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| Victorian Pharmacist-Administered Vaccination Program Guidelines |
| Effective 3 October 2024 |
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Victorian Pharmacist-Administered Vaccination Program Guidelines

Effective 3 October 2024

Department of Health

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Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.

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**ISBN** 978-1-76131-571-8 **(pdf/online/MS word)**

Available at [Victorian Pharmacist-Administered Vaccination Program Guidelines](https://www.health.vic.gov.au/immunisation/victorian-pharmacist-administered-vaccination-program-guidelines) <https://www.health.vic.gov.au/immunisation/victorian-pharmacist-administered-vaccination-program-guidelines>

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| 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 | July2018 | 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 if you require a copy of these templates. |
| 9 | October 2023 | All sections updated | Updated guidance on mpox and COVID-19 vaccines.Significant amendments to content detail to improve readability. |
| 10 | January 2024 | Fees | Update of the fees section with the introduction of the National Immunisation Program Vaccinations in Pharmacy (NIPVIP) Program on 1 January 2024. |
| 11 | March 2024 | Multiple sections updated:4.1 Training requirements5. Vaccines | Amendments in the listed sections to detail expansion.Minor edits to other text to include reference to RSV vaccines. |
| 12 | April 2024 | Multiple sections updated | Updated to reflect authorisation of intern pharmacists to administer approved vaccines. |
| 13 | October 2024 | Multiple sections updated | Update to reflect:* consolidation of COVID-19 vaccine into BAU Secretary Approval
* removal of requirement to complete mandatory training for mpox and Japanese encephalitis
* settings in which pharmacists can administer:
	+ COVID-19 vaccine;
	+ COVID-19 and other approved vaccines when engaged by a Residential Aged Care Home under the Tier 2 of the Aged Care On-site Pharmacist Measure
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# Introduction

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

Authorising appropriately trained pharmacists to administer approved vaccines increases the range of options for the public to access immunisation services, including for people who are most at risk of complications from vaccine-preventable disease.

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.

## Definitions

A ‘Pharmacist Immuniser’ is defined as a pharmacist that holds general registration with the Pharmacy Board of Australia[[1]](#footnote-2) who has completed a recognised ‘Immuniser program of study’ and who administers approved vaccines under the program.

An 'Intern Pharmacist Immuniser’ is defined as a pharmacist that holds provisional registration with the Pharmacist Board of Australia[[2]](#footnote-3) who has completed a recognised ‘immuniser program of study’ and administers approved vaccines under the program under the supervision of an experienced pharmacist immuniser (refer to section 4.3 for definition of direct supervision).

Pharmacist immunisers and intern pharmacist immunisers are referred to as ‘immunisers’ when common requirements apply.

See the department’s [Programs of study webpage](https://dhhsvicgovau.sharepoint.com/sites/RHPEMImmunisationUnit-DHHS-GRP/Shared%20Documents/Immunisation%20Projects%20and%20Policy/Immunisation%20workforce%20authorisations/Pharmacist%20Immunisers/Pharmacist-Administered%20Vax%20Program/Review%202022-23/VPAVP%20Guidelines/VPAP%20Guidelines%202023%20updates/Programs%20of%20study%20webpage) <https://www.health.vic.gov.au/immunisation/programs-of-study>.

These Guidelines also refer to ‘pharmacies’, which may include:

* 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.

# Regulations

The *Drugs, Poisons and Controlled Substances Regulations 2017[[3]](#footnote-4)* (the Regulations) enable the Secretary of the Department of Health (the department) to approve a Schedule 4 poison for administration by a pharmacist (including an intern pharmacist), and to specify the conditions in which a pharmacist is authorised to administer a Schedule 4 poison.

Pharmacists (including intern pharmacists) are permitted to possess and administer Schedule 3 poisons that are necessary for the treatment of anaphylactic reactions to a Schedule 4 poison (i.e. adrenaline).

# Secretary Approvals

Details of the Schedule 4 poisons that immunisers are authorised to administer, and the conditions that apply are set out in the Secretary Approval: Pharmacist Immuniser(the Approval) and the Secretary Approval: Intern Pharmacist Immuniser (Intern Approval).

The Approvals are available from: [Pharmacist immunisers](https://www.health.vic.gov.au/immunisation/pharmacist-immunisers) <https://www.health.vic.gov.au/immunisation/pharmacist-immunisers>.

The Approvals set out conditions in relation to:

* registration, training and certification requirements, including recency of practice and continuing professional development
* premises
* staffing
* registration with the department
* practice and compliance with relevant guidelines and protocols
* vaccines that immunisers are authorised to administer and the circumstances in which they are authorised to do so, including listed exclusions
* supervisory requirements for intern pharmacist immunisers.

The conditions of the Approvals and related requirements for immunisers are described as part of these Guidelines. Under all circumstances, the immuniser should provide immunisation services in accordance with the Regulations and the Approvals.

Immunisers must also conduct immunisation services in accordance with the current versions of the [The Australian Immunisation Handbook](https://immunisationhandbook.health.gov.au/) <https://immunisationhandbook.health.gov.au/>, the ‘[National Vaccine Storage Guidelines ‘Strive for 5](https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5?language=en)’ <https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5>, and the [Victorian cold chain management protocols](https://www.health.vic.gov.au/immunisation/cold-chain-management) <https://www.health.vic.gov.au/immunisation/cold-chain-management> current at the time of administration.

# Training

## Training requirements

All pharmacists and intern pharmacists who have not previously completed any immunisation training must first complete an ‘Immuniser program of study’ that has been recognised by the Victorian Chief Health Officer prior to administering approved vaccines. A list of recognised courses is available from: [Programs of study](https://www.health.vic.gov.au/immunisation/programs-of-study) <https://www.health.vic.gov.au/immunisation/programs-of-study>.

A ‘bridging training program’ should be completed by pharmacists who:

* have completed an interstate immunisation training program that has not been recognised as an ‘Immuniser program of study’ in Victoria;
* are needing to refresh their immunisation knowledge or skills; or
* need to understand the Victorian legislative requirements and the authorised vaccines for administration by immunisers

to ensure that they meet the Victorian pharmacist immuniser training requirements.

Immunisers must also hold a current:

* first aid certificate (to be updated every three years); and
* cardiopulmonary resuscitation certificate (to be updated annually).

Certain vaccines that pharmacist immunisers and intern pharmacist immunisers are authorised to administer may require additional training.

**Table 1: Additional training**

|  |  |  |
| --- | --- | --- |
| **Immunisation product** | **Training**  | **Additional information / context**  |
| Respiratory syncytial virus (RSV)  | **There is currently no additional training required to administer RSV vaccine.**Immunisers should refer to the Department of Health’s Respiratory syncytial virus (RSV) immunisation webpage for any additional training and competency requirements for that immunisation product, at the time of administrationThe webpage contains information and links to the Australian Technical Advisory Group on Immunisation (ATAGI) recommendations, vaccine schedules and resources for immunisation providers.[Respiratory syncytial virus (RSV) immunisation](https://www.health.vic.gov.au/immunisation/respiratory-syncytial-virus-immunisation) <https://www.health.vic.gov.au/immunisation/respiratory-syncytial-virus-immunisation> | There is an extensive pipeline of RSV vaccines and immunisation products at various stages of TGA approval.As new RSV vaccines and immunisation products are TGA approved and immunisers are authorised to administer them in Victoria, an assessment will be made regarding whether additional training is required to support administration.Any additional training requirements will be listed on the Respiratory syncytial virus (RSV) immunisation webpage. |
| COVID-19 | **There is currently no additional training required to administer COVID-19 vaccine.**Immunisers should refer to the Department of Health’s COVID-19 vaccine webpage for any additional requirements (training or otherwise) and for information and links to the Australian Technical Advisory Group on Immunisation (ATAGI) recommendations, vaccine schedules and resources for immunisation providers.[COVID-19 vaccine](https://www.health.vic.gov.au/immunisation/covid-19-vaccine) <https://www.health.vic.gov.au/immunisation/covid-19-vaccine> | From 1 October 2023, the Department of Health and Aged Care removed the mandated requirement for immunisers to complete the COVID-19 Vaccination Training Program (CVTP) prior to participating in the COVID-19 Vaccine Program. The CVTP reference document containing all 18 modules of the former CVTP remains available to immunisation providers. |
| Japanese encephalitis (JE) | **No additional training is required to administer JE or mpox vaccines.** | Pharmacist immunisers were authorised to administer JE and mpox vaccines as part of an emergency response to outbreaks of these diseases. At that time, eLearning modules were developed and mandated to support immunisers administering these vaccines. The Australian Immunisation Handbook has now been updated to include the latest advice and guidance regarding both JE and mpox viruses, the vaccines available, and recommendations for vaccination. The department has also developed additional resources for health professionals administering both JE and mpox vaccines. The JE and mpox vaccine eLearning modules remain available on the Department of Health’s [Immunisation eLearning Portal](https://vic-immunisation-learning.com): <https://vic-immunisation-learning.com> |
| Mpox |

## Continuing education

Immunisers must undertake continuing professional development on the National Immunisation Program (NIP) vaccine schedule and other approved vaccines or immunisation products to ensure currency and competency in delivering safe immunisation services.

## Supervision requirements

Intern pharmacists must be supervised by an experienced pharmacist immuniser, with the supervising pharmacist immuniser required to always be physically present in the workplace while the intern pharmacist immuniser is undertaking immunisation activities, and available during those times to observe and discuss management of people receiving vaccines and/or the performance of the intern pharmacist when necessary.

Pharmacists and intern pharmacists who are undertaking an ‘Immuniser program of study’ can only administer vaccines under the direct supervision of a:

* medical practitioner;
* nurse practitioner;
* Nurse immuniser[[4]](#footnote-5); or
* Pharmacist immuniser who has a minimum of two years’ recent experience in the administration of vaccines.

Intern pharmacist immunisers and pharmacist immunisers must be aware that, in accordance with the Pharmacy Board of Australia Guidelines, the legal responsibility lies with the supervising pharmacist for vaccine-related activities undertaken by the intern pharmacist or pharmacy student under their supervision.

## Pharmacy students

Pharmacy students 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 or provisional registration with the Pharmacy Board of Australia.

# Vaccines

Immunisers are currently authorised to administer the vaccines listed in Table 2 in Victoria. Eligibility and funding criteria may change.

NIP vaccine eligibility criteria is available at: [National Immunisation Program](https://www.health.gov.au/our-work/national-immunisation-program) <https://www.health.gov.au/our-work/national-immunisation-program>.

Victorian state-funded vaccine eligibility is available at: [Immunisation schedule Victoria and vaccine eligibility criteria](https://www.health.vic.gov.au/immunisation/immunisation-schedule-victoria-and-vaccine-eligibility-criteria) <https://www.health.vic.gov.au/immunisation/immunisation-schedule-victoria-and-vaccine-eligibility-criteria>.

Immunisers must check the client’s immunisation history on the Australian Immunisation Register (AIR) before administering any immunisations.

**Table 2: Approved vaccines or immunisation products**

| **Vaccine or immunisation product** | **Approval for pharmacists (and intern pharmacists under supervision) to vaccinate with this vaccine *applies to*** | **Approval for pharmacists (and intern pharmacists under supervision) to vaccinate with this vaccine *excludes* (column 3)** | **Additional notes** |
| --- | --- | --- | --- |
| COVID-19 vaccine | Vaccination of people aged 5 years and older, and included in the patient group for which that COVID-19 vaccine has been approved for by the Therapeutic Goods Administration, or the patient group as recommended by the Australian Technical Advisory Group on Immunisation (ATAGI), excluding those circumstances listed in Column 3.   | 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 (or current recommendations issued by the Australian Technical Advisory Group on Immunisation (ATAGI)).  | Immunisers should refer to the Department of Health’s COVID-19 vaccine website for any additional requirements (training or otherwise) and for information and links to ATAGI recommendations, vaccine schedules and resources for immunisation providers, and regular updates to the program, available at: [COVID-19 vaccine](https://www.health.vic.gov.au/immunisation/covid-19-vaccine) <https://www.health.vic.gov.au/immunisation/covid-19-vaccine>.  |
| Influenza vaccine | 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; Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook. | Refer to NIP eligibility criteria. |
| Diphtheria-tetanus-pertussis vaccine | 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;
	+ 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.
 | * + Usually provided in year 7 (or age equivalent) through the Secondary School Immunisation Program.
	+ Refer to NIP eligibility criteria.
 |
| Human papillomavirus (HPV) vaccine | 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;
	+ Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook*.*
 | * + Provided in year 7 (or age equivalent) through the Secondary School Immunisation Program.
	+ Refer to NIP eligibility criteria.
 |
| Measles-mumps-rubella vaccine (MMR) vaccine | 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;
	+ Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook.
 | * + Live vaccine. Refer to the Australian Immunisation Handbook for contraindications and precautions.
	+ Refer to NIP and state-funded vaccination program eligibility criteria.
 |
| Meningococcal ACWY vaccine | 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;
	+ Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook.
 | * + Provided in year 10 (or age equivalent) through the Secondary School Immunisation Program.
	+ Refer to NIP eligibility criteria.
 |
| Pneumococcal vaccine  | 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;
	+ Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook*.*
 | * Decision making tools to support 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) <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/) <https://www.immunisationcoalition.org.au/resources/pneumococcal-disease-guide/> (issued by the Immunisation Coalition).
	+ Refer to NIP eligibility criteria.
	+ Refer to the Australian Immunisation Handbook for identification of people at increased risk, vaccine and dosing schedule.
 |
| Herpes zoster (Shingles) vaccine | 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;
	+ Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook*.*
 | * There are two vaccines available in Australia for the prevention of herpes zoster and associated complications — Zostavax® and Shingrix®.
* Zostavax® vaccine is a live herpes zoster vaccine. Refer to the Australian Immunisation Handbook for contraindications.
* Refer to the NIP for funding.
 |
| Japanese encephalitis (JE) vaccine | Vaccination of people aged 5 years and older that are recommended for vaccination as listed on the Victorian Department of Health’s Japanese encephalitis webpage at the time of administration. | 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 Japanese encephalitis webpage;Vaccination of people aged 4 years and younger;* + Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook.
 | * + Refer to the Department of Health’s Japanese encephalitis webpage for more information: [Japanese encephalitis](https://www.health.vic.gov.au/infectious-diseases/japanese-encephalitis) <https://www.health.vic.gov.au/infectious-diseases/japanese-encephalitis>.
	+ There are two vaccines available in Australia for the prevention of JE – Imojev® and Jespect®.
	+ Refer to the Australian Immunisation Handbook for contraindications and precautions.
 |
| Mpox (monkeypox / vaccinia virus) vaccine | Vaccination of people aged 5 years and older that are recommended for vaccination as listed on the Victorian Department of Health’s Mpox webpage at the time of administration. | 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 Mpox webpage; 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 ATAGI). | * + Must comply with the Victorian mpox vaccination guidelines*,* available on the [Victorian Department of Health’s Mpox webpage](https://www.health.vic.gov.au/infectious-diseases/mpox-monkeypox) <https://www.health.vic.gov.au/infectious-diseases/mpox-monkeypox>.
 |
| Respiratory syncytial virus (RSV) vaccine or RSV immunisation product as listed on the Victorian Department of Health’s Respiratory syncytial virus (RSV) immunisation webpage | Immunisation of people aged 5 years and older that are recommended for immunisation as listed on the Department of Health’s Respiratory syncytial virus (RSV) immunisation webpage at the time of administration. | Immunisation of people not recommended for immunisation;Immunisation for travel purposes other than those people recommended for immunisation as listed on the Department of Health’s Respiratory syncytial virus (RSV) immunisation webpage; Immunisation of people aged 4 years and younger;Immunisation of people with contraindications defined in the current edition of the Australian Immunisation Handbook (or current recommendations issued by the ATAGI). | * + May require completion of additional training or competency requirements prior to administering certain RSV vaccines or immunisation products (see Table 1).
	+ Must only administer those RSV vaccines and immunisation products authorised for use in Victoria.
	+ Refer to the Victorian Department of Health’s [Respiratory syncytial virus (RSV) immunisation webpage](https://www.health.vic.gov.au/immunisation/respiratory-syncytial-virus-immunisation) <https://www.health.vic.gov.au/immunisation/respiratory-syncytial-virus-immunisation> for more information.
	+ Currently the only RSV vaccines approved for use by immunisers in Victoria is Arexvy (RSV PRE-F3) and Abrysvo (RSV PRE-F) vaccines for RSV, as recommended by the ATAGI.
 |

\* National Immunisation Program (NIP) vaccines may be available to younger cohorts outside the conditions for Approval for administration by immunisers.

## Community Pharmacist Statewide Pilot – vaccination services

Only pharmacist immunisers participating in the Community Pharmacist Statewide Pilot’s vaccination stream have additional authority to:

* administer vaccines against four additional diseases (hepatitis A, hepatitis B, typhoid, poliomyelitis); and
* provide vaccination and healthcare services for the purposes of travel.

Intern pharmacists are not permitted to participate in the Community Pharmacist Statewide Pilot.

Pharmacist immunisers participating in the 12-month pilot should refer to the Secretary Approval: Community Pharmacist Statewide Pilot and associated Protocol for Vaccine Administration for information about the training and additional requirements for this expanded scope (in effect from 27 October 2023). Further information is available at: [Victorian Community Pharmacist Statewide Pilot](https://www.health.vic.gov.au/primary-care/victorian-community-pharmacist-statewide-pilot-resources-for-pharmacists) <https://www.health.vic.gov.au/primary-care/victorian-community-pharmacist-statewide-pilot-resources-for-pharmacists>.

# Premises, professional governance and staffing

Immunisers administering approved vaccines are to be connected to a pharmacy, pharmacy depot or hospital that has registered with the department to provide an immunisation 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 pharmacy.

Immunisers administering the COVID-19 vaccine (only) may additionally be employed, contracted or otherwise engaged by:

1. a medical practitioner; or
2. a municipal council that employs, contracts or ensures access to a medical practitioner or nurse practitioner; or
3. a health services permit holder who employs, contracts or ensures access to a medical practitioner or nurse practitioner.
4. an agency funded by the Victorian Government or Government of Australia that employs, contracts or ensures access to a medical practitioner or nurse practitioner.

Pharmacist immunisers (only) may also administer approved vaccines as part of their responsibilities when engaged by a Residential Aged Care Home under the Tier 2 of the Aged Care On-site Pharmacist Measure[[5]](#footnote-6).

## Premises

Immunisers can immunise in a pharmacy setting, or through outreach or mobile immunisation programs delivered by the pharmacy.

Where immunisations are administered in hospitals, 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](https://pharmacy.vic.gov.au/standard-guidelines/) <http://www.pharmacy.vic.gov.au> that are current at the time of administration.

Pharmacies and immunisers must comply with requirements of the [Australian Guidelines for the Prevention and Control of Infection in Healthcare](https://app.magicapp.org/#/guideline/Jn37kn) <https://app.magicapp.org/#/guideline/Jn37kn> and the [National vaccine storage guidelines – Strive for 5](https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5) <https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5> which includes provisions for caring for vaccines in coolers, data loggers and cooler ice packs for mobile or outreach immunisation clinics.

Immunisers providing immunisation services in other settings, such as mobile or outreach clinics, should comply with immunisation policies and procedures set by their employer, ensuring consideration has been given for the appropriateness of the setting.

Any vaccines ordered need to be delivered to the registered location of the pharmacy, pharmacy depot, hospital or other approved setting.

## Registration of premises

Pharmacies must be registered with the department to deliver immunisation services in Victoria. For more information, see the department’s [Vaccine order forms and stock information webpage](https://www.health.vic.gov.au/immunisation/ordering-vaccines) <https://www.health.vic.gov.au/immunisation/ordering-vaccines>.

## Accreditation

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

## Professional governance and staffing arrangements

### Professional governance

Pharmacies and immunisers have a duty to safeguard their clients from harm. The pharmacy must have in place the following minimum elements to support the provision of safe and high-quality immunisation services:

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

It is recommended that pharmacies also refer to the [Pharmaceutical Society of Australia’s Clinical Governance Principles for Pharmacy Services](https://my.psa.org.au/s/article/Clinical-Governance-Principles-for-Pharmacy-Services) <https://my.psa.org.au/s/article/Clinical-Governance-Principles-for-Pharmacy-Services>in relation to professional governance and clinical considerations.

###  Staffing arrangements for clinical risk management

It is a condition of the Approvals that the 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 immunisations are taking place, and within the line of sight of the person immunised for a minimum period of 15 minutes afterwards.

It is a condition of the Intern Approval that the intern pharmacist immuniser is supervised by an experienced pharmacist immuniser. Refer to section 4.3 for direct supervision requirements.

## Insurance

The pharmacy and the immuniser are required to hold appropriate insurance for the administration of the approved Schedule 4 poisons and provision of an immunisation service.

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

The pharmacy may need to provide details of their insurance coverage to contracted immunisers. This is to enable contracted staff to meet the requirements of their professional registration for evidence of appropriate Professional Indemnity Insurance.

## 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 an immunisation service, subject to meeting National Law requirements, including the Guidelines for advertising a regulated health service.[[6]](#footnote-7)

# Equipment and resources

Compliance with the online version of the Australian Immunisation Handbook[[7]](#footnote-8) and National vaccine storage guidelines – Strive for 5 (current edition)[[8]](#footnote-9) and Victorian Cold Chain Management protocols[[9]](#footnote-10) 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 anaphylaxis response kit
* an appropriately sized sharps container to dispose of clinical waste, including used syringes and needles.

Resources that are required to be readily accessible include:

* the online Australian Immunisation Handbook
* a current edition of the National vaccine storage guidelines – Strive for 5
* materials to support communication about immunisation.

Immunisers should also subscribe to the department’s Immunisation Newsletter, which is available to subscribe at [the departments subscribe to alerts, advisories and newsletters](https://www.health.vic.gov.au/subscribe) webpage <https://www.health.vic.gov.au/subscribe>.

A range of resources exist to support the delivery of safe immunisation services, including the [Pharmaceutical Society of Australia’s Practice Guidelines](https://my.psa.org.au/s/article/immunisation-guidelines) <https://my.psa.org.au/s/article/immunisation-guidelines> for the provision of immunisation services within pharmacy (current edition).

## Professional Practice Standards and self-assessment tools

Immunisers are expected to comply with and achieve the [Pharmaceutical Society of Australia Professional Practice Standards](https://www.psa.org.au/practice-support-industry/pps/) <https://www.psa.org.au/practice-support-industry/pps/>. A self-assessment tool accompanies the standards.

The department and the Victorian Pharmacy Authority have co-designed the [Pharmacy services self-audit tool: immunisation site readiness](https://www.health.vic.gov.au/immunisation/pharmacy-services-self-audit-tool-immunisation-site-readiness) <https://www.health.vic.gov.au/immunisation/pharmacy-services-self-audit-tool-immunisation-site-readiness>. The self-audit tool aims to support pharmacies and immunisers, with successful completion demonstrating compliance with guidelines.

# Protocols

Immunisers should implement a process to regularly monitor online updates to the Australian Immunisation Handbook*[[10]](#footnote-11)*, the National vaccine storage guidelines – Strive for 5[[11]](#footnote-12), the Victorian Cold Chain Management protocols, the Victorian Pharmacy Authority Guidelines[[12]](#footnote-13), these Guidelines, and any other key resources to inform their immunisation practice.

## Pre-screening and consent

Immunisers must undertake pre-screening of people wishing to be immunised to identify contraindications or precautions, obtain valid consent, and ensure that the correct equipment and procedures are in place.

The [Australian Immunisation Handbook’s Preparing for vaccination chapter](https://immunisationhandbook.health.gov.au/contents/vaccination-procedures/preparing-for-vaccination) <https://immunisationhandbook.health.gov.au/contents/vaccination-procedures/preparing-for-vaccination>. outlines the steps for pre-screening and obtaining consent, including consent on behalf of a child, adolescent, or adult lacking capacity.

## After vaccination

The [Australian Immunisation Handbook’s After vaccination chapter](https://immunisationhandbook.health.gov.au/contents/vaccination-procedures/after-vaccination) <https://immunisationhandbook.health.gov.au/contents/vaccination-procedures/after-vaccination> provides guidance on immediate after care, management of adverse events, and documenting immunisation.

Immunisers 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 immunisation. 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.

## Adverse events

An adverse event following immunisation (AEFI) is an unwanted or unexpected event following the administration of a vaccine(s). AEFIs may be caused by a vaccine(s) or may occur by coincidence (that is, the event would have occurred regardless of immunisation).

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

Information available through the department’s website can be provided and is available at [Adverse events following immunisation reporting](https://www.health.vic.gov.au/immunisation/adverse-events-following-immunisation-reporting) <https://www.health.vic.gov.au/immunisation/adverse-events-following-immunisation-reporting>.

## Reporting adverse events

SAEFVIC (Surveillance of Adverse Events Following Vaccination in the Community) is a public health partnership initiative of the Victorian Immunisation Program. SAEFVIC is a specialist service that helps immunisation providers and the community manage people who have had an AEFI.

Immunisers must report any AEFI that is considered significant or vaccine error to SAEFVIC. Common/minor/expected reactions do not need to be reported, however any vaccine reaction which has affected a client’s confidence can and should be reported.

The SAEFVIC requirements for reporting are available from: [Adverse events following immunisation reporting](https://www.health.vic.gov.au/immunisation/adverse-events-following-immunisation-reporting) <https://www.health.vic.gov.au/immunisation/adverse-events-following-immunisation-reporting>.

## Emergency response protocol

Guidance on the management of anaphylaxis is available at the [Australian Immunisation Handbook](https://immunisationhandbook.health.gov.au/contents/vaccination-procedures/after-vaccination) <https://immunisationhandbook.health.gov.au/contents/vaccination-procedures/after-vaccination>.

Immunisers must have access to an anaphylaxis response kit that complies with the recommendations in the current version of the Australian Immunisation Handbook available at: [The Australian Immunisation handbook preparing an anaphylaxis response kit](https://immunisationhandbook.health.gov.au/resources/publications/preparing-an-anaphylaxis-response-kit) <https://immunisationhandbook.health.gov.au/resources/publications/preparing-an-anaphylaxis-response-kit>.

Administration of adrenaline is, at all times, undertaken in accordance with the procedures specified in the current edition of the [Australian Immunisation Handbook; recognition and treatment of anaphylaxis](https://immunisationhandbook.health.gov.au/resources/tables/table-recognition-and-treatment-of-anaphylaxis) <https://immunisationhandbook.health.gov.au/resources/tables/table-recognition-and-treatment-of-anaphylaxis>.

An emergency response protocol must be kept as part of the anaphylaxis response kit.

## Record keeping and reporting

It is mandatory to report administration of National Immunisation Program, influenza and COVID-19 vaccines to the AIR and it is important that reporting occurs in a timely manner. All other vaccines administered are strongly recommended to be reported the AIR. This ensures that individuals have a complete record of their vaccinations. Clients may elect not to have the mpox vaccine recorded to AIR.

Immunisers must also 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[[13]](#footnote-14)

With the client’s permission, a record of immunisation should be provided to their nominated health professional in a timely manner.

## Cold chain

All immunisers should have a documented immunisation management protocol that follows the key principles of safe vaccine storage and cold chain maintenance.

These principles are contained in the National vaccine storage guidelines – Strive for 5*[[14]](#footnote-15)*, and the [Victorian Department of Health Cold Chain Management protocols](https://www.health.vic.gov.au/immunisation/cold-chain-management) <https://www.health.vic.gov.au/immunisation/cold-chain-management> including requirements relating to [automated temperature monitoring systems and back-to-base alarm systems](https://www.health.vic.gov.au/immunisation/automated-temperature-monitoring-and-back-to-base-alarm-systems) <https://www.health.vic.gov.au/immunisation/automated-temperature-monitoring-and-back-to-base-alarm-systems>.

#### Cold Chain Management eLearning

All government-funded vaccine account holders are required to nominate a Vaccine Coordinator and backup person to complete the department's Clinical/Vaccine Coordinator Cold Chain Management eLearning module and upload their certificate of completion to the department’s Cold chain certificate collection portal, see the [Cold chain managment](Cold%20chain%20managment) webpage <https://www.health.vic.gov.au/immunisation/cold-chain-management>.

Other staff involved in the cold chain management (including deliveries) and administration are strongly encouraged to complete the [Cold Chain Management eLearning](https://vic-immunisation-learning.com/) module <https://vic-immunisation-learning.com/> relevant to their role.

#### 8.7.2 Identifying and reporting a cold chain breach

Immunisers must report all cold chain breaches of government-funded vaccines to the department. Refer to [Cold Chain Breach reporting](https://www.health.vic.gov.au/immunisation/cold-chain-breach-reporting) <https://www.health.vic.gov.au/immunisation/cold-chain-breach-reporting>.

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

## Other safety requirements

When immunisers are undertaking immunisation activity, including pre-screening and vaccine administration, 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).

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

## Complaints

Pharmacies should develop a process for complaints regarding immunisation services. At a minimum, all individuals who receive immunisation services should be advised that:

1. Complaints relating to the pharmacist’s professional practice should be directed to the Australian Health Practitioner Regulation Agency (Ahpra) by phoning 1300 419 495 or visiting the [Ahpra website](http://www.ahpra.gov.au/) <www.ahpra.gov.au>.
2. Complaints relating to the pharmacy premises should be directed to the [Victorian Pharmacy Authority](http://www.pharmacy.vic.gov.au/) <www.pharmacy.vic.gov.au>.
3. Individuals may also bring a complaint against a health to the [Health Complaints Commissioner](https://hcc.vic.gov.au/) <https://hcc.vic.gov.au/>.

# Fees

The Australian Government implemented the National Immunisation Program Vaccinations in Pharmacy (NIPVIP) program on 1 January 2024. Community pharmacies that choose to register as a NIPVIP Service Provider will be funded to administer NIP vaccines to eligible individuals 5 years of age and older within the scope of their immunisers’ authorisation, with no out of pocket cost to the individual.

For authorised vaccines, see section 3: Secretary Approvals, and section 5: Vaccines of these guidelines.

More information about the NIPVIP Program is available from the [Pharmacy Programs Administrator webpage](https://www.ppaonline.com.au/programs/national-immunisation-program-vaccinations-in-pharmacy-program) <https://www.ppaonline.com.au/programs/national-immunisation-program-vaccinations-in-pharmacy-program>.

For clients eligible for state-funded (non-NIP) vaccines, pharmacies may wish to charge a service fee for administration of the vaccine. Clients should be aware of the availability of state-funded vaccines and free vaccination services through bulk-billing general practitioners, prior to administering the vaccine.

For those persons who are not eligible for NIP or state-funded vaccines, the pharmacy may charge for the cost of the vaccine plus an administration fee.

All relevant charges should be understood by the person receiving the vaccine, prior to the commencement of any pre-screening activity and/or the administration of any vaccine.

Table 3 summarises the circumstances in which pharmacies may charge people for the cost of the vaccine and for administering the vaccine.

**Table 3. Pharmacy fees**

| Target group | Can the pharmacy charge for the cost of the vaccine? | Can the pharmacy charge for administering the vaccine (a service charge)? |
| --- | --- | --- |
| Pharmacies registered as a NIPVIP provider:Persons **eligible** for government-funded vaccines under the NIP  | **No**Government-funded vaccines should be accessed from the department’s government-funded vaccine order form. See section [6.2](#_Registration_of_premises). | **No**Pharmacies cannot charge clients any additional fees for a NIPVIP service. Pharmacies will claim payment for NIP vaccine administration through the NIPVIP Program. |
| Pharmacies not registered as a NIPVIP provider:Persons **eligible** for government-funded vaccines under the NIP  | **No**Government-funded vaccines should be accessed from the department’s government-funded vaccine order form. See section [6.2](#_Registration_of_premises). | **Yes** Immunisers must advise people about the availability of free vaccination services (e.g. through bulk-billing GP services or NIPVIP registered pharmacies). |
| Persons eligible to receive free Japanese encephalitis (JE) vaccine in Victoria[[15]](#footnote-16)  | **No**State-funded vaccines should be accessed from the department’s government-funded vaccine order form. See section [6.2](#_Registration_of_premises). | **Yes** Immunisers must advise people about the availability of free vaccination services through bulk-billing general practitioners. |
| Persons eligible to receive free mpox vaccine in Victoria[[16]](#footnote-17) | **No**State-funded vaccines should be accessed from the department’s government-funded vaccine order form. See section [6.2](#_Registration_of_premises). | **Yes**The person must be aware of all fees prior to pre-screening and/or any vaccine being administered. |
| Persons **not eligible** for government-funded vaccine under the NIP or state-funded vaccine programs. | **Yes**These vaccines should be accessed from private suppliers. | **Yes**The person must be aware of all fees prior to pre-screening and/or any vaccine being administered. |

# 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 at: <immunisation@health.vic.gov.au>.

1. This does not include limited registration, provisional registration, non-practising registration or student registration. [↑](#footnote-ref-2)
2. This does not include general registration, non-practising registration or student registration. [↑](#footnote-ref-3)
3. Available from: [Drugs, Poisons and Controlled Substances Regulations 2017](https://www.legislation.vic.gov.au/in-force/statutory-rules/drugs-poisons-and-controlled-substances-regulations-2017/018) <https://www.legislation.vic.gov.au/in-force/statutory-rules/drugs-poisons-and-controlled-substances-regulations-2017/018> [↑](#footnote-ref-4)
4. ‘Nurse Immuniser’ is a nurse acting in accordance with a Secretary Approval to administer certain vaccines.   [↑](#footnote-ref-5)
5. Australian Government, Department of Health and Aged Care. 2022. Pharmacy Programs Administrator. Aged Care On-Site Pharmacist (ACOP) Measure Tier 2 – RACH claims and receives payments, available at: <https://www.ppaonline.com.au/programs/aged-care-on-site-pharmacist-measure/tier-2> [↑](#footnote-ref-6)
6. Available at: [Australian Health Practitioner Regulation Agency](https://www.ahpra.gov.au/Resources/Advertising-hub/Advertising-guidelines-and-other-guidance/Advertising-guidelines.aspx) <https://www.ahpra.gov.au/Resources/Advertising-hub/Advertising-guidelines-and-other-guidance/Advertising-guidelines.aspx> [↑](#footnote-ref-7)
7. Available at: [Australian Immunisation Handbook](https://immunisationhandbook.health.gov.au/) <https://immunisationhandbook.health.gov.au/> [↑](#footnote-ref-8)
8. Available at: [National Vaccine Storage Guidelines ‘Strive for 5’](https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5)  <https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5> [↑](#footnote-ref-9)
9. Available at: [Cold chain management](https://www.health.vic.gov.au/immunisation/cold-chain-management) <https://www.health.vic.gov.au/immunisation/cold-chain-management> [↑](#footnote-ref-10)
10. Available at: [The Australian Immunisation Handbook](https://immunisationhandbook.health.gov.au/) <https://immunisationhandbook.health.gov.au/> [↑](#footnote-ref-11)
11. Available at: [National Vaccine Storage Guidelines ‘Strive for 5’](https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5) <https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5> [↑](#footnote-ref-12)
12. Available at: [Victorian Pharmacy Authority](https://pharmacy.vic.gov.au/standard-guidelines/) < https://pharmacy.vic.gov.au/standard-guidelines/ > [↑](#footnote-ref-13)
13. Available at: [The Australian Immunisation Handbook](https://immunisationhandbook.health.gov.au/) <https://immunisationhandbook.health.gov.au/> [↑](#footnote-ref-14)
14. Available at: [National Vaccine Storage Guidelines ‘Strive for 5’](https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5) <https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5> [↑](#footnote-ref-15)
15. Refer to: <https://www.health.vic.gov.au/infectious-diseases/japanese-encephalitis-virus> [↑](#footnote-ref-16)
16. Refer to: <https://www.health.vic.gov.au/infectious-diseases/mpox-monkeypox> [↑](#footnote-ref-17)