

|  |
| --- |
| Victorian Pharmacist-Administered Vaccination Program Guidelines |
| Effective 3 October 2022 |
|  |

Victorian Pharmacist-Administered Vaccination Program Guidelines

Effective 3 October 2022

Department of Health

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Document history and control   | Version | Issue date | Section amended | Amendment | | --- | --- | --- | --- | | 1 | August 2016 | n/a | n/a | | 2 | December 2016 | Fees, Premises, Registration of premises, Immunisation registers | Minor amendment. Inclusion of footnote 6.  Additional refrigerator requirements.  Inclusion of application form hyperlink.  Addition of new section and requirements. | | 3 | July  2018 | Regulations, Education (now Training), Premises, Registration of premises, Record keeping and reporting | Minor amendment from Drugs, Poisons and Controlled Substances Regulations 2006 to Drugs, Poisons and Controlled Substances Regulations 2017 | | 4 | October 2018 | Introduction, Education (now Training), Code of Conduct, Target groups, Fees, Registration of premises, Assessment and consent | Significant amendment to detail expansion.  Removal of Evaluation section.  Amendment to attachment 1 templates. | | 5 | April 2019 | Target groups, Assessment and consent | Minor amendment to the number of weeks gestation recommended for pregnant women – in line with the changes in the Australian Immunisation Handbook. | | 6 | April 2020 | All sections updated | Significant amendment to detail expansion.  Amendment to attachment 1 templates. | | 7 | May 2022 | All sections updated | Significant amendment to detail expansion.  Amendment to attachment 1 templates. | | 8 | October 2022 | Multiple sections updated | Significant amendment to detail expansion.  Sections 1, 4, 5, 8, 10.2.1, 10.5, and 13 with significant edits. Other minor edits to improve readability and update hyperlinks and references.  Removal of attachment 1 templates. Please contact [immunisation@health.vic.gov.au](mailto:immunisation@health.vic.gov.au) if you require a copy of these templates. | |
| To receive this publication in an accessible format, phone 1300 882 008, using the National Relay Service 13 36 77 if required, or email immunisation@health.vic.gov.au  Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.  © State of Victoria, Department of Health, 3 October 2022.  Available at https://www.health.vic.gov.au/public-health/immunisation |
|  |

Contents

[1. Introduction 7](#_Toc115426467)

[2. Regulations 9](#_Toc115426468)

[3. Approval 9](#_Toc115426469)

[4. Pharmacist Immunisers and Service Providers 10](#_Toc115426470)

[5. Training 10](#_Toc115426471)

[5.1 Japanese encephalitis (JE) vaccine-specific training 11](#_Toc115426472)

[5.2 Monkeypox (MPX) vaccine-specific training 11](#_Toc115426473)

[5.3 Vaccinating younger cohorts 11](#_Toc115426474)

[5.4 General training requirements 12](#_Toc115426475)

[6. Code of conduct and professional practice standards 13](#_Toc115426476)

[7. Vaccines 14](#_Toc115426477)

[8. Target groups under the Approval 14](#_Toc115426478)

[8.1 Influenza vaccine 14](#_Toc115426479)

[8.2 Diphtheria-tetanus-pertussis (DTP) vaccines 14](#_Toc115426480)

[8.3 Human papillomavirus (HPV) vaccine 15](#_Toc115426481)

[8.4 Measles-mumps-rubella vaccine 15](#_Toc115426482)

[8.5 Meningococcal ACWY vaccine 15](#_Toc115426483)

[8.6 Pneumococcal vaccine 15](#_Toc115426484)

[8.7 Herpes zoster vaccine 16](#_Toc115426485)

[8.8 COVID-19 vaccine 17](#_Toc115426486)

[8.9 Japanese encephalitis (JE) Vaccine 17](#_Toc115426487)

[8.10 Monkeypox vaccine 17](#_Toc115426488)

[8.11 Exclusions 17](#_Toc115426489)

[9. Clinical governance and risk management 19](#_Toc115426490)

[9.1 Victoria’s clinical governance framework 19](#_Toc115426491)

[9.2 Supporting clinical governance 20](#_Toc115426492)

[9.3 Other safety requirements 20](#_Toc115426493)

[10. Premises, professional governance and staffing 20](#_Toc115426494)

[10.1 Premises 20](#_Toc115426495)

[10.2 Registration of premises 22](#_Toc115426496)

[10.3 Insurance 23](#_Toc115426497)

[10.4 Accreditation 23](#_Toc115426498)

[10.5 Advertising 23](#_Toc115426499)

[10.6 Professional governance and staffing arrangements 23](#_Toc115426500)

[11. Equipment and resources 25](#_Toc115426501)

[11.1 Anaphylaxis response kit 26](#_Toc115426502)

[12. Protocols 27](#_Toc115426503)

[12.1 Emergency response protocol 27](#_Toc115426504)

[12.2 Cold-chain maintenance 27](#_Toc115426505)

[12.3 Assessment and consent 28](#_Toc115426506)

[12.4 Consent on behalf of a child or adolescent 28](#_Toc115426507)

[12.5 Monitoring 29](#_Toc115426508)

[12.6 Adverse events 29](#_Toc115426509)

[12.7 Record keeping and reporting 29](#_Toc115426510)

[12.8 Reporting adverse events 31](#_Toc115426511)

[12.9 Immunisation registers 31](#_Toc115426512)

[12.10 Complaints 32](#_Toc115426513)

[13. Fees 32](#_Toc115426514)

[14. Questions 33](#_Toc115426515)

# Introduction

In 2015, the Victorian Minister for Health announced implementation of the Victorian Pharmacist-Administered Vaccination Program (the program), to commence in 2016.

Authorising Pharmacist Immunisers to administer approved vaccines provides greater public access to vaccination including for people who are most at risk of complications from vaccine-preventable disease.

The vaccines Pharmacist Immunisers are authorised to administer, and the circumstances in which pharmacists may administer these vaccines, are set out in the *Secretary Approval – Pharmacist Immuniser (*the Approval*)[[1]](#footnote-2).*

Following a number of reviews and expansions of the program, Pharmacist Immunisers that have completed a recognised ‘Immuniser program of study’, are currently authorised to administer the below vaccines in Victoria:

Table 1: Approved vaccines

| **Vaccine** | **Approval for pharmacists to vaccinate with this vaccine *applies to*** | **Approval for pharmacists to vaccinate with this vaccine *excludes*** |
| --- | --- | --- |
| Influenza | * Vaccination of people aged 5 years and older, excluding those circumstances listed in Column 3. | Vaccination for travel purposes;  Vaccination of people aged 4 years and younger; or  Vaccination of people with contraindications defined in the current edition of the *Australian Immunisation Handbook*. |
| Diphtheria-tetanus-pertussis vaccines | * Vaccination of people aged 12 years and older, excluding those circumstances listed in Column 3. | * + Vaccination for travel purposes;   + Vaccination of people aged 11 years and younger;   + Vaccination for the express purpose of post-exposure prophylaxis in people with a tetanus-prone wound;   + Vaccination of people that are contacts in the event of a case of pertussis, unless directed by the Department of Health;   + Vaccination of people with contraindications defined in the current edition of the *Australian Immunisation Handbook*. |
| Human papillomavirus (HPV) | * Vaccination of people aged 12 years and older, excluding those circumstances listed in Column 3. | * + Vaccination for travel purposes;   + Vaccination of people aged 11 years and younger;   + Vaccination of people with contraindications defined in the current edition of the *Australian Immunisation Handbook.* |
| Measles-mumps-rubella vaccine (MMR) | * Vaccination of people aged 15 years and older, excluding those circumstances listed in Column 3. | * + Vaccination for travel purposes;   + Vaccination of people aged 14 years and younger;   + Vaccination of people with contraindications defined in the current edition of the *Australian Immunisation Handbook*. |
| Meningococcal ACWY | * Vaccination of people aged 15 years and older, excluding those circumstances listed in Column 3. | * + Vaccination for travel purposes;   + Vaccination of people aged 14 years and younger;   + Vaccination of people with contraindications defined in the current edition of the *Australian Immunisation Handbook*. |
| Pneumococcal | * Vaccination of people aged 50 years and older, excluding those circumstances listed in Column 3 | * + Vaccination for travel purposes;   + Vaccination of people aged 49 years and younger;   + Vaccination of people with contraindications defined in the current edition of the *Australian Immunisation Handbook.* |
| Herpes zoster/varicella zoster | * Vaccination of people aged 50 years and older, excluding those circumstances listed in Column 3 | * + Vaccination for travel purposes;   + Vaccination of people aged 49 years and younger;   + Vaccination of people with contraindications defined in the current edition of the *Australian Immunisation Handbook.* |

Pharmacist immunisers that have also completed an additional *Japanese encephalitis - eLearning module* may also administer:

|  |  |  |
| --- | --- | --- |
| **Vaccine** | **Approval for pharmacists to vaccinate with this vaccine *applies to*** | **Approval for pharmacists to vaccinate with this vaccine *excludes*** |
| Japanese encephalitis (JE) | * Vaccination of people aged 5 years and older that are recommended for vaccination as listed on the Victorian Department of Health’s Japanese encephalitis in Victoria website[[2]](#footnote-3) as amended from time to time. | Vaccination for people not recommended for vaccination;  Vaccination for travel purposes;  Vaccination of people aged 4 years and younger;   * + Vaccination of people with contraindications defined in the current edition of the *Australian Immunisation Handbook*. |

Pharmacist immunisers that have also completed an additional *Monkeypox vaccination eLearning module* may also administer:

|  |  |  |
| --- | --- | --- |
| **Vaccine** | **Approval for pharmacists to vaccinate with this vaccine *applies to*** | **Approval for pharmacists to vaccinate with this vaccine *excludes*** |
| Monkeypox/ smallpox/ vaccinia virus (MPX) | * Vaccination of people aged 5 years and older that are recommended for vaccination as listed on the Victorian Department of Health’s Monkeypox webpage[[3]](#footnote-4) as amended from time to time. | Vaccination for people not recommended for vaccination;  Vaccination for travel purposes other than those people recommended for vaccination as listed on the Department of Health’s Monkeypox webpage3;  Vaccination of people aged 4 years and younger;  Vaccination of people with contraindications defined in the current edition of the *Australian Immunisation Handbook* (or current recommendations issued by the Australian Technical Advisory Group on Immunisation (ATAGI). |

*Pharmacist Immunisers administering the MPX vaccine intradermally*

An intradermal injection - skills and competencies assessment must be satisfactorily completed by Pharmacist Immunisers prior to administering the MPX vaccine intradermally. The assessment checklist is available within the *Victorian monkeypox vaccination program guidelines[[4]](#footnote-5)*. Pharmacist Immunisers must additionally comply with the *Victorian monkeypox vaccination program guidelines* when administering the MPX vaccine. Further detail about the educational requirements of Pharmacist Immunisers is included in the ‘[Training](#_Toc452486141)’ section of these Guidelines below.

*Pharmacist Immunisers administering COVID-19 vaccines*

In February 2021, Pharmacist Immunisers were authorised to administer any COVID-19 vaccine approved by the Therapeutic Goods Administration (TGA) to persons included in the patient group for which the COVID-19 vaccine is approved by the TGA for, or recommended by ATAGI for. This authorisation was part of Victoria’s COVID-19 response and was the subject of a separate COVID-19 Secretary Approval: Pharmacist Immunisers. The COVID-19 Secretary Approval, information about the COVID-19 vaccine-related authorisation and requirements can be accessed via the Department of Health’s *Information for COVID-19 vaccine providers* website4.

Many of the vaccines administered by pharmacists are government funded. The *Victorian Pharmacist-Administered Vaccination Program Guidelines* (Guidelines) describe the requirements of the program and support registered pharmacists to provide safe, high quality immunisation services.

# Regulations

The *Drugs, Poisons and Controlled Substances Regulations 2017* (the Regulations) enable the Secretary of the department to approve a Schedule 4 poison for administration by a pharmacist, and to specify the conditions in which a pharmacist is authorised to administer a Schedule 4 poison.

Pharmacists are permitted to possess and administer Schedule 3 poisons pursuant to Regulation 141 of the Regulations. Accordingly, pharmacists are permitted to possess and administer Schedule 3 Poisons that are necessary for the treatment of anaphylactic reactions to a vaccine. Those Schedule 3 poisons should be kept on hand and utilised should they be required at the time the vaccine is administered.

The Regulations are available from Victoria Law Today at <<http://www.legislation.vic.gov.au/>>.

# Approval

The Approval defines the conditions under which a pharmacist is authorised to administer a Schedule 4 poison. The Approval sets out conditions in relation to:

* registration and training
* recency of practice and continuing professional development
* premises
* staffing
* registration with the department
* practice and compliance with relevant guidelines and protocols
* vaccines that pharmacists are authorised to administer and the circumstances in which they are authorised to do so, including listing important exclusions.

The conditions of the Approval and related requirements for pharmacists are described as part of these Guidelines. Under all circumstances, the Pharmacist Immuniser should provide vaccination services in accordance with the Regulations and the Approval.

The Secretary Approval: Pharmacist Immuniser is available from <<https://www.health.vic.gov.au/immunisation/pharmacist-immunisers>>.

# Pharmacist Immunisers and Service Providers

A registered pharmacist who has completed a recognised ‘Immuniser program of study’ and who administers vaccines under the programis referred to in these Guidelines as a ‘Pharmacist Immuniser’*.*

The Approval defines that Pharmacist Immunisers are required to:

* hold general registration with the Pharmacy Board of Australia[[5]](#footnote-6)
* have satisfactorily completed the assessment of an ‘Immuniser program of study’ recognised by the Victorian Chief Health Officer
* have satisfactorily completed the Japanese encephalitis (JE) eLearning module if administering the JE vaccine to eligible individuals
* have satisfactorily completed the Monkeypox (MPX) vaccination eLearning module if administering the MPX vaccine to eligible individuals[[6]](#footnote-7)
* have satisfactorily completed the intradermal injection – skills and competency assessment, if administering intradermal MPX vaccinations
* have recency of practice and continuing professional development in immunisation (as defined from time to time by the Pharmacy Board of Australia)
* hold a current first aid certificate (to be updated every three years)
* hold a current cardiopulmonary resuscitation certificate (to be updated annually)
* provide evidence of completed training if required.

These Guidelines also refer to Service Providers. Service Providers are defined as:

* a hospital
* a pharmacy as defined in the Pharmacy Regulation Act 2010
* a pharmacy depot, as defined in the Pharmacy Regulation Act 2010, that is a stand-alone business on premises owned or leased by the licensee of the related pharmacy.

Pharmacists administering vaccines are to be connected to a pharmacy, pharmacy depot or hospital that has registered with the department to provide a vaccination service and hold a government-funded vaccine account. This means that they must either own (for example, the pharmacist owner of a pharmacy), be employed or otherwise engaged by that Service Provider.

# Training

All pharmacists administering vaccines in Victoria must first complete an ‘Immuniser program of study’ that has been recognised by the Victorian Chief Health Officer. A list of recognised courses is available from <<https://www.health.vic.gov.au/immunisation/programs-of-study>>.

This program of study provides participants with a comprehensive understanding of the role of a Pharmacist Immuniser in Victoria and assists with development of the knowledge and clinical skills required to safely deliver an immunisation service. Completion of this course is consistent with the educational requirements for Nurse Immunisers in Victoria.

Pharmacists that have completed immunisation training that has **not** been recognised as an ‘Immuniser program of study’ are not authorised to administer vaccinations in Victoria. This includes training programs available in other states and territories, unless they are expressly recognised by the Victorian Chief Health Officer.

A requirement of the Approval is the need to undertake continuing professional development and refreshers on NIP and other approved vaccines to ensure currency and competency in delivering safe vaccination services.

## Japanese encephalitis (JE) vaccine-specific training

Pharmacist Immunisers who are administering the JE vaccine to individuals recommended for vaccination in Victoria must first complete the Japanese encephalitis eLearning module that has been approved by the Deputy Chief Health Officer – Communicable Disease. This training takes approximately 15 minutes to complete and can be accessed free from <<https://www.health.vic.gov.au/immunisation/programs-of-study>>.

## Monkeypox (MPX) vaccine-specific training

Pharmacist Immunisers who are administering the MPX vaccine to individuals recommended for vaccination in Victoria must first complete the Monkeypox vaccination eLearning module that has been approved by the Deputy Chief Health Officer – Communicable Disease. This training takes approximately 30 minutes to complete and can be accessed free from <<https://www.health.vic.gov.au/immunisation/programs-of-study>>. Completion of this training is a condition of authorisation.

The training includes information on the JYNNEOS® vaccine, as the preferred monkeypox vaccine in Victoria, and therefore Pharmacist Immunisers only have the required knowledge, skills and training within their individual scope to administer the JYNNEOS® vaccine. Patients requiring ACAM2000™ vaccine should be referred to a medical practitioner or nurse practitioner for vaccination.

Standard administration of JYNNEOS® vaccine is by subcutaneous injection however, JYNNEOS® vaccine may also be administered via the intradermal route to people without immunocompromise. This technique must only be used by trained and competent immunisers to minimise inadvertent underdosing, leakage or subcutaneous injection.

An intradermal injection skills and competencies checklist has been developed as a guide to verify that immunisers are deemed clinically skilled and competent in the technique of intradermal injection. This checklist must be completed and issued by an appropriately experienced clinician (for example, a medical practitioner, nurse practitioner or other specialist clinician) proficient in intradermal injection technique who can oversee the assessment of the clinical skills and competencies of an immuniser.  The checklist is available within the *Victorian monkeypox vaccination program guidelines[[7]](#footnote-8)*. Pharmacist Immunisers must additionally comply with the *Victorian monkeypox vaccination program guidelines* when administering the MPX vaccine.

## Vaccinating younger cohorts

It is a Pharmacist Immuniser’s professional responsibility to ensure they are appropriately trained and competent and are meeting best practice for vaccinating children aged five years and older, including identification and management of adverse events following immunisation for this age group. The ‘Immuniser program of study’ includes administration of all vaccines listed on the National Immunisation Program to all age groups including childhood immunisation.

However, in recognition of the additional clinical and communication skills required to administer vaccines to younger children, it is **strongly recommended** that pharmacist immunisers also view the Melbourne Vaccine Education Centre (MVEC) *Immunising Children and Infants webinar* which was developed for workforces administering the COVID-19 vaccine to children aged five years and older. This is available free of charge from the MVEC website at: https://education-mvec.mcri.edu.au/

The Pharmacy Guild of Australia and the Pharmaceutical Society of Australia have also developed additional training modules for pharmacist immunisers who may wish to support their competency and currency of practice administering vaccines to this younger age group.

## General training requirements

The Approval states that pharmacists who are training to administer vaccines are required to:

* hold general registration with the Pharmacy Board of Australia[[8]](#footnote-9)
* hold a current first aid certificate (to be updated every three years)
* hold a current cardiopulmonary resuscitation certificate (to be updated annually)
* administer vaccines only when completing clinical practice as part of a recognised ‘Immuniser program of study’ under the direct supervision of a:
  + medical practitioner;
  + nurse practitioner;
  + ‘Nurse Immuniser’[[9]](#footnote-10) who is compliant with Regulation 8(1) of the *Drugs, Poisons and Controlled Substances Regulations 2017*; or
  + pharmacist who is compliant with Regulation 99(c) of the Drugs, Poisons and Controlled Substances Regulations 2017.

Pharmacists who act as Pharmacist Immuniser mentors or supervisors in the delivery and assessment of a recognised ‘Immuniser program of study’ require a minimum of two years’ recent experience in the administration of vaccines.

Pharmacy students and interns are not precluded from enrolling and completing a theoretical component of immunisation training. However, they are unable to participate in a clinical practice component that includes training to administer vaccines, or administration of vaccines. Pharmacists are unable to successfully complete an ‘Immuniser program of study’ until they hold general registration with the Pharmacy Board of Australia.

Pharmacists may undertake a program of study that meets the requirements of the *National Immunisation Education Framework for Health Professionals[[10]](#footnote-11)*. In Victoria, where pharmacists, students or interns have completed a *Framework* program (for example, in another state or territory), they are not permitted to administer vaccines until they meet all the requirements of the Approval.

Pharmacist Immunisers should access immunisation education opportunities to support best practice and continuing professional development. This may include accessing regular updates to practice, research and publications on immunisation and vaccinations such as the National Centre for Immunisation Research and Surveillance’s Australian Immunisation Professionals weekly update, available at <<https://ncirs.org.au/health-professionals/ncirs-newsletters>>.

# Code of conduct and professional practice standards

Pharmacist Immunisers are expected to comply with all elements of the Pharmacy Board of Australia’s *Code of conduct[[11]](#footnote-12),* including (but not limited to):

* arranging investigations and liaising with other treating practitioners;
* facilitating coordination and continuity of care;
* recognising and working within the limits of a practitioner’s competence and scope of practice;
* providing treatment options based on the best available information and not influenced by financial gain or incentives;
* participating in efforts to promote the health of the community, and being aware of obligations in disease prevention, including screening and reporting notifiable diseases where relevant; and
* keeping knowledge and skills up to date to ensure that practitioners continue to work within their competence and scope of practice.

Pharmacist Immunisers are expected to maintain current knowledge of vaccines and immunisation policies and be able to provide information about vaccines and immunisation services to individuals, within the limits of their professional knowledge and experience.

Where information gathered during the pre-vaccination assessment identifies health concerns or the need for management or intervention (whether or not they are relevant to the vaccination), pharmacists should refer the individual back to their medical practitioner for further treatment or advice.

Pharmacists who are administering vaccines should participate in public health promotion by educating individuals about immunisation recommendations, and motivating individuals, particularly those who are considered at risk, to be vaccinated. The pharmacist’s duty of care also extends to discussion of ongoing vaccinations and encouraging individuals to discuss their needs with a health practitioner of the individual’s choice, e.g. general practitioner.

Any concerns with a registered health professional should be reported to Ahpra by phoning 1300 419 495 or visiting their website at <<http://www.ahpra.gov.au/>>, so concerns can be investigated. See section [12.10](#_Complaints) of these Guidelines for further information.

Service Providers (as defined in section [4](#_Pharmacist_Immunisers_and) of these Guidelines) and Pharmacist Immunisers are expected to comply with and achieve the Pharmaceutical Society of Australia *Professional Practice Standards*[[12]](#footnote-13), in particular, Standard 11: Vaccination service. These standards describe the values of the pharmacy profession and the expected professional behaviour of pharmacists towards individuals, the community and society.

A self-assessment tool accompanies the *Professional Practice Standards* and is available from the Pharmaceutical Society of Australia’s website at <<https://my.psa.org.au/s/article/Professional-Practice-Standards>>.

# Vaccines

The Approval authorises pharmacists to administer selected vaccines to persons of particular ages, with some exclusions. See section [8](#_Target_groups_under), Target groups under the Approval, for the vaccine type and age eligibility.

In all circumstances, vaccines should be administered in accordance with the conditions of the Approval, including in relation to exclusions.

Pharmacists are also authorised to administer Schedule 3 poisons (1:1000 adrenaline) if a therapeutic need exists following administration of a Schedule 4 poison (that is, for the treatment of an anaphylactic reaction to a vaccine).

# Target groups under the Approval

Vaccines should be administered in accordance with the conditions of the Approval. See the Approval, column 2 for further details. See the Approval, column 3 for the list of circumstances in which pharmacists are **not** authorised to administer a vaccine under the Approval[[13]](#footnote-14).

## Influenza vaccine

Victorian Pharmacist Immunisers are authorised to administer influenza vaccine to certain target groups without a prescription or other instruction from an authorised prescriber. These include:

* Target group 1
  + people eligible for government-funded influenza vaccine through the National Immunisation Program (NIP), including:
    - people aged 65 years and older
    - Aboriginal and Torres Strait Islander people aged 5 years and older
    - people aged 5 to 64 years with medical conditions that can lead to complications from influenza, such as severe asthma, lung or heart disease, low immunity or diabetes
    - pregnant people in any stage of pregnancy.
* Target group 2
  + people aged between 5 and 64 years, and not eligible for the NIP.

## Diphtheria-tetanus-pertussis (DTP) vaccines

Victorian Pharmacist Immunisers are authorised to administer diphtheria-tetanus-pertussis vaccines to certain target groups without a prescription or other instruction from an authorised prescriber. These include:

* Target group 1
  + people eligible for government-funded DTP vaccine through the NIP and/or the Victorian Government’s Partner Whooping Cough Vaccine Program, including:
    - people aged 12 years and older (in Year 7 of Secondary School, or age equivalent)
    - people aged 12 years and older requiring catch-up vaccination as per the schedule recommendations current at the time of vaccine administration
    - pregnant people in their second or third trimester of pregnancy, from 20 weeks gestation
    - partners of people who are in their third trimester of pregnancy, or at least 28 weeks pregnant, if the partner has not received a pertussis booster in the last ten years
    - parents and/or guardians of babies if the baby is under six months of age and they have not received a pertussis booster in the last ten years
    - refugees and all humanitarian entrants aged 12 years and older.
* Target group 2
  + people aged 12 years and older who are not eligible for the Victorian Government’s Partner Whooping Cough Vaccine Program, who wish to reduce the likelihood of becoming ill with pertussis
  + people aged 12 years and older, and not eligible for the NIP.

## Human papillomavirus (HPV) vaccine

Victorian Pharmacist Immunisers are authorised to administer human papillomavirus (HPV) vaccine to certain target groups without a prescription or other instruction from an authorised prescriber. These include:

* Target group 1
  + people eligible for government-funded HPV vaccine through the NIP, including:
    - people aged 12 years and older
    - refugees and all humanitarian entrants aged 12 years and older.
* Target group 2
  + people aged 12 years and older, and not eligible for the NIP.

## Measles-mumps-rubella vaccine

Victorian Pharmacist Immunisers are authorised to administer measles-mumps-rubella (MMR) vaccine to certain target groups without a prescription or other instruction from an authorised prescriber. These include:

* Target group 1
  + people eligible for government-funded MMR vaccine through the NIP, including:
    - people aged 15 to 19 years requiring catch-up
    - refugees and all humanitarian entrants aged 15 years and older.
* Target group 2
  + people eligible for government-funded MMR vaccine through the Victorian Government’s Measles-Mumps-Rubella Adult Vaccine Program, including:
    - people born during or since 1966 requiring one or two doses of MMR vaccine (at least one month apart)
    - people planning pregnancy or post-partum with low or negative rubella antibody levels.

## Meningococcal ACWY vaccine

Victorian Pharmacist Immunisers are authorised to administer meningococcal ACWY vaccine to certain target groups without a prescription or other instruction from an authorised prescriber. These include:

* Target group 1
  + people eligible for government-funded meningococcal ACWY vaccine through the NIP, including:
    - people aged 15 to 19 years.
* Target group 2
  + people aged 15 years and older, and not eligible for the NIP, including:
    - individuals who wish to reduce the likelihood of becoming ill with meningococcal A, C, W, or Y strains.

## Pneumococcal vaccine

Victorian Pharmacist Immunisers are authorised to administer pneumococcal vaccine to certain target groups without a prescription or other instruction from an authorised prescriber. These include:

* Target group 1
  + people aged 50 years and older eligible for government-funded pneumococcal vaccine through the NIP, including:
    - adults diagnosed with a risk condition
    - Aboriginal and Torres Strait Islanders
    - non-Indigenous people aged 70 years and older.
* Target group 2
  + people aged 50 years and older, and not eligible for the NIP.

See the online edition of the Australian Immunisation Handbook[[14]](#footnote-15) for identification of people at increased risk and dosing schedule.

Pharmacist immunisers are required to check the Australian Immunisation Register (AIR) records for previous doses, record any doses administered in AIR within the required timeframes, and ensure that patients (and their carers) are provided with suitable information about completing the full schedule of vaccines.

Decision making tools to support pharmacist immunisers administering the pneumococcal vaccine include:

* [The National Immunisation Program - Pneumococcal vaccination schedule from 1 July 2020 – Clinical decision tree for vaccination providers](https://www.health.gov.au/resources/publications/national-immunisation-program-pneumococcal-vaccination-schedule-from-1-july-2020-clinical-decision-tree-for-vaccination-providers) (issued by the Commonwealth Government)
* The [PneumoSmart Vaccination Tool](https://www.immunisationcoalition.org.au/pvt/) and [Pneumococcal disease guide](https://www.immunisationcoalition.org.au/resources/pneumococcal-disease-guide/) (issued by the Immunisation Coalition).

If the pharmacist immuniser is in any doubt of the completeness or veracity of any information provided, the **vaccination should not take place** and the patient should be referred to their medical practitioner for further assessment and care.

## Herpes zoster vaccine

Victorian Pharmacist Immunisers are authorised to administer herpes zoster (shingles) vaccine to certain target groups without a prescription or other instruction from an authorised prescriber. These include:

* Target group 1
  + people aged 70 years and older eligible for a government-funded herpes zoster vaccine through the NIP.
* Target group 2
  + people aged 50 years and older, and not eligible for the NIP.

People aged 70 to 79 years are expected to benefit most from herpes zoster vaccination. The Australian Technical Advisory Group on Immunisation (ATAGI) recommend that people aged 60 years of age and older who have not yet received a herpes zoster vaccine should do so. People aged 50 years and older who are household contacts of a person who is immunocompromised are also recommended to receive the vaccine. Otherwise, adults aged 50 years and older are not routinely recommended to receive the vaccine, but may choose to be vaccinated to reduce their risk of shingles.

The Zostavax® vaccine is a live herpes zoster vaccine. It is contraindicated in people with current or recent severe immunocompromising conditions from either:

* a primary or acquired medical condition, or
* medical treatment14.

People who are, or recently have been immunocompromised due to a medical condition or treatment should be counselled regarding their choice of herpes zoster vaccine.

All immunisers must adhere to safeguards such as performing a pre-vaccination checklist for the vaccine proposed for administration, including a medical history of the patient.

If the immuniser is uncertain about the person’s level of immunocompromise and whether vaccination is safe, they **should not vaccinate** with the Zostavax® vaccine. The Shingrix® vaccine is not a live vaccine and is safe to use in immunocompromised, or shortly expected to be immunocompromised persons aged 50 years and older[[15]](#footnote-16).

Where this information is not complete or the veracity of information is uncertain, the **vaccination should not take place** and the patient should be referred to their medical practitioner for further assessment and care.

## COVID-19 vaccine

Victorian Pharmacist Immunisers are authorised to administer any COVID-19 vaccine approved by the Therapeutic Goods Administration (TGA) to persons included in the patient group for which the COVID-19 vaccine is approved by the TGA for, or recommended by ATAGI for. More information regarding the target groups for COVID-19 can be found in the Victorian COVID-19 Vaccination Guidelines available from the department’s *Information for COVID-19 vaccine providers* webpage at: <https://www.coronavirus.vic.gov.au/information-covid-19-vaccine-providers>.

## Japanese encephalitis (JE) vaccine

Victorian pharmacist immunisers are authorised to administer the JE vaccine to people aged five years and older that are recommended for vaccination as listed on the Victorian Department of Health’s *Japanese encephalitis in Victoria* webpage.

This list may be updated from time to time in response to changing circumstances, so Pharmacist Immunisers are required to check this list to confirm an individual’s eligibility prior to administering the vaccine. The website is available at <<https://www.health.vic.gov.au/infectious-diseases/information-for-health-professionals-japanese-encephalitis-in-victoria>>

This page also includes information about vaccine ordering and supply.

## Monkeypox vaccine

Victorian pharmacist immunisers are authorised to administer the monkeypox vaccine to people aged five years and older that are recommended for vaccination as listed on the Victorian Department of Health’s *Monkeypox* webpage.

This list may be updated from time to time in response to changing circumstances, so Pharmacist Immunisers are required to be aware of the priority target groups recommended for vaccination. Please note that individuals requesting the monkeypox vaccine can self-identify that they meet the current eligibility criteria. They do not need to identify which criteria they meet, nor provide any proof of eligibility. The website is available at: <<https://www.health.vic.gov.au/infectious-diseases/monkeypox>>.

Vaccine supply is limited and controlled centrally through the department. For information about vaccine ordering and supply, refer to the Victorian monkeypox vaccination guidelines, available through the above webpage. Compliance with the *Victorian monkeypox vaccination guidelines* is a condition of the Secretary Approval: Pharmacist Immuniser when administering the monkeypox vaccine to people recommended for vaccination.

## Exclusions

The Approval **excludes***:*

* vaccination for travel purposes[[16]](#footnote-17)
* vaccination of people aged 4 years and younger for influenza vaccine, JE vaccine and MPX vaccine
* vaccination of people aged 11 years and younger for diphtheria-tetanus-pertussis vaccine and HPV vaccine
* vaccination of people aged 14 years and younger for measles-mumps-rubella vaccine and meningococcal ACWY vaccine
* administration of the JE vaccine to people that are not recommended for JE vaccination
* administration of the MPX vaccine to people that are not recommended for MPX vaccination
* vaccination of people with contraindications defined in the online version of the *Australian Immunisation Handbook*[[17]](#footnote-18)
* MPX vaccination of people with contraindications listed in current advice from ATAGI
* vaccination for the express purpose of post-exposure prophylaxis in people with a tetanus-prone wound[[18]](#footnote-19)
* vaccination of people who are contacts in the event of a case of pertussis, unless directed by the department[[19]](#footnote-20)
* vaccination of pregnant people against measles, mumps and rubella
* vaccination of people aged 49 years and younger for pneumococcal vaccine and herpes zoster vaccine.

Pharmacist Immunisers should refer to the Approval for specific information about the circumstances that are excluded for each vaccine.

# Clinical governance and risk management

Clinical governance is the integrated systems, processes, leadership and culture that are at that core of providing safe, effective, accountable and person-centred health care, underpinned by continuous improvement.

Service Providers (in this case, pharmacies, pharmacy depots and hospitals) are responsible for service provision and there is an expectation that a formal and effective clinical governance framework is in operation.

## Victoria’s clinical governance framework

Organisations in which Pharmacist Immunisers are employed or otherwise engaged to provide immunisation services (Service Providers) are responsible for ensuring there are sufficient resources to enable safe and competent care for the consumers for whom healthcare services are provided.

In 2018, Safer Care Victoria published an updated version of the *Victorian clinical governance framework* that outlines expectations regarding clinical governance and provides best practice guidance to inform good clinical governance[[20]](#footnote-21). The five domains of the framework, underpinned by continuous monitoring and improvement are leadership and culture, consumer partnerships, workforce, risk management and clinical practice.

Image of a grey circle with the words monitoring, evaluating and improving around the edge, with arrows indicating a continuous cycle.
Coloured circles overlapping in a flower shape include the titles leadership and culture, consumer partnerships, workforce, risk management, and clinical practice. 
At the centre of the diagram includes the words safe, effective, person-centred care.

The framework reinforces the importance of providing a safe environment for both consumers and staff, and that staff have the required knowledge and skills, technology and equipment to provide the best care possible, and are accountable for the care they provide.

It sets out the systems, processes and protocols that should be in place to support:

* contribution to a culture of safety, transparency, multidisciplinary teamwork and collaboration and ensuring high-quality care for every consumer in a way that is seamless and integrated;
* effective monitoring and improved clinical performance, including clinical processes, equipment and technology that are designed to minimise error and support clear communication and accurate reporting of care provision;
* comprehensive strategies and plans for recruiting, allocating, developing, engaging and retaining high-performing staff and includes supporting staff to work within their scope, provide supervision where required and manage performance;
* new procedures and therapies to be introduced in a way that ensures quality and safety issues have been identified; and
* Service Providers and staff involved in immunisation services to actively identify, monitor and manage areas of key risk and lead appropriate escalation, response and mitigation where safety may be compromised.

The framework has been designed so that Service Providers can adapt and implement its components to best meet the needs of their consumers and organisation.

## Supporting clinical governance

The Pharmaceutical Society of Australia’s *Competency Standards Framework for Pharmacists* detail an expectation that all pharmacists understand and contribute to organisational/corporate and clinical governance[[21]](#footnote-22).

Their *Clinical Governance Principles for Pharmacy Services[[22]](#footnote-23)* documentincludes information relating to clinical governance concepts, their application in services led by pharmacists and the ongoing evaluation of pharmacy services, including vaccination services.

## Other safety requirements

When pharmacists are conducting a pre-vaccination assessment and administering vaccinations, they must not engage in any other activity, including dispensing.

All immunisation service staff (including clinical and non-clinical staff) should be familiar with the immunisation service that is being provided, and be informed about their roles and responsibilities, particularly in relation to managing an adverse event following immunisation (AEFI).

Pharmacist Immunisers undertaking a mobile or outreach immunisation clinic as a solo practitioner need to comply with all protocols and procedures set by the Service Provider that employs or otherwise engages them.

**Reporting all vaccinations administered to the Australian Immunisation Register (AIR) is mandatory. It is important that timely reporting of all vaccinations to the AIR occurs.**

# Premises, professional governance and staffing

Pharmacists administering vaccines are to be connected to a pharmacy, pharmacy depot or hospital (Service Provider) that has registered with the department to provide a vaccination service and hold a government-funded vaccine account. This means that they must either own (for example, the pharmacist owner of a pharmacy), be employed or otherwise engaged by that Service Provider.

Service Providers are defined as:

* a hospital
* a pharmacy as defined in the *Pharmacy Regulation Act 2010*
* a pharmacy depot, as defined in the *Pharmacy Regulation Act 2010*, that is a stand-alone business on premises owned or leased by the licensee of the related pharmacy.

## Premises

Victorians can receive vaccinations in a range of settings including:

* pharmacies
* general practices
* Aboriginal Community Controlled Health Services
* community health centres
* aged care facilities
* Local Council clinics
* staff occupational health clinics
* in the home.

All vaccines must be administered in accordance with the relevant legislation, best practice and the guidelines and recommendations in the *Australian Immunisation Handbook*[[23]](#footnote-24).

Service Providers and Pharmacist Immunisers must comply with requirements of the *Australian Guidelines for the Prevention and Control of Infection in Healthcare*[[24]](#footnote-25) and the *National vaccine storage guidelines - Strive for 5 (current version)*[[25]](#footnote-26) which includes provisions for caring for vaccines in coolers, data loggers and cooler ice packs for mobile or outreach immunisation clinics.

Where vaccinations are administered in hospital pharmacies, community pharmacies or pharmacy depots, the Approval requires that these premises meet the guidelines for facilities providing immunisation services, as described in the *Victorian Pharmacy Authority Guidelines*[[26]](#footnote-27) that are current at the time.

Pharmacist Immunisers providing vaccination services in other settings, such as mobile or outreach clinics, should comply with vaccination policies and procedures set by their employer (Service Provider) ensuring consideration has been given for the appropriateness of the setting to the clinical procedure undertaken and the person receiving care.

Pharmacist Immunisers should also ensure they have a safe and suitable vaccination environment for administration of vaccines to young children. Anxiety/pain related reactions to any vaccine is likely to be higher for children and adolescents than adults. While most cases of fainting and syncopal seizures are not serious, some children may sustain injury from high impact falls, so it is important to have a safe vaccination environment and an awareness of the clinical signs of a faint/syncope[[27]](#footnote-28).

Any vaccines ordered need to be delivered to the registered location of the pharmacy, pharmacy depot or hospital and any pharmacies wanting to provide an immunisation service in Victoria must also be registered with the department.

With regard to facilities for immunisation services, the *Victorian Pharmacy Authority Guidelines* state that:

* The dispensary is not to be used for immunisation services.
* The room or area may be dedicated to the purpose, or an existing consulting room may be used. Hand sanitisation facilities are to be in the room.
* The room or private consultation area is to:
  + be clean and hygienic;
  + be designed such that the procedure is not visible or audible to other persons in the pharmacy;
  + have sufficient floor area, clear of equipment and furniture, to accommodate the client and an accompanying person, and to allow the practitioner room to manoeuvre;
  + have a bench with an impervious surface of an adequate area, a chair, a first aid couch or similar; and
  + have an emergency response protocol (preferably laminated) on display, an emergency response kit, and the most recent editions of the *Australian Immunisation Handbook* and the *National Vaccine Storage Guidelines - Strive for 5*25*.*
  + The room or private consultation area should be designed and set up to accommodate people with disability.
* Seating is to be made available post-vaccination, so that the client may be observed in accordance with professional guidelines.

The *Victorian Pharmacy Authority Guidelines* also state that only a temperature-monitored refrigerator manufactured exclusively for the purpose of storage of vaccines may be used, but can also be used to store other medicines. The Approval also requires compliance with the National vaccine storage guidelines – Strive for 5 (current edition), which recommends that the refrigerator used to store vaccines should be a purpose-built vaccine refrigerator, manufactured exclusively for the purpose of storage of vaccines.

The refrigerator must also possess a temperature data logger, in order to comply with the *Victorian Pharmacy Authority Guidelines*. The *Victorian Pharmacy Authority Guidelines* also state that where the refrigerator is not located in the dispensary, it must be fitted with a lock.

An additional refrigerator with a freezer section will be required for storing ice packs and gel packs – purpose-built vaccine refrigerators do not have freezer compartments.

The *National vaccine storage guidelines – Strive for 5* (current edition) provides important information relating to the provision of mobile or outreach immunisation clinics, such as:

* 1. portable purpose-built vaccine refrigerators and ‘coolers’
  2. packaging vaccines and diluents for transport
  3. monitoring equipment and recording refrigerator temperatures, documentation and reporting
  4. environmental considerations.

A copy of certificate of training completion should be displayed in the vaccination area to assure individuals that the Pharmacist Immuniser has successfully completed an ‘Immuniser program of study’ that has been recognised by the Victorian Chief Health Officer.

In mobile or outreach services where a variety of rooms or private consultation areas may be used for vaccination purposes, the Pharmacist Immuniser must keep evidence of completion of their training on hand to present to the individual on their request.

## Registration of premises

### Registration with the department

Pharmacies, pharmacy depots and hospitals are required to nominate a responsible pharmacist and register with the department before they begin administering vaccinations.

Registration with the department will enable pharmacists to:

* 1. receive government-funded vaccines included within the Approval for administration to the target groups eligible for the NIP *and* Victorian Government funded vaccination programs
  2. be provided with important information about vaccine updates, such as schedule changes, new resources and current vaccine recommendations.

Registration requires completion of an application form to provide vaccination services for a government-funded vaccine account, evidence of completion of approved training, and evidence of suitable cold chain management. The application form must be accompanied with the *Australian Immunisation Register – Application to register as a vaccination provider form (IM004)*.

**Service Providers that have already registered with the department do not need to re-register under the expanded program.**

The application for government-funded vaccines account form can be downloaded from <<https://www.health.vic.gov.au/immunisation/vaccine-order-forms-and-stock-information>>.

Nominated Pharmacist Immunisers leaving the practice and/or changes to the Service Provider’s account must be notified to the department’s Immunisation unit **within 5 working days** via email <[immunisation@health.vic.gov.au](mailto:immunisation@health.vic.gov.au)>.

### Registration as a business involving skin penetration

Normally, businesses involving skin penetration are required to be registered by local government and regulated under the Public Health and Wellbeing Act 2008 and the Public Health and Wellbeing Regulations 2019. However, the practice of a person registered under the Health Practitioner Regulation National Law to practise in the pharmacy profession (other than as a student) is exempt from the requirement to register with their local government as a business undertaking skin penetration (or other business to which the registration requirement applies under s 68 of the Act).

The *Public Health and Wellbeing Regulations 2019* are available from Victoria Law Today at <<http://www.legislation.vic.gov.au/>>.

## Insurance

The Service Provider and the Pharmacist Immuniser are required to hold appropriate insurance for the administration of vaccines and provision of a vaccination service.

Pharmacist Immunisers should consult with their insurance provider regarding insurance appropriate to their circumstances, including the provision of care outside of pharmacy premises.

In the context of contract staffing models (refer to section [10.6.3](#_Contract_staffing_models)), the Service Provider may need to provide details of their insurance coverage to contracted Pharmacist Immunisers. This is to enable contracted staff to meet the requirements of their professional registration for evidence of appropriate Professional Indemnity Insurance.

## Accreditation

Pharmacies in which vaccines are administered must have a current accreditation status through an appropriate Pharmacy Accreditation Program, such as the Quality Care Pharmacy Program <[www.qcpp.com](http://www.qcpp.com)>.

## Advertising

All vaccines for human use are classified as prescription-only medicines (Schedule 4) in the Poisons Standard. Advertising of Schedule 4 poisons to the public is strictly prohibited under the *Therapeutic Goods Act 1989* and the *Drugs, Poisons and Controlled Substances Act 1981*.

However, a pharmacy may promote that they offer a vaccination service, subject to meeting National Law requirements. The *Guidelines for advertising a regulated health service* have been developed jointly by the National Boards under section 39 of the National Law. These are available at: <https://www.ahpra.gov.au/Resources/Advertising-hub/Advertising-guidelines-and-other-guidance/Advertising-guidelines.aspx>

## Professional governance and staffing arrangements

### Professional governance

Service Providers have a duty of care to safeguard their consumers from foreseeable harm.

In conjunction with the Approval, the Service Provider has a duty to have in place the following minimum elements to support the provision of safe, high quality immunisation services by pharmacists:

* A clinical risk management strategy for immunisation services.
* A policy and procedure(s) related to the provision of immunisations by pharmacists under the Approval.
* A clinical credentialing process for initial and ongoing employment of pharmacists providing services under the Approval, including Pharmacist Immunisers providing immunisation services to third-party organisations under ‘visiting appointments’.

Service Providers must ensure that any Pharmacist Immuniser meets and maintains the requirements for professional registration for the full period of their employment (or engagement). To this end, it is strongly recommended that service providers develop and institute policies/procedures to:

* Confirm a Pharmacist Immuniser’s registration status on initial employment (or engagement).
* Confirm a Pharmacist Immuniser’s registration status at annual renewal.
* Outline a Pharmacist Immuniser’s individual-level responsibility to immediately advise their employer (or contractor) of any change and/or risk to the maintenance of their professional registration status.
* Manage concerns regarding a Pharmacist Immuniser’s clinical competency, professional behaviour and/or personal conduct which may potentially impact their registration status.
* Outline employer (or contractor) mandatory notification responsibilities pertaining to the Pharmacist Immuniser behaviour(s) which may constitute notifiable contact, as per the requirements of the *Health Practitioner Regulation National Law (Victoria) Act 2009*.

It is recommended that Service Providers also refer to the Pharmaceutical Society of Australia’s *Clinical Governance Principles for Pharmacy Services[[28]](#footnote-29)*  in relation to professional governance and clinical considerations.

### Visiting appointments

Pharmacist Immunisers may, as part of their employment or other arrangement with a Service Provider, as defined in section [4](#_Pharmacist_Immunisers_and) of these Guidelines, be invited and/or requested to access a third-party organisation (such as a community health service or aged care facility) under a ‘visiting appointment’ to provide immunisation services. A visiting appointment does not constitute a contract of employment/service between the Pharmacist Immuniser and the third-party organisation, and although the Pharmacist Immuniser is not paid by the third-party organisation for their input, they may charge a fee for their professional services from the patient/consumer or via another third-party funder.

Under a visiting appointment, both the Pharmacist Immuniser and the third-party organisation have reciprocal rights and responsibilities that should be formalised via an approval process for visiting appointment status. The third-party organisation must establish base standards for visiting appointments, which may vary according to the context in which the service is being provided (e.g. acute, subacute, residential services, community or workplace setting). The expected standard may be the same or similar to the third-party organisation’s standard for employing other pharmacists or health professionals. This may include, but is not limited to:

* Verification of meeting all requirements of the Approval (see section [4](#_Pharmacist_Immunisers_and))
* Proof of identity
* Confirmation of citizenship/permanent residency status/visa
* National police check clearance
* Working with Children certificate
* Insurance indemnity check
* Confirmation of immunisation status
* Compliance with mandatory training requirement (i.e. via recognition of prior learning).

Third-party organisations may need to consider the duration and scope of the visiting appointment approval, as well as the provision of specific privileges, such as access to premises, treatment facilities and individual patients/consumers, and the requirement to document the intervention within the third-party organisation’s patient/consumer record.

Visiting Pharmacist Immunisers also have a number of responsibilities in relation to their visiting status. As well as observing the terms of their visiting appointment approval (i.e. duration, scope of role and privileges), visiting Pharmacist Immunisers must observe organisational guidelines and policies pertaining to incident reporting, open disclosure, privacy and confidentiality, health information management, workplace health and safety and infection control. This may require the visiting Pharmacist Immuniser to undertake mandatory training or demonstrate recognised prior learning to satisfy third-party organisational requirements.

### Contract staffing models

Pharmacist Immunisers may be employed by Service Providers to respond to peaks in demand for services however, the use of contract staff needs to be proactively managed by Service Providers.

The Service Providers’ operational policies and procedures for employing appropriately qualified staff and ensuring consumer safety need to specifically identify how the use of contracted staff is managed. The contracts that employers have with either the Pharmacist Immuniser or any third party (e.g. workforce agency) need to specify the required qualifications, competencies and skills of the staff, and procedures for monitoring the quality of the contracted service.

Service Providers may need to provide additional information to their insurance providers about how employee (or contract services) working under the Approval are managed.

Further, evidence of appropriate Professional Indemnity Insurance is a mandatory requirement for registration of health professionals under Ahpra. As such, Service Providers may need to provide details of the coverage they hold to their employees (so they in turn can provide this to meet the Ahpra requirement).

### Staffing arrangements for clinical risk management

It is a condition of the Approval that the Pharmacist Immuniser ensures at least one other (clinical or non-clinical) staff member, who holds a current first aid and cardiopulmonary resuscitation certificate, is on duty in the pharmacy when the vaccines are administered, and within the line of sight of the person vaccinated for a minimum period of 15 minutes afterwards. See also section [12.1](#_Emergency_response_protocol) of these Guidelines.

# Equipment and resources

Compliance with the online version of the *Australian Immunisation Handbook*[[29]](#footnote-30)28 and *National vaccine storage guidelines – Strive for 5 (current edition)*[[30]](#footnote-31)29 are conditions of the Approval.

All equipment should comply with the recommendations contained in these documents, and should include:

* a purpose-built vaccine refrigerator with a temperature data logger
* coolers, data loggers, cooler ice packs and insulation materials for mobile or outreach immunisation clinics
* all necessary consumables required for vaccine administration
* an appropriately sized sharps container to dispose of clinical waste, including used syringes and needles.

Pharmacist Immunisers must have access to the Australian Immunisation Register[[31]](#footnote-32) and the below resources when providing mobile or outreach immunisation clinics.

Resources that are required to be readily accessible include:

* the online *Australian Immunisation Handbook[[32]](#footnote-33)*
* a current edition of the *National vaccine storage guidelines – Strive for 5*29
* materials to support communication about vaccination, including Questions about vaccination available at <<https://www.health.gov.au/resources/publications/questions-about-vaccination>>.

Pharmacist Immunisers should also subscribe to the department’s *Immunisation Newsletter*, which is available to subscribe at <<https://www.health.vic.gov.au/subscribe>>.

A range of resources exist to support the delivery of safe vaccination services, including the *Practice guidelines for the provision of immunisation services within pharmacy* (current edition) – Pharmaceutical Society of Australia[[33]](#footnote-34).

## Anaphylaxis response kit

Pharmacist Immunisers must have an anaphylaxis response kit accessible when administering vaccines. All equipment should comply with the recommendations in the online version of the *Australian Immunisation Handbook*30, and include:

* adrenaline 1:1000 (minimum of three ampoules). Always regularly check expiry dates, discard and replace expired stock and replenish stock after use
* a minimum of three 1 mL syringes and 25 mm length needles for intramuscular injection
* cotton wool swabs
* a pen, paper and stopwatch to record time of administration of adrenaline
* a laminated copy of adrenaline doses as per the most current edition of the handbook
* a laminated copy of ‘Recognition and treatment of anaphylaxis’ as per the most current edition of the handbook
* an emergency response protocol (preferably laminated and on display) (see section [12.1](#_Emergency_response_protocol) of these Guidelines) identifying assigned roles and responsibilities. All clinical and non-clinical pharmacy staff should be aware of the emergency response protocol, and their roles and responsibilities in the event of an emergency.

Where adrenaline ampoules are unavailable, an adrenaline autoinjector may be kept in an anaphylaxis response kit. Pharmacists should refer to the guidance in the *Australian Immunisation Handbook* regarding the use of autoinjectors in vaccination services.

Pharmacist Immunisers undertaking solo mobile or outreach immunisation clinics require a specific protocol detailing their role and responsibilities in the event of an emergency.

# Protocols

Pharmacist Immunisers should implement a process to regularly monitor online updates to the *Australian Immunisation Handbook30*, the *National vaccine storage guidelines – Strive for 5*[[34]](#footnote-35), the *Victorian Pharmacy Authority Guidelines*[[35]](#footnote-36), these Guidelines, and any other key resources to inform their immunisation practice.

## Emergency response protocol

An emergency response protocol must be kept as part of the anaphylaxis tool kit (preferably laminated and on display or easily accessible in the case of mobile or outreach immunisation clinics). The protocol should identify assigned roles and responsibilities of staff members. All staff should know and understand the protocol. Pharmacist Immunisers undertaking mobile or outreach immunisation clinics as a solo practitioner (employed or otherwise engaged by a Service Provider, as defined in section [4](#_Pharmacist_Immunisers_and) of these Guidelines) require a specific protocol.

This protocol should be checked and available prior to each vaccination session and pharmacists should ensure that:

* systems are in place to regularly review the anaphylaxis response kit and emergency response protocol;
* all Pharmacist Immunisers have current cardiopulmonary resuscitation (updated annually) and first aid certification (updated every three years);
* a suitably qualified staff member with a current cardiopulmonary resuscitation (updated annually) and first aid certification (updated every three years) is on duty within the line of sight of the person vaccinated when vaccines are administered and for at least 15 minutes afterwards;
* all Pharmacist Immunisers maintain recency of practice and continuing professional development in the management of adverse events following immunisation (AEFI).

## Cold-chain maintenance

All Pharmacist Immunisers should follow the principles of safe vaccine storage and cold-chain maintenance to ensure that clients receive effective and potent vaccines. These principles are contained in the *National vaccine storage guidelines - Strive for 5 (current edition)*, compliance with which is a condition of the Approval.

Pharmacist Immunisers undertaking mobile or outreach immunisation clinics must comply with the *National vaccine storage guidelines - Strive for 5*.

Cold chain breaches are defined as:

1. **when vaccine storage temperatures deviate outside the recommended range of +2°C to +8°C.**
2. **exposure to light as vaccine has been removed from the packet and the glass fridge door allows light to penetrate.**

The optimal storage temperature for vaccines is +5°C.

**All vaccine temperatures recorded below +2°C or above +8°C must be reported to the department**. This does not include temperature deviations or excursions in which the temperature reaches a maximum of up to +12°C for 15 minutes or less. **Any deviations below +2°C must be reported**.

In the event of a cold-chain breach related to private vaccine stock, the Pharmacist Immuniser should contact the manufacturer for advice.

Information can be found on the department’s immunisation website on how to manage a cold-chain breach related to government-funded stock provided through the NIP, Victorian Government’s Partner Whooping Cough Vaccine Program or Measles-Mumps-Rubella Adult Vaccine Program. Information is available from <<https://www.health.vic.gov.au/immunisation/cold-chain-breach-reporting>>.

## Assessment and consent

The Pharmacist Immuniser must obtain valid consent from the individual being vaccinated and/or their parent/guardian, and undertake pre-vaccination screening prior to vaccination to identify contraindications or precautions.

The pre-vaccination screening checklist included in the online *Australian Immunisation Handbook*[[36]](#footnote-37)must be completed.

Prior to obtaining consent, the individual or the parent/guardian of the individual being vaccinated, should be:

* provided with information (preferably written), including the risks and benefits, relating to the vaccine and the immunisation procedure and what to do in the event of side effects following vaccination. This should include the name and contact details of the Pharmacist Immuniser and the Service Provider (if different);
* provided with information of any fees that will be charged to the individual or the individual’s parent/ guardian for the vaccine and the service;
* asked if a copy of the individual’s vaccination record should be provided to the individual’s nominated general practitioner and any other relevant health professional suggested by the individual (such as an obstetrician), in the interest of ensuring continuity of care;
* notified that the individual’s vaccination record will be reported to the Australian Immunisation Register.

Pharmacist Immunisers should have a process to obtain and document individual consent, and to ensure that individual privacy and confidentiality are always upheld.

## Consent on behalf of a child or adolescent

In general, a parent or legal guardian of a child or adolescent has the authority to consent to that individual being vaccinated[[37]](#footnote-38).

As outlined in the Australian Immunisation Handbook, in the case the parent and/or guardian of the individual being vaccinated is not present, pharmacists should be satisfied that the individual has the capacity and sufficient maturity to understand what is proposed. Pharmacists must assess whether the:

* individual is mature enough to understand the advice and implications of the vaccine and the immunisation procedure.
* pharmacist has tried to persuade the individual to inform their parent and/or guardian or allow the pharmacist to inform them.
* individual’s health may suffer without the vaccine and assess the individual’s needs including whether the individual has any contraindications.
* individual understands their vaccination history and the pharmacist must verify against the individual’s records on the Australian Immunisation Register.
* individual’s best interests require the pharmacist to administer the vaccine.

Pharmacists who decide not to administer the vaccine based on their assessment of the individual’s maturity and understanding should refer the individual back to their medical practitioner.

If a child or adolescent refuses a vaccination that a parent and/or guardian has given consent for, respect the child’s or adolescent’s wishes, and inform the parent or guardian[[38]](#footnote-39).

## Monitoring

The Pharmacist Immuniser must advise the individual or the individual and their parent and/or guardian to remain on the immunisation premises for a minimum of 15 minutes post-vaccination, to allow for immediate attention in the event of an adverse event following administration of the vaccine. Seating must be offered near the immunisation area and within the line of sight of the pharmacist or a person qualified in first aid and cardiopulmonary resuscitation.

A solo Pharmacist Immuniser undertaking mobile or outreach immunisation clinics must ensure the clinical setting is appropriate for managing an adverse event following immunisation.

Individuals who have been vaccinated should be provided with discrete identifiers (such as a sticker marked with the time of vaccine administration) to enable quick identification of an individual who has received a vaccination, should they require further assistance. Documenting a time of vaccine administration on the discrete identifier will also help individuals know when the minimum 15-minute wait time is complete.

The Pharmacist Immuniser must advise the individual or the parent/guardian of the person being vaccinated of the potential risks associated with leaving during the 15-minute period following the vaccination, and note in the record of vaccination if the individual chooses to do so.

## Adverse events

Equipment and poisons necessary for the management of anaphylaxis and protocols, including the emergency response protocol, should be checked and available before each vaccination session, regardless of the setting (in the case of mobile or outreach services). Each person’s roles and responsibilities should be understood before the Pharmacist Immuniser commences the vaccination session.

Individuals (or their parent and/or guardian) should be informed about the potential side effects of vaccination, how to manage them, and who to notify of delayed adverse events that may occur once they have left the immunisation premises.

## Record keeping and reporting

The Pharmacist Immuniser is required to comply with the record-keeping requirements of the *Drugs, Poisons and Controlled Substances Regulations 2017* and all other relevant legislation, and the recommendations of the *Australian Immunisation Handbook* (online)[[39]](#footnote-40) and reporting to the Australian Immunisation Register. They must record the following details for each vaccine administered:

* date and time of the vaccination
* name, form, and strength of the vaccine, including brand name, batch number and dose number
* name and address of persons to whom the vaccine is administered
* name and contact details of the Pharmacist Immuniser carrying out the administration
* name and contact details of the Service Provider
* injection site
* date the next vaccination is due (if applicable)
* any adverse events observed or reported.

A suggested record keeping and reporting template is available at Attachment 1.

A copy of the individual’s vaccination record, and any other relevant individual consent and screening documents should be stored in a format and location that allows timely access, easy retrieval and protects individual confidentiality. Records must be retained and provided in accordance with the relevant legislation and regulations. **It is important that timely reporting of all vaccinations to the Australian Immunisation Register occurs.**

If consent was granted by the individual, or the parent/guardian of the individual being vaccinated, to provide a copy of their vaccination record to their nominated general practitioner and any other relevant health professional, the copy must be provided, preferably by fax or secure messaging, **within one week of administering the vaccine.**

The copy must contain the:

* Pharmacist Immuniser’s name and contact information
* Service Provider’s name and contact information
* individual’s name and address
* date and time of the vaccine administration
* name (including brand name) of the vaccine
* any adverse events observed.

## Reporting adverse events

Pharmacist Immunisers must report any Adverse Event Following Immunisation (AEFI) to the Surveillance of Adverse Events Following Vaccination in the Community (SAEFVIC). The SAEFVIC requirements for reporting are available from <<https://www.health.vic.gov.au/immunisation/adverse-events-following-immunisation-reporting>>.

SAEFVIC is a public health partnership initiative of the Victorian Immunisation Program. The service helps providers report and look after children and adults who have experienced an AEFI. Providing information about an AEFI to SAEFVIC (the AEFI-Clinical Assessment Network (AEFI-CAN)) will help detect any problems with vaccines or systems as early as possible, and will help ensure a safe immunisation program in Victoria.

## Immunisation registers

The Australian Immunisation Register (AIR) is a national register that records vaccinations given to people of all ages in Australia.

Pharmacists must register with the AIR as part of the requirements to provide a vaccination service in Victoria and the department’s government-funded vaccine account application requirements. Pharmacists can apply as a business to register with the AIR to obtain login details which enables pharmacists to report all vaccinations administered to the AIR.

Registration forms are available from <<https://www.humanservices.gov.au/organisations/health-professionals/forms/im004>>

**Pharmacist Immunisers or the Service Provider are required to record all NIP vaccines administered to AIR in a timely manner**.

It is **strongly recommended** that all non-NIP vaccines are recorded to AIR. Patients may elect not to have the MPX vaccine recorded to AIR.

## Complaints

Pharmacist Immunisers and Service Providers should develop a process for complaints regarding vaccination services. At a minimum, all individuals who receive vaccination services should be advised that:

1. Complaints relating to the pharmacist’s professional practice should be directed to the Australian Health Practitioner Regulation Agency by phoning 1300 419 495 or visiting the Ahpra website at <[www.ahpra.gov.au](http://www.ahpra.gov.au)>.
2. Complaints relating to the pharmacy premises should be directed to the Victorian Pharmacy Authority at <[www.pharmacy.vic.gov.au](http://www.pharmacy.vic.gov.au)>.
3. Complaints relating to the vaccination setting (non-pharmacy setting) should be directed to the Immunisation Unit, Department of Health by email at <[immunisation@health.vic.gov.au](mailto:immunisation@health.vic.gov.au)>.
4. Individuals may also bring a complaint against a health service provider to the Health Complaints Commissioner at <<https://hcc.vic.gov.au/>>.

# Fees

Pharmacist Immunisers may wish to charge a service fee for administration of the vaccination to people who are eligible for government-funded vaccines or state-funded vaccination programs. **If they wish to do so,** **Pharmacist Immunisers are required to advise these persons about the availability of government-funded vaccines and free vaccination services through bulk-billing general practitioners, prior to administering the vaccine**.

For those persons who are not eligible for government-funded vaccines, the pharmacist may charge for the cost of the vaccine plus an administration fee

Table 1 summarises the circumstances in which a Pharmacist Immuniser may charge people for the cost of the vaccine and for administering the vaccine. Please read in conjunction with section [8](#_Target_groups_under), Target groups under the Approval.

**Table 2. Pharmacist Immuniser fees**

| Target group | Can the Pharmacist Immuniser charge for the cost of the vaccine? | Can the Pharmacist Immuniser charge for administering the vaccine (a service charge)? |
| --- | --- | --- |
| Persons **eligible** for government-funded vaccines under the NIP (influenza, HPV, DTP, MMR, meningococcal ACWY, pneumococcal and herpes zoster vaccines), Victorian Government’s Partner Whooping Cough Vaccine Program or Measles-Mumps-Rubella Adult Vaccine Program | **No**  Government-funded vaccines should be accessed from the department’s government vaccine order form. See section [10.2.1](#_Registration_with_the). | **Yes**  However, Pharmacist Immunisers must advise people about the availability of free vaccination services through bulk-billing general practitioners. |
| Persons listed on the Victorian Department of Health’s Japanese encephalitis in Victoria webpage as recommended to receive the JE vaccine | **No** | **Yes**  However, Pharmacist Immunisers must advise people about the availability of free vaccination services through bulk-billing general practitioners. |
| Persons listed on the Victorian Department of Health’s Monkeypox webpage as recommended to receive the MPX vaccine | **No** | **Yes** |
| Persons **not eligible** for government-funded vaccine under the NIP (influenza, HPV, DTP, MMR meningococcal ACWY, pneumococcal and herpes zoster vaccines), Victorian Government’s Partner Whooping Cough Vaccine Program or Measles-Mumps-Rubella Adult Vaccine Program | **Yes**  These vaccines should be accessed from private suppliers. | **Yes** |
| Persons **not** listed on the Victorian Department of Health’s Japanese encephalitis in Victoria webpage as recommended to receive the JE vaccine  Persons **not** listed on the Victorian Department of Health’s Monkeypox webpage as recommended to receive the MPX vaccine | **No** – pharmacist immunisers are not authorised to administer vaccines to people that are not recommended to receive the vaccine | |

# Questions

If you have any questions regarding the Victorian Pharmacist-Administered Vaccination Program or these Guidelines, please contact the Immunisation unit, Department of Health via email: <[immunisation@health.vic.gov.au](mailto:immunisation@health.vic.gov.au)>.

1. Available from: <https://www2.health.vic.gov.au/public-health/immunisation/immunisers-in-victoria/pharmacist-immunisers> [↑](#footnote-ref-2)
2. Victorian Department of Health, Japanese encephalitis in Victoria – Information for Health Professionals available at: <https://www.health.vic.gov.au/infectious-diseases/information-for-health-professionals-japanese-encephalitis-in-victoria> [↑](#footnote-ref-3)
3. Monkeypox webpage: <https://www.health.vic.gov.au/infectious-diseases/monkeypox>

   4<https://www.coronavirus.vic.gov.au/information-covid-19-vaccine-providers> [↑](#footnote-ref-4)
4. [↑](#footnote-ref-5)
5. This does not include limited registration, provisional registration, non-practising registration or student registration. [↑](#footnote-ref-6)
6. Available from: <https://www.health.vic.gov.au/infectious-diseases/monkeypox> [↑](#footnote-ref-7)
7. Available from: <https://www.health.vic.gov.au/infectious-diseases/monkeypox> [↑](#footnote-ref-8)
8. This does not include limited registration, provisional registration, non-practising registration or student registration. [↑](#footnote-ref-9)
9. ‘Nurse Immuniser’ is a nurse acting in accordance with a Secretary Approval to administer certain vaccines.   [↑](#footnote-ref-10)
10. Available from: <https://www.health.gov.au/resources/publications/national-immunisation-education-framework-for-health-professionals> [↑](#footnote-ref-11)
11. Pharmacy Board Code of Conduct available from: <http://www.pharmacyboard.gov.au/Codes-Guidelines/Code-of-conduct.aspx> [↑](#footnote-ref-12)
12. Pharmaceutical Society of Australia, 2017. Professional Practice Standards (version 5). Available at <https://my.psa.org.au/s/article/Professional-Practice-Standards> [↑](#footnote-ref-13)
13. Available from: <https://www2.health.vic.gov.au/public-health/immunisation/immunisers-in-victoria/pharmacist-immunisers> [↑](#footnote-ref-14)
14. Australian Immunisation Handbook, available at <https://immunisationhandbook.health.gov.au/>. [↑](#footnote-ref-15)
15. Australian Government, Australian Technical Advisory Group on Immunisation, 2022, available at: <https://www.health.gov.au/sites/default/files/documents/2022/05/statement-on-the-clinical-use-of-zoster-vaccine-in-older-adults-in-australia-statement-on-the-clinical-use-of-zoster-vaccine-in-older-adults-in-australia.pdf>  [↑](#footnote-ref-16)
16. Travel medicine is a specialist area that is outside the scope of the Approval. [↑](#footnote-ref-17)
17. Australian Immunisation Handbook, available at <https://immunisationhandbook.health.gov.au/>. [↑](#footnote-ref-18)
18. Pertussis-containing vaccine is only available in Australia in combination with diphtheria and tetanus, or diphtheria, tetanus and poliomyelitis. Patients needing DTP vaccine for tetanus prophylaxis should be referred to a medical practitioner or nurse practitioner for full assessment. [↑](#footnote-ref-19)
19. A case of this vaccine-preventable disease is notifiable to the Department of Health under the *Public Health and Wellbeing Regulations 2019*. The department will advise on management of the case and contacts. [↑](#footnote-ref-20)
20. Department of Health. Safer Care Victoria. Delivering high-quality healthcare: Victorian clinical governance framework June 2017. Available at <https://www.bettersafercare.vic.gov.au/reports-and-publications/clinical-governance-framework> [↑](#footnote-ref-21)
21. Pharmaceutical Society of Australia. National Competency Standards Framework for Pharmacists in Australia 2016, published 2017. Available at: <https://www.psa.org.au/practice-support-industry/national-competency-standards/> [↑](#footnote-ref-22)
22. Pharmaceutical Society of Australia. Clinical Governance Principles for Pharmacy Services, 2018. Available at: <https://www.psa.org.au/wp-content/uploads/2019/05/PSAClinicalGovernancePrinciples2018_FINAL.pdf> [↑](#footnote-ref-23)
23. Available at <https://immunisationhandbook.health.gov.au/vaccination-procedures/preparing-for-vaccination> [↑](#footnote-ref-24)
24. Available at <https://nhmrc.govcms.gov.au/about-us/publications/australian-guidelines-prevention-and-control-infection-healthcare-2019> [↑](#footnote-ref-25)
25. Available at <https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5> [↑](#footnote-ref-26)
26. The Victorian Pharmacy Authority Guidelines are available at: [http://www.pharmacy.vic.gov.au](http://www.pharmacy.vic.gov.au/index.php?view=guidelines) [↑](#footnote-ref-27)
27. Victorian COVID-19 Vaccination Guidelines – Appendix 20: COVID-19 vaccinations for children aged 5-11 years available at: https://www.coronavirus.vic.gov.au/information-covid-19-vaccine-providers [↑](#footnote-ref-28)
28. Available at: <https://my.psa.org.au/s/article/Clinical-Governance-Principles-for-Pharmacy-Services> [↑](#footnote-ref-29)
29. 28 Available at <https://immunisationhandbook.health.gov.au/> [↑](#footnote-ref-30)
30. 29 Current version is available online at: <https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5> [↑](#footnote-ref-31)
31. Access the Australian Immunisation Register at <https://www.humanservices.gov.au/organisations/health-professionals/services/medicare/australian-immunisation-register-health-professionals> [↑](#footnote-ref-32)
32. Available at <https://immunisationhandbook.health.gov.au/> [↑](#footnote-ref-33)
33. Pharmaceutical Society of Australia Ltd, 2017, Practice guidelines for the provision of immunisation services within pharmacy, available at: <https://my.psa.org.au/s/article/immunisation-guidelines> [↑](#footnote-ref-34)
34. Available at <https://www.health.gov.au/sites/default/files/national-vaccine-storage-guidelines-strive-for-5_0.pdf> [↑](#footnote-ref-35)
35. The Victorian Pharmacy Authority Guidelines are available at: [http://www.pharmacy.vic.gov.au](http://www.pharmacy.vic.gov.au/index.php?view=guidelines) [↑](#footnote-ref-36)
36. Available at <https://immunisationhandbook.health.gov.au/> [↑](#footnote-ref-37)
37. Australian Government Department of Health. Australian Immunisation Handbook. Available at <https://immunisationhandbook.health.gov.au/vaccination-procedures/preparing-for-vaccination> [↑](#footnote-ref-38)
38. The Medical Defence Association of Victoria Ltd (MDAV). Medicine and the law: a practical guide for doctors. Carlton, Victoria: MDAV; 2005 as cited in: Australian Government Department of Health. Australian Immunisation Handbook. Available at <https://immunisationhandbook.health.gov.au/vaccination-procedures/preparing-for-vaccination> [↑](#footnote-ref-39)
39. Available at <https://immunisationhandbook.health.gov.au/> [↑](#footnote-ref-40)