

# Appendix 4: Authorisation of vaccinators and criteria for pharmacist vaccinators

## A4.1 Protocol for authorisation of vaccinators and pharmacist vaccinators

### A4.1.1 Authority

#### Authorised vaccinators<sup>1</sup>

The authorisation of vaccinators in New Zealand is in accordance with the Medicines Regulations 1984, clause 44A(2). The Director-General of Health or a medical officer of health may authorise any person to administer a vaccine (which is a prescription medicine) for the purposes of an approved immunisation programme.<sup>2</sup>

Clause 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.

The usual protocol requires authorised vaccinator applications to be submitted to a medical officer of health in the applicant's local region. Any authorisation given under subclause (2) of the Regulation is valid for a period of two years from the date of initial vaccinator foundation course (VFC) and is subject to such conditions as the Director-General or the medical officer of health thinks fit. However, as part of the COVID-19 response, all authorised vaccinators and provisional authorised vaccinators are approved 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 the Immunisation Handbook) by the Director of Public Health. This means they do not need to apply for authorisation in different PHU areas.

<sup>1</sup> Authorised vaccinators were previously called 'authorised independent vaccinators'.

<sup>2</sup> 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](http://www.health.govt.nz/our-work/preventative-health-wellness/immunisation)).

Successful applicants will be authorised to administer either all or specific vaccines as recommended in the current *Handbook*<sup>1</sup> and any other vaccine as authorised by a medical officer of health.

## Pharmacist vaccinators

A number of vaccines have been reclassified by the Medicines Classification Committee, from prescription medicines to restricted medicines when administered by a registered pharmacist or registered intern pharmacist who has successfully completed a VFC approved by the Ministry of Health and is complying with the immunisation standards of the Ministry of Health.

For the purposes of this appendix the term pharmacist vaccinator refers to both registered pharmacists and registered intern pharmacists who have met the educational and clinical requirements. Although the scope of vaccines they can administer is different, the process they undergo to gain vaccinator status is the same.

The reclassification means that pharmacists and pharmacist interns are able to administer specific vaccines if they have: successfully completed a Ministry of Health-approved VFC (including the open-book assessment) and clinical assessment, and are complying with the immunisation standards and guidelines 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.

Under the vaccine reclassification, pharmacist vaccinators are not required to apply to a medical officer of health for authorised vaccinator status for vaccines that have been reclassified.

Pharmacist and intern pharmacist should notify Pharmaceutical Society of New Zealand (PSNZ) when they have completed the requirements specified above, including the course completion date.

Vaccinator status is valid for two years from the date of the initial VFC, once all the requirements are met. (For details of provisional authorised vaccinator status see section A4.1.4).

### A4.1.2 Process for all vaccinators

To achieve vaccinator status, all applicants must first meet the following requirements.

1. Demonstrate that within the preceding 24 months they have attended, completed and passed a VFC and have received a vaccinator training certificate. The VFC must meet the current *Vaccinator Training Course Standards* (published by IMAC) and the course should consist of:
  - a. a minimum of 16 hours' educational input

<sup>1</sup> See the 'Introduction' chapter in this *Handbook* or [www.health.govt.nz/our-work/preventative-health-wellness/immunisation](http://www.health.govt.nz/our-work/preventative-health-wellness/immunisation) for more information about the National Immunisation Schedule.

- 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).<sup>1</sup> Information 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 A4.2 for details).

## Authorised vaccinators

Authorised vaccinator applicants<sup>2</sup> who have successfully completed their clinical assessment will then need to apply for authorisation by submitting an application, including the documentation described above, to their local medical officer of health (as part of the COVID-19 response, vaccinators are approved to vaccinate nationally and are approved by the Director of Public Health).

## Pharmacist vaccinators

Pharmacists and intern pharmacists who have completed the theoretical and clinical assessments 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
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](mailto:p.society@psnz.org.nz) and need to include 'pharmacist vaccinator' in the subject line.

It is recommended that all pharmacist vaccinators keep a copy of their record of their vaccinator training and other requirements in a file at the pharmacy for audit purposes.

<sup>1</sup> 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.

<sup>2</sup> Authorised vaccinators will not be able to vaccinate without a prescription or standing order until they have completed all the required processes.

### A4.1.3 Additional endorsement process for BCG vaccinators

All BCG vaccinators are 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](http://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.

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](http://www.immune.org.nz/health-professionals/education-training)).

### A4.1.4 Process for provisional authorised vaccinators

In April 2020, as part of the New Zealand COVID-19 response, a pathway to provisional authorisation for vaccinators (PAV) was developed. This is a short-term measure with the Provisional Vaccinator Foundation Course being available through to end of June 2021 (to be completed by 31 December 2021).

To achieve provisional authorised vaccinator status, vaccinators are required 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 Annual Practising Certificate
4. have evidence of current CPR certificate (see section A4.2 for details)
5. submitted completed applications for provisional authorised vaccinator approval to IMAC to be approved by the Director of Public Health
6. on approval, 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 June 2022 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 need to be approved as full authorised vaccinators or pharmacist vaccinators prior to June 2022 will be required to complete a full VFC. More information is available from IMAC education website ([www.immune.org.nz/health-professionals/education-training](http://www.immune.org.nz/health-professionals/education-training)).

#### A4.1.5 Process for two-yearly renewal of vaccinator status for all vaccinators

Authorised vaccinator or pharmacist vaccinator status is valid for two years from the date of the initial VFC. To maintain status as a vaccinator this must be renewed two yearly. The vaccinator must meet the requirements specified below.

To renew their vaccinator status, all 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*<sup>1</sup>
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 A4.2 for details).

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

## Authorised vaccinators

Prior to the expiry of their authorised vaccinator status, authorised vaccinators are required 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).

## Pharmacist vaccinators

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

### A4.1.6 Process when 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 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 A4.2 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, they will be required to attend, complete 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 all vaccinators.

### A4.1.7 Process when a vaccinator is new to the health district in which they intend to practise

If an 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 services is already being offered this is not required.

### A4.1.8 Process for approval to administer COVID-19 vaccines for authorised and pharmacist vaccinators

To administer any COVID-19 vaccine, all qualified/authorised, provisional and pharmacist vaccinators need to produce evidence that they have completed the online COVID-19-specific education course. This includes a module for the mRNA COVID-19 vaccine (Comirnaty). Additional authorisation or the need for local immunisation programmes is not required.

## A4.2 Resuscitation requirements for all authorised vaccinators and pharmacist 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 all 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 demonstrate/validate their resuscitation certification every two years. (Note: employer protocols may require this more frequently.)

**All** vaccinators need to be able to administer intramuscular adrenaline in the event of an anaphylactic reaction to an immunisation event (see section 2.3.3).

**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.

### **A4.3 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 approve local immunisation programmes by Medical Officers of Health.

As part of the COVID-19 response all authorised vaccinators and temporary authorised vaccinators are approved to provide National Immunisation Schedule and funded vaccinations for those at increased risk of vaccine-preventable disease (as identified in the Immunisation Handbook) by the Director of Public Health. This means they do not need to apply for authorisation in different PHU areas.

### **A4.4 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.

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****1. Equipment**

Yes / No

The following should be available:

- Emergency kit containing:
  - 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
- cellphone 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)<sup>a</sup>
- data logger with a probe, external display and alarm<sup>1</sup>
- vomit bowl
- tissues
- gloves
- appropriate surface cleaner
- approved biohazard bag

**2. Optional additional emergency equipment**

Yes / No

- 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:
- intravenous fluids
- hydrocortisone for injection
- saline flush

- 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](http://www.health.govt.nz/publication/national-standards-vaccine-storage-and-transportation-immunisation-providers-2017)).