6 months following the completion of a primary course of a COVID-19 vaccine. Advice for clinicians is also available from IMAC.
Novavax as a second booster dose	Pfizer (Comirnaty) is the preferred second booster vaccine in New Zealand. However, consumers who are 18 years and older, and meet eligibility criteria, can receive a Novavax second booster dose at a minimum of 6 months following the completion of a first booster dose. For further information such as the eligibility criteria please refer to the COVID-19 booster vaccination policy statement. Advice for clinicians is also available from IMAC.
Novavax and other vaccines on the National Immunisation Schedule.	If possible, the COVID-19 vaccination should be given 7-days before or after administering the live-attenuated shingles vaccine (Zostavax), and 3-days before or after the Shingrix or Fluad Quad vaccines. Other vaccines on the National Immunisation Schedule can be given before, after or at the same time as the COVID-19 vaccination.

Policy Statement Objectives

The following section outlines the programme objectives for the different elements of the policy statement related to the Novavax vaccine:

1. Equity
2. Access
3. Use of Novavax
4. Delivery
5. Logistics
6. Correct Procedures
7. Workforce
8. Reporting and Monitoring
9. Post Vaccination

Equity

1. Equity	
1.1	A Provider must ensure sites administering the Novavax vaccine provides equitable opportunity to Māori and Pacific people, other ethnic communities and disabled people per the COVID-19 Vaccine Programme Operating Guidelines.
1.2	A Provider must ensure sites administering COVID-19 vaccines and other vaccines on the Schedule are actively incorporating the principles and intent of Te Tiriti o Waitangi in their practice. Practical steps are available in the COVID-19 Vaccine Programme Operating Guidelines.
1.3	The Programme will ensure equitable access to the Novavax vaccine to consumers throughout New Zealand.

Access

2. Access	
2.1	A Provider must ensure sites administering the Novavax vaccine are easily accessible as per the COVID-19 Vaccine and Immunisation Programme Operating Guidelines.
2.2	The Programme recommends that a Provider will administer the Novavax and the Pfizer vaccine at the same vaccination practice site.
2.3	The Programme will provide consumers with sufficient information that is easily accessible and readable to determine if they are eligible for Novavax. This will be provided through a wide range of channels and languages to promote equitable outcomes.
2.4	The Programme will ensure a consumer can access bookings through bookmyvaccine.nz and Whakarongorau Aotearoa (0800 28 29 26).
2.5	Where provision of Novavax vaccinations is proposed for rural/remote areas a Provider should consider initiatives which may assist access for consumers. Such initiatives could include and are not limited to liaising with local communities to assist with publicity, arranging transport for consumers to attend a vaccination site and hours of operation. Initiatives increasing uptake will also contribute to the minimisation of vaccine waste.
2.6	A Provider may provide walk-in options for sites administering Novavax vaccines. Walk-in sites allow consumers to receive their vaccination without the need to book an appointment in advance.
2.7	The Programme will ensure equitable access to the Novavax vaccine to consumers throughout New Zealand.

Use of Novavax

3. Use of Novavax			
		Who can administer?	**Administration requirements**
3.1	**Novavax as:** **A first primary dose** **and** **A second primary dose (following a Novavax first dose)**	• Fully authorised vaccinators • Pharmacist vaccinators • Provisional vaccinators • COVID-19 vaccinators working under supervision	• No prescription required. • Standard informed consent procedures as per the COVID-19 Vaccine and Immunisation Programme Operating Guidelines apply to all ages.
3.2	**Novavax as a second primary dose following a non-Novavax dose**	• Fully authorised vaccinators • Pharmacist vaccinators • Provisional vaccinators (but not COVID-19 vaccinators working under supervision).	• It is required that the administration of the Novavax vaccine as a second primary dose following a non-Novavax COVID-19 vaccine is prescribed by an authorised prescriber, in accordance with Section 25 of The Medicines Act 1981, as it is considered off-label use. • The vaccine program requires written consent for all consumers receiving a second primary dose of the Novavax vaccine following a non-Novavax COVID-19 vaccine for dose 1.
3.3	**Novavax as a first or second booster dose**	• Fully authorised vaccinators • Pharmacist vaccinators • Provisional vaccinators • COVID-19 vaccinators working under supervision	Those consumers aged 18 years and older No prescription required if eligibility criteria are met (please refer to the). • Standard informed consent procedures as per the COVID-19 Vaccine and Immunisation Programme Operating Guidelines apply to all ages.

Planning and delivery

4. Planning and delivery	
4.1	Providers will establish a controlled number of sites that are enabled to safely administer Novavax. The location and nature of the provider will be specifically designed to promote access and achieve equity.
4.2	A Site will be staffed with a suitably qualified health professional capable to discuss the clinical suitability of the Novavax vaccine on a person-by-person basis.
4.3	A Provider will ensure sites have access to an authorised prescriber to allow for the use of Novavax as a second dose following another COVID-19 vaccination.
4.4	A Provider will ensure Novavax vaccines are only administered by a fully authorised or a provisionally authorised Vaccinator. For clarity this includes Pharmacist Vaccinators but not COVID-19 Vaccinators working under supervision.
4.5	A Provider where possible will minimise wastage of the Novavax vaccine by vaccinating consumer in cohorts.

Logistics

5. Logistics	
5.1	The Programme will ensure the distribution of the vaccine will follow the programme requirements on handling and cold chain management of the Novavax vaccine.
5.2	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.
5.3	The Programme will verify conformance to relevant standards and recommended practice within the domestic logistics warehousing and distribution supply chain.
5.4	A Provider will ensure that the handling and cold chain management of the Novavax are followed.

5.5	A Provider will ensure that vaccine is planned, ordered, receipted and Stock on Hand updated (stock consumed) through the CIR Inventory system replicating the existing process for the Pfizer vaccine.
5.6	A Provider will ensure that good inventory management practices are followed, replicating the existing process for the Pfizer vaccine.

Correct procedures

6. Correct procedures	
6.1	A Provider will ensure they meet the National Standards for Vaccine Storage and Transportation for Immunisation Providers (2017) and the 2021 Addendum.
6.2	The Programme will make available the COVID-19 Service Standards and the COVID-19 Vaccine and Immunisation Programme Operating Guidelines with updated Novavax resources.
6.3	A Provider will ensure that the Novavax Vaccination screening and guidance form from IMAC is followed.
6.4	A Provider will ensure written consent is recorded.
6.6	A Provider will ensure all Novavax vaccinations are correctly recorded in the CIR.
6.7	The programme and providers will verify conformance to relevant standards and recommended practice is followed.
6.8	A Provider will ensure the correct safety requirements are met for the Novavax vaccine.
6.9	A Provider will have a local standard operating procedure for the preparation and administration of Novavax vaccine.

Workforce

7. Workforce	
7.1	IMAC has available the necessary training collateral, and updates to the clinical guidance within the Immunisation Handbook.
7.2	A Provider will ensure only fully authorised or provisionally authorised Vaccinators (this includes Pharmacist Vaccinators but not COVID-19 Vaccinators working under supervision) administer the Novavax vaccine.
7.3	IMAC has available a Novavax training module.
7.4	Novavax Vaccinators must complete the required training module prior to administering Novavax vaccine.

Reporting and monitoring

8. Reporting and monitoring	
8.1	The Programme will provide the same reporting and monitoring channels for the Novavax vaccine.
8.2	A Provider will report Novavax vaccine usage to allow accuracy of waste reporting
8.3	A Provider will report Novavax vaccine supply to allow accuracy of waste reporting.
8.4	The Programme will monitor levels of Novavax vaccine use.
8.5	The Programme will report levels of Novavax vaccine waste.

Post Vaccination monitoring

9. Post Vaccination monitoring	
9.1	A Provider will report any Adverse Event Following Immunisation (AEFI) as per the COVID-19 Vaccine Operating Guidelines.
9.2	The Programme will provide AEFI reporting in-line with the regulatory requirements for Novavax in the standard reporting channels.
9.3	The Programme will not include consumers who have been vaccinated with Novavax in the proactive post event monitoring (using the post vaccination symptom check).
9.4	A Provider will support that all known Novavax adverse events will be reported to the Centre for Adverse Reactions Monitoring (CARM).

References

Nuvaxovid COVID-19 Vaccine. 2021. New Zealand Data Sheet. Christchurch: Biocelect Pty Ltd. Retrieved from: https://www.medsafe.govt.nz/profs/Datasheet/n/Nuvaxovidinj.pdf

Ministry of Health. 2019. National Standards for Vaccine Storage and Transportation for Immunisation Providers (2nd edition). Wellington: Ministry of Health. Retrieved from: https://www.health.govt.nz/publication/national-standards-vaccine-storage-and-transportation-immunisation-providers-2017

Ministry of Health. 2020. Immunisation Handbook. Wellington: Ministry of Health. Retrieved from: https://www.health.govt.nz/publication/immunisation-handbook-2020

Ministry of Health. 2021. COVID-19 Vaccine Operating Guidelines. Wellington: Ministry of Health. Retrieved from:: 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

Ministry of Health. 2021. Service Standards. Wellington: Ministry of Health. Retrieved from: 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