
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 vaccinators²¹

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.²²

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:

- a. can carry out basic emergency techniques, resuscitation and the treatment of anaphylaxis; and
- b. have knowledge of the safe and effective handling of immunisation products and equipment; and
- c. can demonstrate clinical interpersonal skills; and

²¹ Authorised vaccinators were previously called 'authorised independent vaccinators'.

²² 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).

- d. have knowledge of the relevant diseases and vaccines in order 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 current 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 training course (VTC), and is subject to such conditions as the Director-General or the medical officer of health thinks fit.

Successful applicants will be authorised to administer either all or specific vaccines on the National Immunisation Schedule²³ and any other vaccine as authorised by a medical officer of health.

Pharmacist vaccinators

Since 2011, a number of vaccines have been reclassified by the Medicines Classification Committee, from prescription medicines to restricted medicines when administered by a registered pharmacist who has successfully completed a VTC approved by the Ministry of Health and is complying with the immunisation standards of the Ministry of Health.

The reclassification means that pharmacists are able to administer specific vaccines as pharmacist vaccinators if they have successfully completed a Ministry of Health-approved VTC (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*.

Under the vaccine reclassification, pharmacist vaccinators are not required to apply to a medical officer of health for authorised vaccinator status as the vaccine is not a prescription medicine when administered by a pharmacist vaccinator (who meets the conditions of the vaccine classification).

²³ See the 'Introduction' chapter in this *Handbook* or www.health.govt.nz/our-work/preventative-health-wellness/immunisation for more information about the National Immunisation Schedule.

The Pharmaceutical Society of New Zealand (PSNZ), maintains a register of pharmacist vaccinators. Pharmacist vaccinators should notify PSNZ when they have completed the requirements specified above, including the course completion date.

Pharmacist vaccinator status is valid for two years from the date of the initial VTC.

A4.1.2 Process for all vaccinators

In order to achieve authorised vaccinator or pharmacist vaccinator status, all applicants must first meet the following requirements.

1. Demonstrate that within the preceding 12 months they have attended, completed and passed a VTC and have received a vaccinator training certificate. The VTC must meet the current *Vaccinator Training Course Standards*²⁴ and the course should consist of:
 - a minimum of 16 hours' educational input
 - 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). Information about the practice environment will be collected at the time of the clinical assessment including cold chain and emergency management processes.
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).

²⁴ Published by IMAC.

Authorised vaccinators

Authorised vaccinator applicants²⁵ (eg, registered nurses) 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.

Pharmacist vaccinators

Pharmacist vaccinators²⁶ should notify PSNZ when they have completed the requirements specified above, including the course completion date.

A4.1.3 Additional endorsement process for BCG vaccinators

As of 4 January 2017, the requirement for gazettement of BCG vaccinators no longer applies.

All new BCG vaccinators will need to become authorised vaccinators with BCG endorsement, authorised by the local medical officer of health as described below.

BCG vaccinators who were gazetted prior to 4 January 2017 will be granted one-off national BCG endorsement by the Ministry of Health for a two-year period up until 4 January 2019, after which they will be required to seek regional BCG endorsement from their local medical officer of health.

New BCG vaccinators and gazetted BCG vaccinators seeking regional BCG endorsement.

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

1. be an authorised vaccinator
2. be nominated by their employer to become a BCG vaccinator

²⁵ Authorised vaccinators will not be able to vaccinate without a prescription or standing order until they have completed all of the required processes.

²⁶ Pharmacist vaccinators will not be able to vaccinate without a prescription or standing order until they have completed all of the required processes.

3. successfully complete a Ministry of Health-approved online BCG vaccination course
4. complete under clinical supervision a minimum of 5 BCG vaccinations
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.

For more information, see the Ministry of Health policy *Bacillus Calmette-Guérin (BCG) Vaccinator Endorsement* (www.health.govt.nz/our-work/preventative-health-wellness/immunisation/immunisation-programme-decisions/bacillus-calmette-guerin-bcg-vaccinator-endorsement).

A4.1.4 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 VTC, but it can be renewed two-yearly if the vaccinator meets the requirements specified below.

To renew their vaccinator status, all vaccinators are required to:

1. during the past two years, have attended a vaccinator update course that meets the current *Vaccinator Update Course Standards*²⁷ and have evidence of attendance
2. have a summary²⁸ of their immunisation practice over the past 12 months
3. have evidence of a current practising certificate
4. have evidence of a current CPR certificate (see section A4.2 for details).

²⁷ Published by IMAC.

²⁸ 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).

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.

A4.1.5 Process when vaccinator status has not been renewed or has not been achieved

If it is less than five years since the vaccinator status expired and the vaccinator has been attending vaccinator update training every two years

When a vaccinator has failed to renew their vaccinator status, they must:

1. have a further clinical assessment by an immunisation coordinator or approved assessor (as approved by the medical officer of health) within the past three months
2. for each two-year period since they were last renewed, have attended a vaccinator update course that meets the current *Vaccinator Update Course Standards*²⁹ and have evidence of attendance
3. have a summary of their immunisation practice over the past 12 months
4. have evidence of a current practising certificate
5. have evidence of a current CPR certificate (see section A4.2 for details).

²⁹ Published by IMAC.

Authorised vaccinators

Authorised vaccinator applicants must submit the documentation described above to the medical officer of health. Applicants will be assessed on a case-by-case basis.

Pharmacist vaccinators

Pharmacist vaccinators should notify PSNZ when they have completed the requirements specified above.

If it is less than five years since the applicant completed vaccinator training but they have not achieved vaccinator status

To achieve authorised vaccinator or pharmacist vaccinator status, the applicant must:

1. within the past three months, have had a clinical assessment by an immunisation coordinator or approved assessor (as approved by the medical officer of health)
2. within the past five years, have successfully attended, completed and passed a VTC that meets the current *Vaccinator Training Course Standards*³⁰ and have received a vaccinator training certificate
3. during each two-year period since they completed the VTC, have attended a vaccinator update course that meets the current *Vaccinator Update Course Standards*³¹ and have evidence of attendance
4. have a summary of their immunisation practice over the past 12 months
5. have evidence of a current practising certificate
6. have evidence of a current CPR certificate (see section A4.2 for details).

Note: If the applicant has not attended the two-yearly vaccinator update courses, they may be required to attend, complete and pass another VTC.

³⁰ Published by IMAC.

³¹ Published by IMAC.

Authorised vaccinators

Authorised vaccinator applicants must submit the documentation described above to their local medical officer of health. Applicants will be assessed on a case-by-case basis.

Pharmacist vaccinators

Pharmacist vaccinators are advised to notify PSNZ when they have completed the requirements specified above.

If it is more than five years since the applicant completed vaccinator training and they have not achieved or renewed vaccinator status

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

All applicants are required to:

1. undergo a clinical assessment by an immunisation coordinator or approved assessor (as agreed by the medical officer of health) – information about the practice environment will be collected at the time of this assessment
2. have attended, completed and passed a VTC that meets the current *Vaccinator Training Course Standards*³² and have received a vaccinator training certificate
3. have a summary of their immunisation practice over the past 12 months
4. have evidence that they hold a current practising certificate
5. have evidence of a current CPR certificate (see section A4.2 for details).

³² Published by IMAC.

Authorised vaccinators

Applicants must submit the documentation described above to their local medical officer of health. Applicants will be assessed on a case-by-case basis.

Pharmacist vaccinators

Pharmacist vaccinators are advised to notify PSNZ when they have completed the requirements specified above.

A4.1.6 Process when an authorised vaccinator is new to the health district in which they intend to practise

If an authorised vaccinator wishes to practise in another health district, they must get authorisation from the local medical officer of health before practising as an authorised vaccinator. The applicant will be required to provide:

1. evidence of current authorisation in another health district
2. evidence of a current practising certificate
3. evidence of a current CPR certificate (see section A4.2 for details)
4. details of their proposed work in the district.

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. use of airway adjuncts, including the sizing and insertion of oropharyngeal airways
3. use of an automated external defibrillator

4. one- and two-person bag valve mask ventilation and mouth-to-mask technique
5. use of supplemental oxygen
6. use of laryngeal mask airways (only if included in the emergency equipment).

Resuscitation training for all vaccinators should be at a standard equivalent to that set for New Zealand Resuscitation Council: 'Health Professional Responder, CORE Immediate – Adult and Child' (www.nzrc.org.nz/training/rescuers). The first five specific skills outlined above must be included in any vaccinator resuscitation course. The 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 (refer to 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.

A4.3 Authorised vaccinators delivering a local immunisation programme

A local immunisation programme may be approved by the Director-General or a medical officer of health. For example, a medical officer of health may approve the use of unfunded vaccines to meet a specific need within their region, such as:

- influenza vaccination to healthy adults aged 64 years and under, in general practice and workplace settings; or
- hepatitis B vaccination in occupational health settings.

Authorisation for vaccinating non-funded populations will require application to the medical officer of health for approval.

Authorised vaccinators need to supply the following details of their practice, which will be considered if they decide to seek medical officer of health approval for a local immunisation programme. Application forms are available from the local regional public health office.

	Office use only
1. Location/s (specify)	Yes / No
2. Staff There should be two people present for outreach or non-clinical setting immunisations, one of whom must be an authorised vaccinator; the other must be a competent adult who is able to call for emergency support and has a basic life support certificate.	Yes / No
3. Linkages with the immunisation coordinator Do you have processes for regular contact with your immunisation coordinator?	Yes / No
4. Person specification. Attach copies of the following documentation: <ul style="list-style-type: none"> • current approval as an authorised vaccinator issued by the local medical officer of health for all vaccinators covered by the local programme is required (provide list of names on the last page of this document and attach copies of the authorised vaccinator approvals)* • indemnity insurance.* 	Yes / No
5. Legal You should have knowledge of the provisions contained in the following legislation: <ul style="list-style-type: none"> • Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996 • Privacy Act 1993 (in relation to the storage and transfer of information) • Health and Safety in Employment Act 1992 (in relation to having a suitable area for post-vaccination observation, correct disposal of vaccines, etc) • Medicines Act 1981. 	Yes / No

Note: Please ensure that you have included the documentation marked with an asterisk (*).

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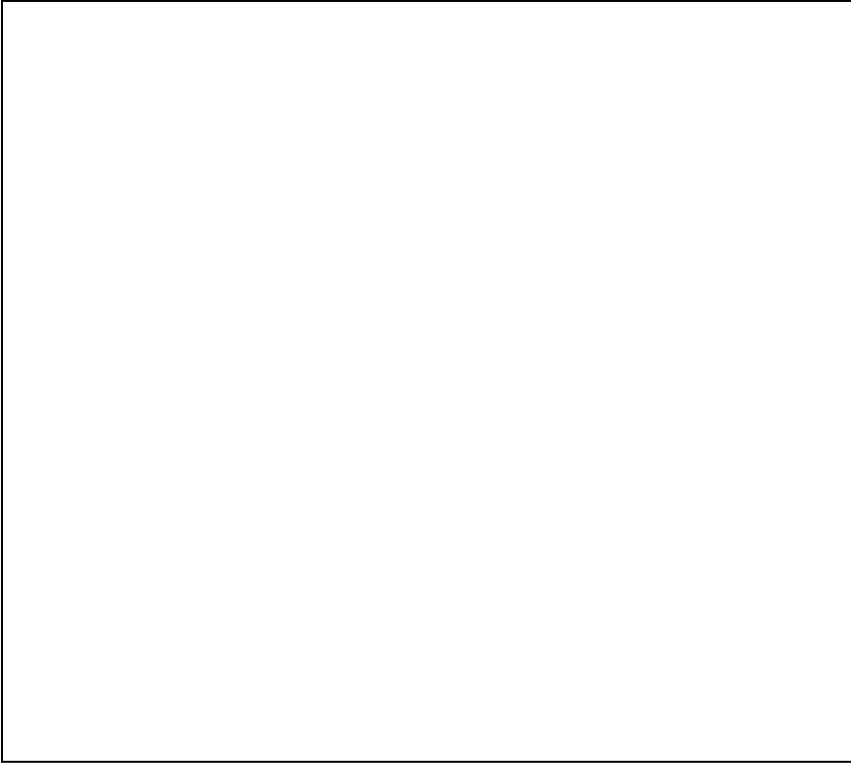
	Office use only
<p>6. Venue</p> <p>The venue must allow for the safe management of delivering of immunisations, including:</p> <ul style="list-style-type: none"> • privacy • a resting space • a waiting space • ensuring privacy of records. 	Yes / No
<p>7. Documentation</p> <p>You should have documented processes for the following.</p> <ul style="list-style-type: none"> • Pre-vaccination <ul style="list-style-type: none"> – What information is provided to individuals (including consent and, if applicable, information about the NIR)?* – How do you identify persons eligible for free vaccination?* • Post-vaccination <ul style="list-style-type: none"> – How will an individual's details be recorded?* – What are the means of recording administration of a vaccine(s) and any post-vaccination adverse events?* – How will notice of administration be provided to the primary health care provider?* – What information will be provided to the vaccinee post-vaccination (including provision of emergency care)?* – How will information on adverse reactions be reported?* <p>Note: For influenza vaccinations delivered by occupational health without NIR access, it will be necessary to provide the following information to the medical officer of health:</p> <ul style="list-style-type: none"> • number of recipients who were ≥65 years (free vaccines) • number of people <65 years eligible for free influenza vaccine • number of non-eligible influenza vaccines given. 	Yes / No

Note: Please ensure that you have included the documentation marked with an asterisk (*).

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	Office use only
<p>8. Equipment</p> <p>The following should be available:</p> <ul style="list-style-type: none"> • cellphone or phone access • an oxygen cylinder, flow meter, tubing and paediatric/adult masks • airways – infant through to adult • bag valve mask resuscitator (eg, Ambu bag) suitable for the population being vaccinated • adrenaline • syringes (1 mL, 2.5 mL, 5 mL), needles (1.58 cm to 3.8 cm) • sharps box • alcohol swabs, cotton wool balls, gauze • thermometer and blood pressure monitoring equipment • vaccines • appropriately monitored insulated vaccine containers and equipment for transporting vaccine off-site • data logger with a probe, external display and alarm[#] • gloves • 0.5% hypochlorite • approved biohazard bag. 	Yes / No
<p>9. Optional additional emergency equipment</p> <p>Intravenous cannula and administration sets:</p> <ul style="list-style-type: none"> • intravenous fluids • hydrocortisone for injection • sodium bicarbonate solution • saline flush. 	Yes / No
<p>[#] Consider using a secondary back-up device, in case the data logger gets damaged. See the <i>National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017</i> (available at www.health.govt.nz/coldchain).</p>	

List of vaccinators taking part in the programme (all vaccinators must be fully authorised, with copies of approval document attached):



Note: Please ensure that you have included the documentation marked with an asterisk (*).

Applicant's name:

Applicant's signature:

Date: