

Appendix 4: Authorisation and criteria of vaccinators

This section provides details around the authorisation of vaccinators. There are three main categories of authorisation: fully authorised, provisionally authorised and COVID-19 vaccinators working under supervision (CVWUS). Pharmacists can vaccinate, having met certain criteria, as either fully authorised or provisionally authorised vaccinators. All vaccinators are required to meet resuscitation requirements as given in section A4.4. See Table A4.1 for details of the criteria and authorisation of each group.

Table A4.1: Details of authorisation criteria, vaccine and age groups by vaccinator type

Note: All vaccinators are required to meet resuscitation requirements (see section A4.4).

Vaccinator type	Authorisation requirements	Profession	Vaccines they may be able to administer	Age groups	Sites for injection	Authority to obtain informed consent
Fully authorised vaccinator	Director-General or Medical Officer of Health (under reg 44A of the Medicines Regulations 1984)	Health professionals with current annual practicing certificate ^a	Vaccines on the National Immunisation Schedule and any other vaccines part of an approved immunisation programme (approved by the Director-General or Medical Officer of Health)	All ages	Vastus lateralis Deltoid	Yes
Pharmacist vaccinator	Pharmacists are enabled to vaccinate pursuant to the Medicines Regulations classifications on completion of full vaccinator training. It is then recommended that they inform the Pharmaceutical Society of New Zealand to be added to the vaccinator database.	Registered Pharmacists Pharmacist interns	Influenza MMR HPV Meningococcal Tdap Zoster	Ages 13 years and over Ages 16–49 years Ages 9–27 years Ages 16 years and over Ages 18 years and over. Pregnant women aged 13 years and over Ages 50 years and over	Deltoid only ^b	Yes
Provisional pharmacist vaccinator MMR, Influenza and COVID 19 ^c	Director-General or Medical Officer of Health (under reg 44A of the Medicines Regulations 1984)	Registered Pharmacists Pharmacist interns	Influenza MMR COVID-19 ^c MMR and influenza	Ages 13 years and over Ages 16 to 49 years Age groups covered in the Ministry approved COVID-19 training Ages 3 years and over	Deltoid only Deltoid only	Yes Yes

Vaccinator type	Authorisation requirements	Profession	Vaccines they may be able to administer	Age groups	Sites for injection	Authority to obtain informed consent
Provisional Vaccinator MMR, Influenza and COVID 19 ^c	Director-General or Medical Officer of Health (under reg 44A of the Medicines Regulations 1984)	Health professionals with current annual practicing certificate ^a	COVID-19 ^c	Age groups covered in the Ministry approved COVID-19 training		
COVID-19 Vaccinator working under supervision (CVWUS)	Director-General or Medical Officer of Health (under reg 44AB of the Medicines Regulations 1984)	Person working under clinical supervision and direction of a suitably qualified health practitioner	COVID-19 vaccines only ^c	Age groups covered in the Ministry approved COVID-19 vaccinator training	Deltoid only	No

- a. Practitioners without a New Zealand practicing certificate may be unable to get indemnity insurance.
- b. Vastus lateralis site can be used provided the vaccinator is competent in the technique and the vaccine data sheet does not preclude it.
- c. Upon completion of appropriate COVID-19 vaccine education course.

A4.1 Protocols for full authorisation of vaccinators and pharmacist vaccinators

A4.1.1 Authority for fully authorised vaccinators¹ and pharmacist vaccinators

A person may be authorised under regulation 44A(2) of the Medicines Regulations 1984 by the Director-General of Health or a Medical Officer of Health to administer a vaccine for the purposes of an approved immunisation programme.²

Regulation 44A(2) stipulates that the person seeking approval must apply in writing to the Director-General or a medical officer of health and provide documentary evidence that they:

- can carry out basic emergency techniques including resuscitation and the treatment of anaphylaxis
- have knowledge of the safe and effective handling of immunisation products and equipment
- can demonstrate clinical interpersonal skills
- have knowledge of the relevant diseases and vaccines to be able to explain the vaccination to the individual, parent or guardian who is to consent to the vaccination on behalf of the individual, to ensure that the individual or parent or guardian of the individual can give informed consent to the vaccination.

The usual protocol requires fully authorised vaccinator applications to be submitted to a medical officer of health in the applicant's local region. Authorisation given under Regulation 44A(2) is valid for a period of two years from the date of authorisation and is subject to such conditions as the Director-General or the Medical Officer of Health thinks fit. During the early stages of the COVID-19 response, the Director of Public Health, in their capacity as a National Medical Officer of Health, authorised all authorised vaccinators and provisional authorised vaccinators to provide National Immunisation Schedule and funded vaccinations (as noted in their authorisation) for those at increased risk of vaccine-preventable disease (as identified in this Immunisation Handbook). This meant they did not need to apply for authorisation in different PHU areas.

Successful applicants will be authorised to administer either all or specific vaccines depending on the training they have completed. Details of the training they must complete is set out in section **Error! Reference source not found..**

¹ Fully authorised vaccinators were previously called 'authorised independent vaccinators'.

² See the Ministry of Health document *Definition of an Approved Immunisation Programme* (available for download from www.health.govt.nz/our-work/preventative-health-wellness/immunisation).

Authority for pharmacist vaccinators

A number of vaccines have been reclassified by the Medicines Classification Committee from prescription medicines to prescription medicine except when administered by pharmacists or registered intern pharmacists who have successfully completed the *Vaccinator Foundation Course* (or any equivalent training course approved by the Ministry of Health, but excluding vaccinators who have completed the *Provisional Vaccinator Foundation Course*) and who comply with the immunisation standards of the Ministry of Health.

The reclassification means that pharmacists and pharmacist interns can administer specific vaccines once they have: successfully completed a Ministry of Health-approved VFC (including the open-book assessment); and are complying with the immunisation standards as described in Appendix 3 of this Handbook. Pharmacist and intern pharmacist vaccinators are expected to be aware of which vaccines have been reclassified for their scope (see Table A4.1).

Due to these classifications, pharmacist vaccinators are not required to apply to a medical officer of health for authorised vaccinator status to be able to administer vaccines that have been reclassified. However, the expectation is they notify Pharmaceutical Society of New Zealand (PSNZ) when they have completed the requirements specified above, including the course completion date (see Completion of authorisation).

Like all vaccinators, pharmacists and pharmacist interns must attend an approved vaccinator update every two years to be able to continue to administer vaccines. The training required for pharmacists and intern pharmacists is detailed in section A4.1.3.

A4.1.2 Process for full authorisation for vaccinators and pharmacist vaccinators

Assessment requirements

To become a fully authorised vaccinator or pharmacist/intern pharmacist vaccinator, all applicants must first meet the following Ministry of Health requirements.

1. Demonstrate that within the preceding 24 months they have attended, completed and passed a Vaccine Foundation Course (VFC) and have received the associated certificate. The VFC must meet the current *Vaccinator Foundation Course Standards* (published by IMAC) and the course should consist of:
 - a. a minimum of 16 hours' educational input
 - b. a written open-book assessment (minimum one-hour duration), which may be oral at the facilitator's discretion.
2. Undergo an independent clinical assessment by an immunisation coordinator or an approved assessor (as agreed by the Medical Officer of Health).¹ Information

¹ If it has been more than 12 months but less than 24 months since the applicant completed a full VFC, they should complete an online update prior to the clinical assessment.

about the practice environment, including cold chain and emergency management processes, will be collected at the time of the clinical assessment.

3. Have evidence that they hold a current practising certificate from their registration authority (eg, Nursing Council of New Zealand, Pharmacy Council of New Zealand).
4. Have a current cardiopulmonary resuscitation (CPR) certificate (see section **Error! Reference source not found.** for details).

Completion of authorisation

Fully authorised vaccinator applicants

Authorised vaccinator applicants¹ who have successfully completed their clinical assessment will then need to apply for authorisation under Regulation 44A(2) by submitting an application, including the documentation described above, to a medical officer of health. Generally, this will be their local Medical Officer of Health but in some instances this authorisation may be given by a national Medical Officer of Health.

Pharmacist vaccinator applicants

Pharmacists and intern pharmacists who have met the assessment requirements detailed above and should notify the Pharmaceutical Society (PSNZ) by an email containing the following information:

1. full name
2. membership number
3. name of the pharmacy or pharmacies which vaccinations will be provided from, or if the pharmacist is a locum
4. date of the course (or update course)
5. date of their clinical assessment.

Copies of the vaccination certificate or resuscitation certificates are not required. Emails should be sent to p.society@psnz.org.nz and need to include 'pharmacist vaccinator' in the subject line.

For audit purposes, it is recommended that all pharmacist vaccinators keep a copy of the record of their vaccinator training and other relevant documentation in a file at their current place of work.

A4.1.3 Process for renewal of vaccinator status for fully authorised vaccinators and pharmacist vaccinators

Authorisation of fully authorised vaccinators is valid for two years from the date of the authorisation approval letter from the Medical Officer of Health. To maintain status as

¹ Fully authorised vaccinators will not be able to vaccinate without a prescription or standing order until they have completed all the required processes.

an authorised vaccinator, authorisation must be renewed two yearly. To be authorised, the vaccinator must meet the requirements specified below.

To renew their vaccinator status, vaccinators are required to:

1. during the past two years or within a month of expiry of status, have completed a vaccinator update course that meets the current *Vaccinator Update Course Standards*¹
2. have a summary of their immunisation practice over the past 12 months. The summary should include type of immunisation practice as a vaccinator (eg, general practice, occupational health, pharmacy etc); types of vaccinations given (eg, intramuscular, subcutaneous, intradermal); and other responsibilities related to immunisation (eg, cold chain-designated person, etc)
3. have evidence of a current practising certificate
4. have evidence of a current CPR certificate (see section **Error! Reference source not found.** for details).

Fully authorised vaccinators

To continue vaccinating, fully authorised vaccinators need to apply for renewal of their authorisation to their local Medical Officer of Health and submit all relevant documentation (ie, immunisation update, CPR certificates and immunisation summary), prior to the expiry of their authorised vaccinator status.

Pharmacist vaccinators and intern pharmacist vaccinators

Prior to the expiry of their pharmacist vaccinator status, pharmacist vaccinators should notify PSNZ when they have completed the Ministry of Health requirements specified above.

A4.1.4 Process when fully authorised vaccinator status has not been maintained or has not been achieved

If it is less than five years since the vaccinator attended and completed an approved vaccinator foundation course

When a vaccinator has not achieved or maintained their vaccinator status, they must:

1. have a clinical assessment by an immunisation coordinator or approved assessor within the past three months (only required if vaccinator status expired more than a month earlier)
2. have completed a vaccinator update course that meets the current *Vaccinator Update Course Standards* in the last two years
3. have a summary of their immunisation practice over the past 12 months or intended area of practice. The summary should include type of immunisation

¹ Authorised vaccinators will not be able to vaccinate without a prescription or standing order until they have completed all the required processes.

practice as a vaccinator (eg, general practice, occupational health, pharmacy, etc); types of vaccinations given (eg, intramuscular, subcutaneous, intradermal); and other responsibilities related to immunisation (eg, cold chain-designated person)

4. have evidence of a current practising certificate
5. have evidence of a current CPR certificate (see section **Error! Reference source not found.** for details).

If it is five or more years since the applicant completed an approved vaccinator training and they have not achieved or maintained their vaccinator status.

If it is more than five years since the applicant completed their initial VFC or approved vaccinator update, they will be required to attend and pass another VFC. This is because there will have been significant developments in vaccination delivery in the intervening interval.

See section A4.1.2 Process for full authorisation for vaccinators and pharmacist vaccinators.

A4.1.5 Process when a vaccinator is new to the health district in which they intend to practise

If a fully authorised vaccinator wishes to practise in another health district and/or public health area, they must advise the local Medical Officer of Health and send through a copy of their current authorisation.

Pharmacist and intern pharmacist vaccinators are required to advise the local immunisation coordinator of their intention to set up a new pharmacist vaccinator service; this is to ensure that the coordinator is aware of which pharmacies require three-yearly spatial logging of the refrigerator. Where a vaccination service is already being offered this is not required.

A4.1.6 Additional endorsement process for BCG vaccinators

All BCG vaccinators are fully authorised vaccinators with BCG endorsement. They are authorised by the local Medical Officer of Health as described below.

New BCG vaccinators and gazetted BCG vaccinators seeking regional BCG endorsement

To be endorsed as a BCG vaccinator, the applicant needs to:

1. complete an approved VFC
2. be nominated by their employer to become a BCG vaccinator
3. successfully complete a Ministry of Health-approved online BCG vaccination course

4. complete under clinical supervision a minimum of five BCG vaccinations (using a standing order or prescription)
5. successfully complete a BCG clinical assessment by an approved BCG assessor
6. apply to the Medical Officer of Health for BCG endorsement approval, providing documented evidence of these requirements.

If a BCG vaccinator needs to administer additional Schedule vaccines, they will need to undertake a clinical assessment appropriate for the age group they will be vaccinating. Standing orders or prescriptions are required for the clinical assessment process.

For more information, see the Ministry of Health webpage *BCG vaccine and vaccinator endorsement* (available at www.health.govt.nz/our-work/preventative-health-wellness/immunisation/immunisation-programme-decisions/bcg-vaccine-and-vaccinator-endorsement).

Process for two-yearly renewal of BCG vaccinator status

To renew BCG endorsement, vaccinators must apply to their local Medical Officer of Health prior to the expiry date and provide documented evidence that they:

1. are a current authorised vaccinator, and
2. have completed an online vaccination course that includes an update on BCG.
3. A BCG vaccinator who also holds full authorisation will need to complete a standard vaccinator update course, in addition the BCG update.

Note: BCG vaccinators must complete a *BCG Vaccinator Update* course every two years. This online course is available as part of IMAC education (available at www.immune.org.nz/health-professionals/education-training).

A4.2 Protocols for provisional authorised vaccinators and provisional pharmacist vaccinators

In April 2020, as part of the New Zealand COVID-19 response, a pathway to provisional authorisation for vaccinators (PAV) was developed. This pathway is a short-term measure alongside the *Provisional Vaccinator Foundation Course* available from IMAC, which currently is to be completed by 31 December 2021.

A4.2.1 Authority for provisional authorised vaccinators and provision authorised pharmacist vaccinators

Provisional authorised vaccinators and provisional authorised pharmacist vaccinators, like fully authorised vaccinators, are authorised under regulation 44A(2). Regulation

44A(2) stipulates that the person seeking approval must apply in writing to the Director-General or a Medical Officer of Health and provide documentary evidence that they:

1. can carry out basic emergency techniques, resuscitation and the treatment of anaphylaxis
2. have knowledge of the safe and effective handling of immunisation products and equipment
3. can demonstrate clinical interpersonal skills
4. have knowledge of the relevant diseases and vaccines to be able to explain the vaccination to the individual, parent or guardian of the individual who is to consent to the vaccination on behalf of the individual, to ensure that the individual or parent or guardian of the individual can give informed consent to the vaccination.

Provisional authorised vaccinators and provisional authorised pharmacist vaccinators are only able to be authorised to administer influenza, MMR and COVID-19 vaccines (these are the only vaccines covered by the *Provisional Vaccination Foundation Course* and the *COVID-19 Vaccine Education Course* that these vaccinators complete).

A4.2.2 Process for provisional authorised vaccinators

To achieve provisional authorised vaccinator or provisional authorised pharmacist vaccinator status, Ministry of Health requires vaccinators to:

1. complete the online *Provisional Vaccinator Foundation Course* (including learning assessment and webinar)
2. successfully complete a peer assessment of clinical practice
3. hold a current *New Zealand Annual Practising Certificate*
4. final year students completing a degree within a relevant field of study to provide proof of enrolment and student identification
5. have evidence of current CPR certificate or a CPR certificate that has expired within the last 12 months at time of application (see section **Error! Reference source not found.** for details)
6. submitted a completed application for authorisation as a provisional authorised vaccinator to the Ministry of Health
7. on receipt of written authorisation from a medical officer of health, provisional authorised vaccinators send copy of authorisation and peer assessment to the local immunisation coordinator.

Provisional authorised vaccinators who wish to continue to vaccinate after expiration of their authorisation will be required to transition to become a fully authorised vaccinator or pharmacist vaccinator. A bridging course will be made available in late 2021 from IMAC. Those who want to be approved as full authorised vaccinators or pharmacist vaccinators before this bridging course is available will be required to complete a full VFC. More information is available from the IMAC education website (immune.org.nz/health-professionals/education).

A4.3 Protocols for COVID-19 vaccinators (working under supervision)

In May 2021, as part of the New Zealand COVID-19 immunisation programme rollout, a new COVID-19 vaccinator (working under supervision) role was created through the addition of regulation 44AB of the Medicines Regulations 1984. This is a short-term measure to aid with the unprecedented scale of the COVID-19 immunisation programme, to increase the ethnic diversity of the vaccinator workforce and ultimately help ensure positive outcomes for New Zealanders. These COVID-19 vaccinators (CVWUS) must, at all times, work under the clinical supervision and direction of a suitably qualified health practitioner.

A4.3.1 Authority for COVID-19 vaccinators working under supervision

COVID-19 vaccinators (working under supervision) have a narrow scope as outlined below. Regulation 44AB of the Medicines Regulations, and the authority granted to any COVID-19 vaccinators under this regulation, will expire on 1 June 2023.

In accordance with section 44AB, a person seeking approval must provide documentary evidence to satisfy the Director-General or a medical officer of health, as relevant.

1. That the person has successfully completed training as approved by the Director-General for the administration of the COVID-19 vaccine(s) as per section 44AB; (excluding obtaining informed consent and screening).
2. That the person also has the following competencies:
 - a. the person can carry out basic emergency techniques, including resuscitation and the treatment of anaphylaxis; and
 - b. the person has knowledge of the safe and effective handling of immunisation products and equipment.
3. COVID-19 vaccinators (CVWUS) are not required to be registered health care professionals, but they are required to:
 - a. complete an approved training course for the administration of a COVID-19 vaccine
 - b. be able to carry out basic emergency techniques, including resuscitation and hold a current basic life support certificate (see section A4.4)
 - c. have knowledge of the safe and effective handling of immunisation products and equipment.

A4.3.2 Process for approval of COVID-19 vaccinators

Following meeting these requirements, and to attain COVID-19 vaccinator (CVWUS) status, applicants are required to apply to the Ministry of Health and provide the following evidence:

1. a current CPR certificate in basic life support (anaphylaxis management is covered through Ministry-approved training for COVID-19 vaccinators)
2. COVID-19 vaccinator (working under supervision) eLearning course completion certificate, and a completed competency assessment from *IMAC Training and Competency Workbook*
3. A completed and signed COVID-19 vaccinator (working under supervision) authorisation application form.

A4.4 Resuscitation requirements for all vaccinators

All vaccinators, by virtue of their occupation, need to be able to resuscitate patients and therefore need to achieve and maintain the following resuscitation skills:

1. infant, child and adult CPR, including mouth-to-mouth, mouth-to-mask and the management of choking
2. administration of IM adrenaline for treatment of anaphylaxis
3. use of an automated external defibrillator
4. one- and two-person bag valve mask ventilation and mouth-to-mask technique.

Resuscitation training for vaccinators should cover the specific skills outlined above. The use of oxygen, sizing of airways, insertion of intravenous lines and the preparation of emergency medications (except for intramuscular adrenaline) are not skills specifically required of a vaccinator.

All vaccinators must maintain their current resuscitation certification, typically, this is required every two years. (Note: employer protocols may require this more frequently.)

All vaccinators, except COVID-19 vaccinators (working under supervision), need to be able to administer intramuscular adrenaline in the event of an anaphylactic reaction to an immunisation event (see section 2.3.3).

COVID-19 vaccinators (CVWUS) must be aware of the signs of anaphylaxis and have the knowledge to treat it but are not expected to administer adrenaline in practice.

All vaccinators must meet the emergency equipment and management requirements, regardless of the immunisation setting (eg, in general practice and in non-clinical settings, such as homes, schools, rest homes, workplaces and pharmacies), as listed in section 2.3.3.

All vaccinators are expected to keep up to date with any guidance changes, including infection control and requirements for PPE.

A4.5 Local immunisation programmes

Medical Officers of Health may approve additional vaccinations (funded or unfunded) for authorised vaccinators to administer either as part of the standard authorisation process or as part of a local immunisation programme. Public health units (PHU) need to maintain a register of the authorised vaccinators in their region. Temporary authorised vaccinators can be added to approved local immunisation programmes by Medical Officers of Health.

During the early stages of the COVID-19 response all authorised vaccinators and temporary authorised vaccinators were approved to provide National Immunisation Schedule and funded vaccinations for those at increased risk of vaccine-preventable disease by the Director of Public Health, in their capacity as national Medical Officer of Health. This means they did not need to apply for authorisation in different PHU areas.

A4.6 Minimum staff and equipment requirements for vaccination services

All vaccinators providing immunisation services need to have a minimum of two people present, one of whom must be an authorised vaccinator or pharmacist vaccinator; the other must be a competent adult who is able to call for emergency support and has a basic life support certificate.

COVID-19 vaccinators (CVWUS) must work at all times under clinical supervision and direction of a suitably qualified health practitioner.

The following check list contains the emergency equipment that is required when vaccinating offsite.

Check list of Emergency Equipment required for off-site vaccinations	Office use only
<p>1. Equipment</p> <p>The following should be available:</p> <ul style="list-style-type: none"> • Emergency kit containing: <ul style="list-style-type: none"> – adrenaline 1:1000 (minimum of 3 ampoules) – syringes (1 mL), 25 mm needles for IM injection (minimum of six) – adrenaline IM dose chart (ideally laminated) – cotton wool balls, gauze <ul style="list-style-type: none"> • cell-phone or phone access • sharps box • bag valve mask resuscitator (eg, Ambu bag) suitable for the population being vaccinated • pen and paper for emergency use • appropriately sized syringes and needles for specific vaccine programme • cotton wool balls, gauze, surgical tape or plasters • vaccines • cold chain equipment as required by the National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 (2nd edition) (see link in note below)^a • data logger with a probe, external display and alarm¹ • vomit bowl • tissues • gloves • appropriate surface cleaner • approved biohazard bag 	<p>Yes / No</p>
<p>2. Optional additional emergency equipment</p> <ul style="list-style-type: none"> • an oxygen cylinder, flow meter, tubing and paediatric/adult masks • airways – infant through to adult • blood pressure monitoring equipment • thermometer • Intravenous cannula and administration sets: <ul style="list-style-type: none"> • intravenous fluids • hydrocortisone for injection • saline flush 	<p>Yes / No</p>

a. Consider using a secondary back-up device in case the data logger gets damaged. See the *National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 (2nd edition)* (available at www.health.govt.nz/publication/national-standards-vaccine-storage-and-transportation-immunisation-providers-2017).