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COVID-19 Immunisation   
Policy Statement

Aotearoa New Zealand

National Immunisation Programme

Version 5.0

# Document Version Control

### Revision history

|  |  |  |  |
| --- | --- | --- | --- |
| Version | Date | Section/Appendix | Update |
| V1.0 | October 2022 | New document | The National Immunisation Programme (Te Whatu Ora) has prepared this document as a comprehensive COVID-19 Immunisation Policy Statement outlining the operational minimum requirements for the safe use of COVID-19 vaccines. This policy document replaces all other covid policy documents and combines all relevant COVID-19 Immunisation policies. |
| V2.0 | November 2022 | Comirnaty (Pfizer) COVID-19 vaccine | Updated second booster eligibility age range change for Māori and Pacific adults aged 40 to 49 years. |
| V3.0 | February 2023 | Comirnaty (Pfizer) and Nuvaxovid (Novavax) | Maroon top Comirnaty added  Reformatted eligibility criteria for Comirnaty and Nuvaxovid  Removed section ‘About written consent forms’ please refer to Operating Guidelines |
| V4.0 | February 2023 | Comirnaty (Pfizer) | Section updated to support the vaccine exchange to Pfizer Comirnaty grey top |
| V5.0 | March 2023 | Comirnaty (Pfizer)  Nuvaxovid (Novavax) | Sections updated to support dose interval changes  Booster terminology updated to “additional booster dose” |

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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. |
| Concomitant vaccination | Concomitant vaccination refers to administration of more than one vaccination at the same time.  Concomitant vaccination aims to provide optimal protection against disease as quickly as possible by completing a person’s recommended vaccination schedule in the shortest but most effective time frame.  Most routine vaccines can be safely and effectively administered at the same visit. When a person is delayed in their immunisation schedule, administration of multiple vaccines at the same visit ensures catch-up immunisation. |
| 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 Aotearoa New Zealand data sheet. |
| Comirnaty | Comirnaty (Pfizer-BioNTech) refers to the range of formulations of the COVID-19 vaccine made by Pfizer-BioNTech (Grey cap 30mcg 12+, Grey cap 15/15mcg Original/Omicron BA.4/5 Bivalent 16+, orange cap 10mcg 5-11 years, maroon cap 3mcg 6 months – 4 years). |
| [Medicines Act 1981 section 25](https://www.legislation.govt.nz/act/public/1981/0118/latest/DLM55417.html) | Section 25 of the Medicines Act. |
| Medsafe | Medsafe is the Aotearoa 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 Aotearoa New Zealand. |
| Medsafe Approval of a Clinical Trial under [section 30 of the Medicines Act 1981](https://www.legislation.govt.nz/act/public/1981/0118/latest/DLM55429.html?search=sw_096be8ed81c5751b_section+30_25_se&p=1) | 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](https://www.legislation.govt.nz/act/public/1981/0118/69.0/DLM55054.html), or provisional consent under [section 23](https://www.legislation.govt.nz/act/public/1981/0118/69.0/DLM55061.html) of the [Medicines Act 1981](https://www.legislation.govt.nz/act/public/1981/0118/latest/whole.html). |
| National Immunisation Schedule | The National Immunisation Schedule is the series of publicly funded vaccines available in Aotearoa New Zealand. Some vaccines are also offered as part of an extended immunisation programme for targeted special groups in response to a recognised need. For further information refer to the [Immunisation Handbook 2020](https://www.health.govt.nz/our-work/immunisation-handbook-2020/introduction#table1). |
| Nuvaxovid | Nuvaxovid (Novavax) refers to the formulation of the COVID-19 vaccine for 12 years and older. |
| 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 COVID-19 vaccine training to be able to discuss the benefits, risks, and alternatives with the consumer. |

# Introduction

COVID-19 vaccines have been rolled out in Aotearoa New Zealand through the National Immunisation Programme (the Programme) overseen by Te Whatu Ora – Health New Zealand (Te Whatu Ora). 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) from the Ministry of Health continuously reviews evidence and provides advice to the Programme.

This policy statement includes advice on the Pfizer-BioNTech and Novavax COVID-19 vaccines and outlines the minimum requirements in the operational setting as it relates to these vaccines and other associated matters including informed consent.

# Background and context

Te Whatu Ora recommends COVID-19 vaccination for everyone of eligible age in Aotearoa New Zealand. The Comirnaty COVID-19 vaccines are the first line vaccines where the consumer has no contraindications.

Medsafe, Aotearoa New Zealand Medicines and Medical Devices Safety Authority, continues to closely monitor the safety of the COVID-19 vaccines through pharmacovigilance.

The CV TAG has advised the eligibility criteria for the COVID-19 vaccines as outlined in this policy statement.

# Purpose

To provide a policy statement on the use of the COVID-19 vaccines in Aotearoa New Zealand and provide guidance on their use. 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](https://www.health.govt.nz/our-work/immunisation-handbook-2020), the  [National Immunisation Programme Operating Guidelines,](https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals/covid-19-vaccine-operating-and-planning-guidelines) the [COVID-19 Vaccine Immunisation Programme Service Standards](chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https:/www.health.govt.nz/system/files/documents/pages/covid-19-vaccine-immunisation-programme-service-standards-29oct2021.pdf) and other relevant [policy statements](https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals/covid-19-vaccine-policy-statements-and-clinical-guidance) available on the Ministry of Health’s website.

**Te Tiriti o Waitangi**

Te Whatu Ora has a responsibility to contribute to the Crown meeting its obligations under Te Tiriti o Waitangi (Te Tiriti). The principles of Te Tiriti o Waitangi, as articulated by the Courts and the Waitangi Tribunal provide the framework for how we will meet our obligations under Te Tiriti in the National Immunisation Programme (the Programme).

**Tino rangatiratanga**

The guarantee of tino rangatiratanga, which provides for Māori self-determination and Mana Motuhake in the design, delivery, and monitoring of health and disability services*.*

**Equity**

The principle of equity, which requires the Crown to commit to achieving equitable health outcomes for Māori.

**Active protection**

The principle of active protection, which requires the Crown to act, to the fullest extent practicable, to achieve equitable health outcomes for Māori. This includes ensuring that it, its agents, and its Treaty partner are well informed on the extent, and nature, of both Māori health outcomes and efforts to achieve Māori health equity.

**Partnership**

The principle of partnership, which requires the Crown and Māori to work in partnership in the governance, design, delivery, and monitoring of health and disability services. Māori must be co-designers, with the Crown, of the primary health system for Māori.

Meeting our obligations under Te Tiriti is necessary for the overall aim of Pae Ora (healthy futures for Māori) under He Korowai Oranga (the Māori Health Strategy).

**Options**

The principle of options, which requires the Crown to provide for and properly resource kaupapa Māori health and disability services. Furthermore, the Crown is obliged to ensure that all health and disability services are provided in a culturally appropriate way that recognises and supports the expression of Hauora Māori models of care.

# 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, Pacific and Tāngata whaikaha 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. These communities may face inequitable access to appropriate healthcare services, be disproportionately impacted by COVID-19 and/or be at risk of more severe illness.

Whānau-based approaches, alongside the provision of accessible vaccination services and communications, will provide an opportunity to improve delivery and uptake of the COVID-19 vaccine among Māori, Pacific and Tāngata whaikaha peoples as well as uptake of the wider National Immunisation Schedule.

**Note:** ‘Disabled’ has been translated as ‘Tāngata whaikaha’, which means to enable people and is mana enhancing, to have strength, to have ability, otherly abled. This word was created with the Māori disabled community and has a deliberate emphasis on gaining strength and ability.

# Policy Statement

Te Whatu Ora recommends eligible people stay up to date with their COVID-19 vaccinations. A primary course of two doses of COVID-19 vaccine followed by an additional booster dose of COVID-19 vaccine is recommended for those that are eligible. Those at risk may also be eligible for a third primary dose and/or another additional booster dose. For further information on COVID-19 vaccinations, please refer to the [Ministry of Health website](https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines).

As with any vaccine, being up to date with your vaccinations (based on age, eligibility, and other factors) may not mean you’ll be fully protected from infection, however it significantly reduces your chances of becoming seriously ill or ending up in hospital. This is particularly if you have the full course (two doses for Comirnaty and Nuvaxovid) and an additional booster dose (one or more, depending on your eligibility).

Comirnaty is the preferred COVID-19 vaccine for use in Aotearoa New Zealand because of its safety and effectiveness profile, however Nuvaxovid is also available for use in Aotearoa New Zealand.

## Prescription and Informed Consent

As part of the informed consent process, all consumers must be fully informed of the benefits and potential risks of the COVID-19 vaccine. This consent may be verbal unless specified in **Appendix One**. For a summary of consent and prescription please refer to **Appendix One**.

For further information on informed consent see the [Immunisation Handbook section 2.1.2](https://www.health.govt.nz/our-work/immunisation-handbook-2020/2-processes-safe-immunisation) and the [Code of Rights Health and Disability Commissioner](https://www.hdc.org.nz/your-rights/the-code-and-your-rights/)

A prescription from an authorised prescriber is required when a vaccine is being administered off-label under [section 25 of the Medicines Act 1981](https://www.legislation.govt.nz/act/public/1981/0118/latest/DLM55417.html), such as when an approved medicine is being used for an un-approved indication. However, no prescription is required if the administration is authorised under [section 34A of the Medicines Act 1981](https://www.legislation.govt.nz/act/public/1981/0118/latest/whole.html#LMS711105) which 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 vaccine data sheet.

# Policy Statement Objectives

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

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

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| * 1. Equity | |
| 1.1 | A provider must ensure sites administering COVID-19 vaccines provides equitable opportunity to Māori and Pacific people, other ethnic communities, and people with disabilities as per the [National Immunisation Programme Operating Guidelines.](https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals/covid-19-vaccine-operating-and-planning-guidelines#operate) |
| 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 [[National Immunisation Programme Operating Guidelines](https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals%23operate)](https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals/covid-19-vaccine-operating-and-planning-guidelines#operate). |

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| * 1. Access | |
| 2.1 | A provider should ensure sites administering vaccines are easily accessible and there is enough physical space as per the [COVID-19 Vaccine and Immunisation Programme Operating Guidelines](https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals%23operate). This includes space to accommodate whānau groups to have their vaccines together. |
| 2.2 | The Programme recommends that a provider will administer the COVID-19 vaccines and other vaccines that can be given concomitantly at the same vaccination site where possible. |
| 2.3 | The Programme will provide consumers with sufficient information that is easily accessible and readable to determine if they are eligible for a COVID-19 vaccination. 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 COVID-19 vaccination 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 COVID-19 vaccines. Walk-in sites allow consumers to receive their vaccination without the need to book an appointment in advance. |

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| * 1. Planning and Delivery | |
| 3.1 | Providers will establish sites that are enabled to safely administer the COVID-19 vaccines. The location and nature of the provider will be specifically designed to promote access and achieve equity, for example wheelchair access, longer clinic hours or clinic hours outside business hours. |
| 3.2 | The Programme will plan to optimise the usage of the vaccines through all the various phases of the Programme. |
| 3.3 | The provider will forecast demand for vaccines according to the health district forecast and allocation plans. |
| 3.4 | The Programme and providers will plan to have processes and procedures in place to optimise the usage of the vaccines. |
| 3.5 | No direct contact will be made with young people under the age of 16 to promote or otherwise communicate about COVID-19 vaccination. This includes any invitation to be vaccinated or any outbound calls. |

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| * 1. Logistics | |
| 4.1 | The Programme will ensure an equitable distribution of the COVID-19 vaccines and will follow the Programme requirements on handling and cold chain management of the COVID-19 vaccines. |
| 4.2 | 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. |
| 4.3 | The Programme will verify conformance to relevant standards and recommended practice within the domestic logistics warehousing and distribution supply chain. |
| 4.4 | A provider will ensure that the handling and cold chain management of the COVID-19 vaccines are followed as per [Vaccine Storage and Transportation for Immunisation Providers (2017)](https://www.health.govt.nz/publication/national-standards-vaccine-storage-and-transportation-immunisation-providers-2017) and [Annual Cold Chain Management Record (2017)](https://www.health.govt.nz/publication/annual-cold-chain-management-record) |
| 4.5 | A provider will ensure that vaccine is planned, ordered, receipted, and stock on hand updated (stock consumed) through the CIR (COVID Immunisation Register) Inventory system. |
| 4.6 | A provider will ensure that good inventory management practices are followed. |

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| * 1. Correct Procedures | |
| 5.1 | The Programme and providers will verify conformance to relevant standards and recommended practice is followed to increase vaccine usage and reduce the risk of vaccine waste. |
| 5.2 | The Programme will provide a reporting system embedded in CIR for providers to record vaccine use and waste. Further information on vaccine waste performance and categories refer to **Appendix Four.** |
| 5.3 | The Programme reporting on waste will be categorised as either unopen vaccine wastage or open vaccine wastage, as per the World Health Organization Waste Definitions [[1]](#footnote-2). Further information on waste is in **Appendix Four.** |
| 5.4 | A provider will ensure they meet the [Vaccine Storage and Transportation for Immunisation Providers (2017)](https://www.health.govt.nz/publication/national-standards-vaccine-storage-and-transportation-immunisation-providers-2017). |
| 5.5 | The Programme will make available the COVID-19 [Service Standards](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) and the [COVID-19 Vaccine Operating Guidelines](https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals/covid-19-vaccine-operating-and-planning-guidelines#operate) with updated COVID-19 vaccine resources. |
| 5.6 | A provider will ensure that the correct [COVID-19 vaccination screening and guidance form](https://covid.immune.org.nz/sites/default/files/2021-09/Pre-vaccination%20screening%20and%20guidance%20form.pdfhtmlfile/Shell/Open/Command) from the IMAC is followed. |
| 5.7 | The provider is required to ensure meaningful and appropriate informed consent is received from the consumer as outlined in the [Code of Health and Disability Services Consumers Rights](https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/). This includes providing the latest post vaccination information both verbally and written to the consumer.  A provider will ensure this informed consent is recorded in CIR including the person who has provided legal consent for the consumer as appropriate.  Further guidance on informed consent can be found in the [Immunisation Handbook section 2.1.2](http://www.health.govt.nz/our-work/immunisation-handbook-2020/2-processes-safe-immunisation) |
| 5.8 | A provider will ensure all COVID-19 vaccinations are correctly recorded in a timely fashion in CIR. |
| 5.9 | A provider will ensure the relevant standards, recommended practice and correct safety requirements are met for administration of the COVID-19 vaccines. |
| 5.10 | A provider will have a local standard operating procedure for the preparation and administration of COVID-19 vaccines. |

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| * 1. Workforce | |
| 6.1 | The IMAC provides the necessary training collateral, and updates to the clinical guidance within the [[[Immunisation Handbook 2020](https://www.health.govt.nz/our-work/immunisation-handbook-2020)](https://www.health.govt.nz/publication/immunisation-handbook-2020)](https://www.health.govt.nz/publication/immunisation-handbook-2020) including vaccine training modules. |
| 6.2 | A provider will ensure vaccinators (this includes pharmacist vaccinators, authorised vaccinators, provisional vaccinators, vaccinating health workers, and COVID-19 vaccinators working under supervision) administer vaccines within their scope of practice based on their training and assessment completed. Vaccinators administering COVID-19 vaccines must complete the appropriate IMAC training [module](https://lms.immune.org.nz/course/20258/covid-19-vaccinator-education-course-pfizerbiontech-vaccine-v10) prior to administering these vaccines. |

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| * 1. Reporting and Monitoring | |
| 7.1 | The Programme will provide the reporting and monitoring channels for the COVID-19 vaccines. |
| 7.2 | A provider will report COVID-19 vaccine usage to allow accuracy of waste reporting. |
| 7.3 | A provider will report COVID-19 vaccine supply to allow accuracy of waste reporting. |
| 7.4 | The Programme will monitor levels of COVID-19 vaccine use. |
| 7.5 | The Programme will report levels of COVID-19 vaccine waste. |

**Note:** Further information on waste is in **Appendix Four.**

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| 1. Post Vaccination Monitoring | |
| 8.1 | A provider will report any Adverse Event Following Immunisation (AEFI) to the [Centre for Adverse Reactions Monitoring](https://nzphvc.otago.ac.nz/carm/) (CARM) using the COVID-19 vaccine specific [form](https://report.vaccine.covid19.govt.nz/s/) as per the [COVID-19 Vaccine Operating Guidelines](https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals/covid-19-vaccine-operating-and-planning-guidelines#operate). |
| 8.2 | The Programme will provide AEFI reporting in-line with the regulatory requirements for COVID-19 vaccines in the standard reporting channels. |
| 8.3 | A provider will report all known COVID-19 vaccine related incidents to the Programme as outlined in the [COVID-19 Vaccine Operating Guidelines](https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals/covid-19-vaccine-operating-and-planning-guidelines#operate). |

# Comirnaty (Pfizer BioNTech) COVID-19 Vaccines

The Comirnaty vaccines are the first line of COVID-19 vaccines for Aotearoa New Zealand.

Appendices relevant to this section:

* [Appendix one](#_Appendix_One_Consent)

| Comirnaty Eligibility and Timing of Doses | |
| --- | --- |
| **Discontinued** | From 1 March 2023 the Pfizer-BioNTech Comirnaty 30mcg purple cap vaccine will no longer be available. Please follow directions included in the Comirnaty 30mcg non dilute grey cap vaccine delivery box or contact the District Logistics lead.  Please ensure that there is no stock left in your vaccine fridge.  If this vaccine is administered after 28th February 2023 follow the incident management process outlined in the Operating Guidelines Appendix I **which will include contacting IMAC for clinical advice.**  **Note:** For sites who are yet to receive deliveries of the new Comirnaty products, **contact IMAC** for clinical advice prior to administering a Comirnaty 30 mcg purple cap dose. |
| Comirnaty 30mcg  12+ years  Grey cap  Do not dilute  Primary course | **Primary course (first and second dose) eligibility** |
| Consumers aged 12 years and over who are unvaccinated or incompletely vaccinated for a primary course of the Comirnaty vaccine.   |  |  | | --- | --- | | Timing for primary course of Comirnaty 30 mcg (12+ years) | | | First primary dose | Date given | | Second primary dose | At least **3 weeks (21 days)** after the first primary dose |   For consumers aged 12 to 18 years, the recommended dose interval is **8 weeks (56 days)** between the first and second doses.  Consumers who have received one dose of another COVID-19 vaccine (such as Nuvaxovid), should receive the Comirnaty vaccine as their second dose, at least **4 weeks** (**28 days)** after the most recent dose of the other COVID-19 vaccine. |
| **Third primary dose eligibility (prescription required)** |
| A third primary dose can be prescribed by an authorised prescriber in accordance with [Section 25 of The Medicines Act 1981](https://www.legislation.govt.nz/act/public/1981/0118/latest/DLM55417.html) for severely immunocompromised consumers, aged 12 years and over.   |  |  | | --- | --- | | Timing for third primary dose of Comirnaty 30 mcg (12+ years) | | | Third primary dose | At least **8 weeks (56 days)** after the second primary dose |   Clinical judgement should be applied by the authorised prescriber to determine whether a third primary dose is required for conditions or medicines that are not listed and are associated with severe immunocompromise.  See the [Immunisation Handbook Section 5.5.8](https://www.health.govt.nz/our-work/immunisation-handbook-2020/5-coronavirus-disease-covid-19#23-5) for guidance on prescribing a third primary dose including indications.  **Note:** Comirnaty 15/15mcgOriginal/ Omicron BA.4/5 is the recommended formulation for additional doses in Aotearoa New Zealand. If a consumer requests Comirnaty 30 mcg to be used instead this needs to be discussed as part of the informed consent conversation and requires a prescription if administered at less than 6 months after previous dose. |
| Comirnaty 10mcg  5-11 years  Orange cap  Requires dilution  Primary course | **Primary course eligibility** |
| Consumers aged 5 to 11 years who are unvaccinated or incompletely vaccinated for a primary course, and have a parent, legal guardian, or caregiver to provide consent for them to be vaccinated with the Comirnaty orange cap vaccine.  Further information on informed consent for consumers aged 5 to 11 years is in **Appendix Three** or in the [Immunisation Handbook section 2.1.2](http://www.health.govt.nz/our-work/immunisation-handbook-2020/2-processes-safe-immunisation)   |  |  | | --- | --- | | Timing for primary course of Comirnaty 10 mcg (5 – 11 years) | | | First primary dose | Date given | | Second primary dose\* | At least **8 weeks (56 days)** after the first primary dose |   \*In the event of a community COVID-19 outbreak, international travel posing risk of COVID-19 infection or if medically indicated this interval may be shortened to a minimum of 3 weeks (21 days). The consumer’s healthcare provider or IMAC may be contacted for clinical guidance if required.  **Note:** If a child receives the Comirnaty orange cap vaccine (for ages 5 to 11 years) and then turns 12 years old before their second dose, they should receive the Comirnaty 30 mcg grey cap vaccine (12+) for any subsequent doses. |
| **Third primary dose eligibility (prescription required)** |
| A third primary dose can be prescribed by an authorised prescriber in accordance with [Section 25 of The Medicines Act 1981](https://www.legislation.govt.nz/act/public/1981/0118/latest/DLM55417.html) for severely immunocompromised consumers, aged 5 years and over.   |  |  | | --- | --- | | Timing for third primary dose of Comirnaty 10 mcg (5 – 11 years) | | | Third primary dose | At least **8 weeks (56 days)** after the second primary dose |   Clinical assessment should be applied by the authorised prescriber to determine whether a third primary dose is required for conditions or medicines that are not listed and are associated with severe immunocompromise.  See the [Immunisation Handbook Section 5.5.8](https://www.health.govt.nz/our-work/immunisation-handbook-2020/5-coronavirus-disease-covid-19#23-5) for guidance on prescribing a third primary dose including indications. |
| Comirnaty 3mcg  6 months to 4 years  Maroon cap  Requires dilution  Primary course | **Primary course eligibility** |
| Consumers aged 6 months to 4 years who meet the [current eligibility criteria.](https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-ages-6-months-4-years-old)  These consumers should also be previously unvaccinated or incompletely vaccinated with a COVID-19 vaccine primary course, and have a parent, legal guardian, or caregiver to provide consent for them to be vaccinated with the Comirnaty maroon cap vaccine.   |  |  | | --- | --- | | Timing for primary course of Comirnaty 3 mcg (6 months – 4 years) | | | First primary dose | Date given | | Second primary dose | At least **3 weeks (21 days)** after the first primary dose | | Third primary dose | At least **8 weeks (56 days)** after the second primary dose |   **Note:** Children under 5 years receive the Comirnaty maroon cap. The child who starts the three-dose primary course under the age of 5 years, receives three doses even if they turn 5 after the first, or second dose. Children under 5 years receive the Comirnaty maroon cap and children **over 5 years receive Comirnaty orange cap**, even when previous doses 1 or 2 were Comirnaty maroon cap.  For further information refer to the Immunisation Handbook or call 0800IMMUNE (0800 466863).  Further information on informed consent for consumers aged 6 months to 11 years is in **Appendix Three** or in the [Immunisation Handbook section 2.1.2](http://www.health.govt.nz/our-work/immunisation-handbook-2020/2-processes-safe-immunisation) |
| Comirnaty 15mcg/ 15mcg  Original/ Omicron BA.4/5  16+ years for those eligible  Do not dilute  Additional booster dose | **Additional booster dose eligibility** |
| Additional dose eligibility criteria can be found on the [Ministry of Health website.](https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-boosters)   |  |  | | --- | --- | | Timing for Comirnaty 15/15 mcg additional booster doses | | | Additional booster dose  For eligible consumers aged 16 years and over (and aged 12 to 15 years who are severely immunocompromised with a prescription and written consent). | At least **6 months (180 days**) after the last dose of COVID-19 vaccine. |   **Note:** This includes consumers who may be pregnant or are severely immunocompromised and have received a 3-dose primary course.  Clinical criteria in support of additional booster dose eligibility can be found on the [Ministry of Health website.](https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-boosters/covid-19-vaccine-bivalent)  **Note**: if being used as a primary dose, a prescription and written consent is required. Refer to Appendix 1 for consent and prescription requirements. |

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| Comirnaty Contraindications |
| All Comirnaty vaccines are contraindicated in individuals with known severe allergic reaction (ie, anaphylaxis) to a previous dose of Comirnaty vaccine or any component of the vaccine as outlined in the vaccine datasheets. |

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| Caution to receiving the Comirnaty Vaccine |
| A second or subsequent dose of the Comirnaty vaccine should not be given to those who have experienced a serious vaccine induced adverse event (eg, myocarditis or pericarditis) to the first or subsequent dose of any COVID-19 vaccine without seeking advice from a medical professional.  Note: A vaccine dose, if due, should be postponed for 3 months after a COVID-19 infection. Clinical discretion can be applied when considering vaccination prior to three months after infection. |

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| Comirnaty Concomitant Vaccine usage | |
| Comirnaty and other vaccines on the National Immunisation Schedule | The Comirnaty vaccine may be concomitantly administered at any time before, after, or at the same time as influenza, MMR, HPV, Diphtheria/Tetanus/Pertussis, and other vaccines in the National Immunisation Schedule. |

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| --- | --- |
| Administration of the Comirnaty vaccine | |
| **Comirnaty 30mcg (12+years) &** **Comirnaty 15mcg/15mcg Original/ Omicron BA.4-5 (16+ years)** | * Fully Authorised Vaccinators * Pharmacist Vaccinators * Provisional Vaccinators * COVID-19 Vaccinators working under supervision and Vaccinating Health Worker. |
| **Comirnaty 10mcg** **(5 – 11 years)** | * Fully Authorised Vaccinators * Pharmacist Vaccinators * Provisional Vaccinators  Note: COVID-19 Vaccinators working under supervision are not authorised to vaccinate this age group. |
| **Comirnaty 3mcg** **(6 months – 4 years)** | * Fully Authorised Vaccinators\* * Pharmacist Vaccinators\* * Provisional Vaccinators **deltoid only**   \*Must have completed assessment to administer vaccines into the vastus lateralis if this route is to be used. The vastus lateralis assessment is not available for provisional vaccinators. Note: COVID-19 Vaccinators working under supervision are not authorised to vaccinate this age group. |

Further information on authorisation and vaccinator criteria can be found in the [Immunisation Handbook Appendix 4.](https://www.health.govt.nz/our-work/immunisation-handbook-2020/appendix-4-authorisation-and-criteria-vaccinators)

# Nuvaxovid (Novavax) COVID-19 Vaccine

The Nuvaxovid vaccine is the second line COVID-19 vaccine for Aotearoa New Zealand.

Appendices relevant to this section:

* [Appendix one](#_Appendix_One_Consent)

| Nuvaxovid Eligibility and Timing of doses | |
| --- | --- |
| Nuvaxovid (12+)  Do not dilute  Blue cap  Primary and/or additional booster dose A picture containing beverage, drinking water  Description automatically generated | **Primary course (first and second dose) eligibility** |
| Consumers who are aged 12 years and older and unvaccinated or incompletely vaccinated who are contraindicated to receive the Comirnaty COVID-19 vaccine or people who prefer to receive Nuvaxovid.   |  |  | | --- | --- | | Timing for primary course of Nuvaxovid only (12+ years and over) | | | First primary dose | Date given | | Second primary dose | At least **3 weeks (21 days)** after the first primary dose |   Consumers who have received a first dose of another COVID-19 vaccine (such as Comirnaty), should receive the Nuvaxovid vaccine **28 days** after the most recent dose of the other COVID-19 vaccine.  A prescription from an authorised prescriber is required when using the Nuvaxovid vaccine as a second primary dose for the primary course. |
| **Third primary dose eligibility (prescription required)** |
| A third primary dose can be prescribed by an authorised prescriber in accordance with [Section 25 of The Medicines Act 1981](https://www.legislation.govt.nz/act/public/1981/0118/latest/DLM55417.html) for severely immunocompromised consumers, aged 12 years and over.   |  |  | | --- | --- | | Timing for third primary dose of Nuvaxovid (18 years and over) | | | Third primary dose | At least **8 weeks (56 days)** after the second primary dose |   See the [Immunisation Handbook 2020 for details of eligibility](https://www.health.govt.nz/our-work/immunisation-handbook-2020/5-coronavirus-disease-covid-19#table23-1).  Clinical judgement should be applied by the authorised prescriber to determine whether a third primary dose is required for conditions or medicines that are not listed and are associated with severe immunocompromise. |
| **Additional booster dose eligibility** |
| Additional dose eligibility criteria can be found on the [Ministry of Health website.](https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-boosters)   |  |  | | --- | --- | | Timing for Nuvaxovid additional booster doses | | | Additional booster dose  For eligible consumers aged 18 years and over | At least **6 months (180 days**) after the last dose of COVID-19 vaccine. |   **Note:** Pfizer is the recommended booster during pregnancy as there has been insufficient data on Nuvaxovid during pregnancy. |

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| Nuvaxovid Contraindications |
| The Nuvaxovid vaccine is contraindicated in individuals with known severe allergic reactions (such as anaphylaxis) to any component of the vaccine as outlined in the [vaccine datasheet](https://www.medsafe.govt.nz/profs/Datasheet/n/Nuvaxovidinj.pdf) or a previous dose of the Nuvaxovid vaccine. |

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| Caution to receiving the Nuvaxovid Vaccine |
| A second or subsequent dose of the Nuvaxovid vaccine should not be given to those who have experienced a serious vaccine induced 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.  Note: A vaccine dose, if due, should be postponed for 3 months after a COVID-19 infection. Clinical discretion can be applied when considering vaccination prior to three months after infection. |

|  |  |
| --- | --- |
| Nuvaxovid Concomitant Vaccine usage | |
| Nuvaxovid and other vaccines on the National Immunisation Schedule | The Nuvaxovid vaccine may be concomitantly administered at any time before, after, or at the same time as influenza, MMR, HPV, Diphtheria/Tetanus/Pertussis, and other vaccines. |

|  |  |
| --- | --- |
| Administration of the Nuvaxovid vaccine | |
| A first primary dose  and  A second primary dose (following a Nuvaxovid first dose)  and  Additional booster doses | * Fully authorised vaccinators * Pharmacist vaccinators * Provisional vaccinators |
| Second primary dose (Nuvaxovid) following a non- Nuvaxovid dose  and  Third primary dose (Nuvaxovid) | * Fully authorised vaccinators * Pharmacist vaccinators * Provisional vaccinators * (Not COVID-19 vaccinators working under supervision). |

Further information on authorisation and vaccinator criteria can be found in the [Immunisation Handbook Appendix 4.](https://www.health.govt.nz/our-work/immunisation-handbook-2020/appendix-4-authorisation-and-criteria-vaccinators)

# COVID-19 Trial Vaccines

According to the World Health Organisation (WHO), globally there are over 600 COVID-19 vaccine trials in progress, all proceeding at various phases. These trials help scientists understand the safety and efficacy of current, new, or experimental COVID-19 vaccines. The evidence collected from these clinical trials is then reviewed by national authorities and regulatory agencies for consideration of approval to use.

A small number of New Zealanders have consented to be participants in international clinical trials for experimental COVID-19 vaccines that are not approved by Medsafe. The Programme recognises the importance of representing the Aotearoa New Zealand population in international clinical trials and values their contribution to new COVID-19 vaccine research.

A consumer who is a participant in a COVID-19 vaccine clinical trial may receive the approved national COVID-19 vaccines if they wish.

Receiving a Medsafe-approved COVID-19 vaccine such as Comirnaty following a vaccine clinical trial would require individualised clinical advice, including the consideration of timing of the dose. This can be obtained through their usual health care provider such as a general practitioner with advice available from the Immunisation Advisory Centre (IMAC).

**Note:** Medsafe receives, processes, and evaluates both clinical trials of new medicines and applications to market new vaccines. A Medsafe-approved clinical trial does not mean it is an approved, or provisionally approved vaccine in Aotearoa New Zealand nor does it mean it is approved for use in the Programme.

Vaccine trial participants can only have their vaccine dose information recorded in CIR once the trial vaccine has been added to the WHO ‘vaccines approved by at least one country list’ or the WHO Emergency Use List (EUL). Trial participants need to contact Te Whatu Ora Help Desk to have their trial vaccine recorded in CIR.

# References

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<https://www.medsafe.govt.nz/profs/Datasheet/c/ComirnatyOriginalOmicronBA4-5inj.pdf> (accessed March 2023).

Pfizer New Zealand Limited. COMIRNATY® (orange cap, must dilute) vaccine data sheet. 2022. <https://www.medsafe.govt.nz/profs/Datasheet/c/Comirnaty0.2mlOrangeCapinj.pdf> (accessed March 2023)

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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>

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Ministry of Health. 2021. COVID-19 Vaccine Immunisation 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>

# Appendix One Consent and Prescription for COVID-19 Vaccines

## Comirnaty

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| **Comirnaty 30mcg grey cap (12 years and older)** | | | | | | | | | | |
| **Process step** | | **Primary course dose 1** | | **Primary course dose 2** | | **Primary course dose 3** | | | | **Additional booster dose** |
| **Informed consent**  (Verbal or written must always be recorded in CIR) | | Verbal or written | | Verbal or written | | Written consent**\*\*** | | | | Written consent**\*\*\*\*** |
| **Prescription** | | No | | No | | Yes | | | | Yes |
| **Comirnaty 15mcg/15mcg Original/Omicron BA.4-5 grey cap (16 years and older)** | | | | | | | | | | |
| **Process step** | | **Any primary course dose\*\*** | | | | | **Additional booster dose** | | | |
| **Informed consent**  (Verbal or written must always be recorded in CIR) | | Written consent | | | | | Verbal or written**\*\*\*** | | | |
| **Prescription** | | Yes | | | | | No | | | |
| **Comirnaty 10 mcg orange cap (5 to 11 years)** | | | | | | | | | | |
| **Process step** | | **Primary course dose 1** | | | **Primary course dose 2** | | | **Primary course dose 3** | | |
| **Informed consent**  (Verbal or written must always be recorded in CIR) | | Verbal or written | | | Verbal or written | | | Written consent**\*\*** | | |
| **Prescription** | | No | | | No | | | Yes | | |
| **Comirnaty 3 mcg maroon cap (6 months to 4 years)** | | | | | | | | | | |
| **Process step** | | **Primary course dose 1** | | | **Primary course dose 2** | | | **Primary course dose 3** | | |
| **Informed consent**  (Verbal or written must always be recorded in CIR) | | Verbal or written | | | Verbal or written | | | Verbal or written | | |
| **Prescription** | | No | | | No | | | No | | |
| **Key** | | | | | | | | | | |
| **Approved use of vaccine** | **Off label use of vaccine** | | \*\*Off label additional dose eg, severely immunocompromised third primary dose, extension, replacement.  \*\*\*\*Not recommended as first line additional booster dose in New Zealand | | | | | | \*\*\*Eligibility must be met | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Nuvaxovid (12 years and older) | | | | | | | | |
| Process step | | **Primary Course Dose 1** | | **Primary Course Dose 2** | | **Additional booster dose** | | **Primary course Dose 3\*\*** |
| Informed consent  (Verbal or written must always be recorded in CIR) | | Verbal or written | | Verbal or written | | Verbal or written (18 years and older)**\*\*\*** | | Written consent (12 years and older)**\*\*** |
| Prescription Required | | No | No | | **Yes\*** (2nd Dose only) | No | | Yes |
| Key | | | | | | | | |
| Approved use of vaccine | **Off label use of vaccine** | **\***If first primary dose was not Nuvaxovid.  **\*\***Off-label additional dose eg, severely immunocompromised third-primary dose, extension, replacement. | | | | | **\*\*\*** Eligibility must be met | |

## Nuvaxovid

# Appendix Two Informed consent for people aged 12-15 years

The following outlines the Programme objectives for the different elements of the policy statement related to informed consent for our younger people aged 12-15 years.

1. School-based vaccination
2. Community-based vaccination
3. Facility or residential care-based vaccination

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| School Based Vaccination | |
| 1.1 | All school-based vaccinations will adhere to the Ministry of Health’s [Professional Standards for School-based Immunisation Service Delivery 2016](https://www.health.govt.nz/publication/professional-standards-school-based-immunisation-service-delivery). |
| 1.2 | The Programme will provide age-appropriate information to young people to help inform their decision. This will include after vaccination care and advice. |
| 1.3 | IMAC will provide an online learning module to support healthcare providers with the consent process for younger people. |
| 1.4 | Education providers will provide students, parents and guardians information about the vaccine that aligns with the Ministry of Health guidance and education materials to help inform their decision. |
| 1.5 | School-based vaccination providers will adhere to the [Ministry of Education Informed Consent Guidelines](https://parents.education.govt.nz/assets/Documents/Special-Education/Informed-Consent-Guidelines.pdf) when administering the vaccine, in that written consent is obtained from a parent or guardian prior to vaccine administration and the details recorded in CIR. This includes all students aged 12 years and over. |
| 1.6 | Healthcare providers administering the vaccine will engage with and inform students about the vaccine and confirm the student’s consent prior to vaccination. |
| For further guidance on [School-Based Vaccination refer to the Ministry of Health Professional Standards](http://www.health.govt.nz/publication/professional-standards-school-based-immunisation-service-delivery) | |

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| Community Based Vaccination | |
| 2.1 | Healthcare provider will presume the young person aged 12-15 years is competent unless there is a reason to consider them not to be. The Programme will provide age-appropriate information to young people to help inform their decision. This will include after vaccination care and advice information. |
| 2.2 | Healthcare providers will recognise that young people aged 12-15 years have the right to give informed consent for the vaccination where competent to do so, and their decision is recorded in the CIR. |
| 2.3 | Healthcare providers are required to use their professional judgement to evaluate the young person’s competence, understanding and maturity to form a balanced judgement to ensure they have the ability to provide informed consent. |
| 2.4 | Where a healthcare provider is not satisfied a young person is capable of giving informed consent then either a second opinion should be sought, or parent or guardian informed and written consent obtained. |
| 2.5 | When consent has been appropriately obtained on their behalf, the provider will provide the young people aged 12-15 years with information about the vaccine in an age-appropriate way and respond to and consider their views. |
| 2.6 | The Immunisation Advisory Centre will provide an online learning module to support healthcare providers with the consent process for younger people. |

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| Facility or Residential Care Based Vaccination | |
| 3.1 | Where a young person lives in a residence or supported accommodation, the informed consent will follow their usual process for other medical treatments and vaccination. |
| 3.2 | Healthcare providers must recognise the young person’s views and wishes, and where there is disagreement, consultation with and advice from legal services, and the consumer’s usual healthcare provider would be required. |
| 3.3 | Healthcare providers will utilise supported decision-making tools where appropriate to ensure the consumer has a good understanding of the vaccination and their decision is recorded in the CIR. |

# Appendix Three Informed consent process

Under the [Code of Health and Disability Services Consumers’ Rights](https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/), every consumer has the right to the information they need to make an informed choice or to give informed consent.

For details on which vaccines require written consent please see **Appendix One**.

## Consumers aged 6 months -11 years

A parent, legal guardian, caregiver, or person with an enduring power of attorney will need to accompany a child to their appointment(s) as the responsible adult and be able to provide consent for them to be immunised.

Accommodations must be made to enable parents, legal guardians, caregivers, or an enduring power of attorney to make informed decisions. For example, provision of interpreters, including Aotearoa New Zealand Sign Language interpreters, and information available in preferred languages or formats.

In some situations, a whanaungatanga approach may be required. If a child presents to their vaccination with whānau who cannot provide consent for the child to be immunised, written or verbal consent should be obtained from a parent, legal guardian, or person with an enduring power of attorney prior to administration of the paediatric Comirnaty vaccines.

Where a child is aged 6 months to 11 years and lives in a residence or supported accommodation, the informed consent will follow the usual process for other medical treatments and vaccination.

The Immunisation Advisory Centre (IMAC) will provide information to support healthcare providers with the consent process for children in an online learning module.

## Whanaungatanga (informed consent)

A responsible adult needs to accompany the child to their appointment(s). This may be a parent, adult family member, trusted family friend, legal power of attorney, or whanaungatanga carer.

Consent for vaccination needs to be given by a legal guardian of the child (under 12 years of age).

If the adult who accompanies the child to the appointment is not the child’s legal guardian:

* the vaccinator will need to verbally confirm by phone with a legal guardian that they consent to the child being vaccinated, or
* the responsible adult can bring a signed copy of the COVID-19 vaccination consent form completed by a guardian.

This is standard consent process.

**Consumers aged 12-15 years**

The Programme recommends young people aged 12-15 years discuss the vaccination with whānau or a trusted support person. Young people can find out more information about how the vaccine protects them and answers to questions they may have on the [Ministry of Health website](https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-ages-12-18).

**Community-based vaccination**

A health professional will discuss the vaccination with the young person prior to giving the vaccine and can answer any questions. If the young person has a good understanding, they can say yes or no to getting the vaccine themselves. A parent or caregiver can provide consent if preferred.

**School-based vaccination**

The Programme will align its policy with previous school-based vaccination Programmes and require written consent from the young person’s parent or guardian for all COVID-19 vaccines administered in schools.

**Facility or residential care-based vaccination**

Young people who reside in a care facility or a residence under the care of Oranga Tamariki will follow their usual process for informed consent for other medical treatments and vaccination. For further details of vaccinating consumers aged 12 to 15 years in these sites please refer to **Appendix Two**. See [The Immunisation Handbook Appendix 4](https://www.health.govt.nz/our-work/immunisation-handbook-2020/appendix-4-authorisation-and-criteria-vaccinators) for vaccination authorisation details including age range of consumer for specific vaccines.

Appendix Four  
Vaccine Waste

## Performance

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| **Vaccine Waste Performance** |
| The Programme’s ‘line of sight’ on vaccine usage will be enabled by an efficient, Programme-wide reporting and monitoring system. |
| In delivering the primary objective of the Programme of administering the vaccines to as many of the population across Aotearoa New Zealand who are willing and eligible to receive the vaccine. The Programme recognises there will be vaccine waste due to warranted system and process factors including the influence of human factors[[2]](#footnote-3). |
| While there is no usage measure set for any vaccine, usage will be monitored and reported on to determine actions that can be implemented such that usage may be further increased, and wastage reduced. |

## Categories

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| --- | --- | --- |
| Vaccine Waste Type/Categories | | |
| Cold Chain Excursion | Includes any vial that has breached the National Standards for Vaccine Storage and Transportation for Immunisation Providers. |
| Drop/Damage | Includes any vial that is damaged or dropped. |
| Expired Vial | Includes any vial that is past its expiry date. |
| Other Quality Issue | Includes any vial that does not meet quality requirements, for example, discoloured solution, presence of participate or reduced volume of vaccine, presence of foreign body or contamination |
| Unused | Includes any vial that is unopened and not administered within the required expiry timeframe. |
| Missing Stock | Includes any vial that is not able to be administered as it has been lost, misplaced or stolen. |

1. Human factors examine the relationship between people and the systems with which they interact by focusing on improving efficiency, creativity, productivity and job satisfaction, with the goal of minimising errors. A failure to apply human factors principles in service design or system process is a key aspect of most adverse events in health care. [↑](#footnote-ref-2)
2. Human factors examine the relationship between people and the systems with which they interact by focusing on improving efficiency, creativity, productivity, and job satisfaction, with the goal of minimising errors. A failure to apply human factors principles in service design and system processes is a key aspect of most adverse events in health care. [↑](#footnote-ref-3)