

Victorian Pharmacist-Administered Vaccination Program Guidelines

October 2018

THIS DOCUMENT HAS BEEN RELEASED
UNDER THE FREEDOM OF INFORMATION ACT 1982
BY THE DEPARTMENT OF HEALTH

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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.
	July 2018	Regulations, Education, 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
3	October 2018	Introduction, Education, 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.

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Available at <https://www2.health.vic.gov.au/public-health/immunisation>

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1. Introduction

In 2015, the Victorian Minister for Health announced implementation of the Victorian Pharmacist-Administered Vaccination Program (the program), to commence in 2016. Under this program, individuals across Victoria can receive influenza and pertussis-containing vaccinations from their pharmacist.

Pharmacists are able to administer government-funded vaccines to eligible individuals under the National Immunisation Program and the Victorian Government's Partner Whooping Cough Vaccine Program.

Expanding the role of pharmacists to administer these vaccines provides greater access to vaccinations for people who are most at risk of complications from vaccine-preventable disease. It also gives new parents more options for vaccination against pertussis to protect their newborn infants.

On 12 August 2018, the Minister for Health (the Minister) announced a planned expansion of the program as part of a statewide approach to protect Victorians against measles infection. The expansion enables appropriately trained and registered pharmacists to administer measles-mumps-rubella (MMR) vaccine and all vaccines under the current and expanded program to people aged 16 years and over.

The Victorian Pharmacist-Administered Vaccination Program Guidelines (the guidelines) describe the requirements of the program and support registered pharmacists to provide safe, high quality immunisation services. Compliance with the most current version of these guidelines is a condition of the Secretary Approval – Pharmacist Immuniser (the Approval).

The previous version of these Guidelines was released in July 2018. This version, released in October 2018, provides changes to the program, refer to Document history and control.

2. Regulations

The Drugs, Poisons and Controlled Substances Regulations 2017 (the Regulations) enable the Secretary of the Department of Health and Human Services (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.

The Regulations also authorise pharmacists to administer a Schedule 3 poison if a therapeutic need exists, following administration of a Schedule 4 poison. The Regulations are available from Victoria Law Today at <http://www.legislation.vic.gov.au/>.

3. 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://www2.health.vic.gov.au/public-health/immunisation/immunisers-in-victoria/pharmacist-immunisers>>.

4. Pharmacist Immunisers

A registered pharmacist who has completed a recognised 'Immuniser program of study' and who administers vaccines under the Victorian Pharmacist-Administered Vaccination Program is referred to in these guidelines as a 'Pharmacist Immuniser'.

The Secretary Approval – Pharmacist Immuniser defines that Pharmacist Immunisers are required to:

- hold general registration with the Pharmacy Board of Australia¹
- have satisfactorily completed the assessment of an 'Immuniser program of study' recognised by the Victorian Chief Health Officer
- 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).

Pharmacist Immunisers should be able to provide evidence of completed training if required.

5. Education

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://www2.health.vic.gov.au/public-health/immunisation/immunisers-in-victoria/pharmacist-immunisers/pharmacist-immuniser-study-programs>>.

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.

¹ This does not include limited registration, provisional registration, non-practising registration or student registration.

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

- hold general registration with the Pharmacy Board of Australia¹
- 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
 - a nurse practitioner
 - a 'Nurse Immuniser' who is compliant with Regulation 8(1) of the *Drugs, Poisons and Controlled Substances Regulations 2017*
 - a 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*. 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 <<http://www.ncirs.edu.au/provider-resources/aip/>>.

6. Code of conduct

Pharmacist Immunisers are expected to comply with all elements of the Pharmacy Board of Australia's *Code of conduct*², 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
- 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.

² Available from: <http://www.pharmacyboard.gov.au/Codes-Guidelines/Code-of-conduct.aspx>

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.

7. Vaccines

The Secretary Approval – Pharmacist Immuniser authorises pharmacists to administer certain vaccines to individuals aged 16 years and over, with some exclusions. These include influenza vaccines, pertussis-containing vaccines and measles-mumps-rubella vaccines.

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).

8. Target groups

8.1 Influenza vaccine

Victorian pharmacists are authorised to administer influenza vaccine to certain target groups without a prescription or other instruction from a health practitioner. These include:

- Target group 1 – individuals eligible for government-funded influenza vaccine through the National Immunisation Program (NIP). This includes individuals aged 65 years and over, people of Aboriginal and Torres Strait Islander descent aged 16 years and over, and people aged 16 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.
- Target group 2 – individuals aged between 16 and 64 years, and not eligible for the National Immunisation Program.

Vaccines should be administered in accordance with the conditions of the Approval. Appendix 1 (column 3) of the Approval lists the circumstances in which pharmacists are **not** authorised to administer a vaccine.

8.2 Pertussis-containing vaccine

Victorian pharmacists are authorised to administer pertussis-containing vaccine for the express purpose of achieving immunity against pertussis in certain target groups, being:

- Target group 1 – individuals eligible for government-funded pertussis-containing vaccine through the NIP and the Victorian Government's Partner Whooping Cough Vaccine Program, including:
 - pregnant women in their third trimester of pregnancy from 28 weeks gestation
 - partners of women who are at least 28 weeks pregnant, if the partner has not received a pertussis booster in the last ten years
 - parents and 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

- individuals aged 16 to 19 years requiring catch-up
- refugees and all humanitarian entrants aged 16 years and over.
- Target group 2 – individuals from 16 years of age 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.

Vaccines should be administered in accordance with the conditions of the Approval. Appendix 1 (column 3) of the Approval lists the circumstances in which pharmacists are **not** authorised to administer a vaccine.

8.3 Measles-mumps-rubella vaccine

Victorian pharmacists are authorised to administer measles-mumps-rubella vaccine for the express purpose of achieving immunity against measles, mumps and rubella in certain target groups, being:

- Target group 1 – individuals eligible for government-funded measles-mumps-rubella vaccine through the NIP, including:
 - individuals aged 16 to 19 years requiring catch-up
 - refugees and all humanitarian entrants aged 16 years and over.
- Target group 2 – individuals eligible for government-funded measles-mumps-rubella vaccine through the Victorian Government's Measles-Mumps-Rubella Adult Vaccine Program, including:
 - individuals born during or since 1966 requiring one or two doses of measles-mumps-rubella vaccine (at least one month apart)
 - women planning pregnancy or post-partum with low or negative rubella antibody levels.

Vaccines should be administered in accordance with the conditions of the Approval. Appendix 1 (column 3) of the Approval lists the circumstances in which pharmacists are **not** authorised to administer a vaccine.

8.4 Exclusions

The Secretary Approval – Pharmacist Immuniser **excludes**:

- vaccination for travel purposes³
- vaccination of people aged 15 years and under
- vaccination of inpatients in hospitals
- vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook⁴
- vaccination for the express purpose of achieving immunity against diphtheria, tetanus or poliomyelitis⁵
- vaccination of people who are contacts in the event of a case of pertussis, unless directed by the department⁶
- vaccination of pregnant women against measles, mumps and rubella

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

³ Travel medicine is a specialist area that is outside the scope of the Approval.

⁴ Current version is available online.

⁵ Pertussis vaccine is only available in Australia in combination with diphtheria and tetanus, or diphtheria, tetanus and poliomyelitis.

⁶ A case of this vaccine-preventable disease is notifiable to the Department of Health and Human Services under the *Public Health and Wellbeing Regulations 2009*. The department will advise on management of the case and contacts.

9. Fees

Pharmacist Immunisers can administer government-funded vaccines under the National Immunisation Program, Victorian Government's Partner Whooping Cough Vaccine Program and Measles-Mumps-Rubella Adult Vaccine Program to eligible individuals 16 years of age and over.

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

For those individuals who are not eligible for government-funded vaccines through the National Immunisation Program, Victorian Government's Partner Whooping Cough Vaccine Program or Measles-Mumps-Rubella Adult Vaccine Program, the pharmacist may charge a fee for the vaccine and their services.

Table 1 summarises the circumstances in which a Pharmacist Immuniser may charge individuals for the cost of the vaccine and for administering the vaccine.

Table 1. 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)?
Individuals eligible for government-funded vaccines under the National Immunisation Program (Influenza, MMR and Pertussis – containing 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 10.2.1 .	Yes • However, Pharmacist Immunisers must advise individuals about the availability of free vaccination services through bulk-billing general practitioners.
Individuals not eligible for government-funded vaccine under the National Immunisation Program (Influenza), Victorian Government's Partner Whooping Cough Vaccine Program	Yes These vaccines should be accessed from private suppliers.	Yes

10. Premises and staffing

10.1 Premises

The Approval requires that the premises on which a pharmacist administers vaccines is either:

- 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
- a general practice or immunisation clinic in which clinical practice is being undertaken as part of an 'Immuniser program of study' recognised by the Victorian Chief Health Officer under the direct supervision of a medical practitioner, nurse practitioner, or Nurse Immuniser who is compliant with Regulation 8(1) of the *Drugs, Poisons and Controlled Substances Regulations 2017*, to the extent that the supervising health professional is authorised to administer vaccines on those premises. Given that pharmacists are not authorised to administer vaccines in general practice or immunisation clinics, the Approval means that pharmacists are **not** able to supervise other pharmacists that are undertaking clinical placement in a general practice or immunisation clinic.

Where vaccinations are administered in hospitals, pharmacies or pharmacy depots, the Approval also requires that these premises meet the guidelines for facilities providing immunisation services, as described in the Victorian Pharmacy Authority Guidelines⁷ that are current at the time.

With regard to facilities for immunisation services, these 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. It is not to be used as a storeroom or staff room. Hand sanitisation facilities are to be in the room.
- The room or private consultation area is to:
 - 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 adequate room to manoeuvre;
 - have a bench with an impervious surface of at least 0.6 m², 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*⁸.
- 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 a dispensary refrigerator may be used to store vaccines. However, the Secretary Approval – Pharmacist Immuniser 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 temperature-monitored 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.

⁷ The Victorian Pharmacy Authority Guidelines are available at: <http://www.pharmacy.vic.gov.au>

⁸ Current version is available online at: <https://beta.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5-2nd-edition>

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 hospitals and pharmacy depots where a variety of rooms may be used for vaccination services, the Pharmacist Immuniser must keep evidence of completion of their training on hand to present to the individual on their request.

10.2 Registration of premises

10.2.1 Registration with the Department of Health and Human Services

As a condition of the Secretary Approval – Pharmacist Immuniser, pharmacies 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 receive government-funded influenza, pertussis-containing and measles-mumps-rubella vaccines for administration to the target groups eligible for the National Immunisation Program, Victorian Government's Partner Whooping Cough Vaccine Program and Victorian Government Measles-Mumps-Rubella Adult Vaccine Program, and will provide important information about vaccine updates, such as schedule changes, new resources and current vaccine recommendations.

Registration requires completion of an application form for a government-funded vaccines account and evidence of completion of approved training. This application form must be accompanied with the Australian Immunisation Register – Application to register as a vaccination provider form (IM004).

The application for government-funded vaccines account form can be downloaded from <https://www2.health.vic.gov.au/public-health/immunisation/vaccine-order-and-stock/new-account-application>.

Nominated pharmacist immunisers leaving the practice and/or changes to the pharmacy's account must notify the department's Immunisation unit within 5 working days on 1300 882 008 or email immunisation@dhhs.vic.gov.au.

The Australian Immunisation Register – Application to register as a vaccination provider form (IM004) can be downloaded from:

<https://www2.health.vic.gov.au/public-health/immunisation/vaccine-order-and-stock/new-account-application> OR <https://www.humanservices.gov.au/health-professionals/forms/im004>.

10.2.2 Registration as a business involving skin penetration

To support implementation of the Victorian Pharmacist-Administered Vaccination Program, a consequential amendment has been made to the Public Health and Wellbeing Regulations 2009, which will exempt pharmacies from registering with their local government as a business undertaking skin penetration, where they are administering vaccines in accordance with the Approval. Pharmacies are still required to register if they were undertaking skin penetration for ear piercing or any other reason.

The Public Health and Wellbeing Regulations 2009 are available from Victoria Law Today at <http://www.legislation.vic.gov.au/>.

10.2.3 Insurance

Both the pharmacy 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.

10.2.4 Accreditation

Pharmacies in which vaccines are administered must be accredited through an appropriate quality assurance program, such as the Quality Care Pharmacy Program <www.qcpp.com>.

10.2.5 Advertising

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*.

10.3 Staffing

It is a condition of the Approval that the Pharmacist Immuniser ensures at least one other staff member who holds a current first aid and cardiopulmonary resuscitation certificate is on duty in the pharmacy when the vaccines are administered, and for a minimum period of 15 minutes afterwards.

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

All pharmacy 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.

11. Equipment and resources

Compliance with the current edition of the Australian Immunisation Handbook and National Vaccine Storage Guidelines – Strive for 5⁹ are conditions of the Approval.

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

- a temperature-monitored refrigerator manufactured exclusively for the purpose of storage of vaccines with a temperature data logger
- all necessary consumables required for vaccine administration
- an appropriately sized sharps container to dispose of clinical waste, including used syringes and needles.

Other resources that are required to be readily accessible include:

- a current edition of the Australian Immunisation Handbook
- a current edition of the National Vaccine Storage Guidelines – Strive for 5
- materials to support communication about vaccination, including Myths and realities: Responding to arguments against vaccination, which is available from <<http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/myths-about-immunisation>>.

Pharmacist Immunisers should also subscribe to the department's Immunisation Newsletter, which is available from <<https://www2.health.vic.gov.au/public-health/immunisation/immunisation-newsletters>>.

A range of resources exist to support the delivery of safe vaccination services. These include:

- Practice guidelines for the provision of immunisation services within pharmacy (current edition) – Pharmaceutical Society of Australia¹⁰
- Guidelines for Conducting Immunisation Services within a Community Pharmacy Environment (current edition) – Pharmacy Guild of Australia.

⁹ Current version is available online at: <https://beta.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5-2nd-edition>

¹⁰ Pharmaceutical Society of Australia Ltd, 2014, Practice Guidelines for the provision of immunisation services within pharmacy, available at: <https://www.psa.org.au/policies/guidelines-for-the-provision-of-immunisation-services-within-pharmacy>

11.1 Anaphylaxis response kit

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

- adrenaline 1:1000 (minimum of three ampoules). Always regularly check expiry dates 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 10.1 and 12.1 of these guidelines) identifying assigned roles and responsibilities. All pharmacy staff should be aware of the emergency response protocol, and their roles and responsibilities in the event of an emergency.

12. Protocols

Pharmacist Immunisers should implement a process to regularly monitor online updates to the Australian Immunisation Handbook, the National Vaccine Storage Guidelines – Strive for 5, the Victorian Pharmacy Authority Guidelines, the Victorian Pharmacist-Administered Vaccination Program Guidelines, and any other key resources to inform their immunisation practice.

12.1 Emergency response protocol

An emergency response protocol must be kept as part of the anaphylaxis tool kit (preferably laminated and on display). The protocol should identify assigned roles and responsibilities of staff members. All staff should know and understand the 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 when vaccines are administered and for 15 minutes afterwards
- all Pharmacist Immunisers maintain recency of practice and continuing professional development in the management of adverse events following immunisation.

12.2 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, compliance with which is a condition of the Approval.

Cold chain breaches include:

- freeze breach
- heat breach ≥ 6 hours
- heat breach $\geq 25^{\circ}\text{C}$
- vaccines breached on more than one occasion.

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 National Immunisation Program, Victorian Government's Partner Whooping Cough Vaccine Program or Measles-Mumps-Rubella Adult Vaccine Program. Information is available from <<https://www2.health.vic.gov.au/public-health/immunisation/cold-chain-management/cold-chain-breach-reporting>>.

12.3 Assessment and consent

The Pharmacist Immuniser must obtain written consent from the individual and undertake pre-vaccination screening prior to vaccination to identify contraindications or precautions. The pre-vaccination screening checklist included in the Australian Immunisation Handbook (current edition) must be completed.

Prior to obtaining consent, individuals should be:

- provided with information, including the risks and benefits, relating to the vaccine and the immunisation procedure
- provided with information of any fees that will be charged to the individual 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 upheld at all times.

12.3.1 Consent for 16 and 17 year olds

In the case the parent and/or guardian of the 16 or 17 year old 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.
- The pharmacist has tried to persuade the individual to inform their parent and/or guardian or allow the pharmacist to inform them.
- The individual's health may suffer without the vaccine and assess the individual's needs including whether the individual has any contraindications.
- The individual understands their vaccination history and the pharmacist must verify against the individual's records on the Australian Immunisation Register.
- The 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.

12.4 Monitoring

The Pharmacist Immuniser must advise the individual to remain on the pharmacy 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.

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 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.

12.5 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. Each person's roles and responsibilities should be understood before the Pharmacist Immuniser commences the vaccination session.

Individuals 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 pharmacy premises.

12.6 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 (current edition). 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 of the Pharmacist Immuniser carrying out the administration
- 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.

If consent was granted by the individual 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 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.

12.6.1 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://www2.health.vic.gov.au/public-health/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 will help detect any problems with vaccines or systems as early as possible, and will help ensure a safe immunisation program in Victoria.

12.6.2 Immunisation registers

From 30 September 2016, the Australian Childhood Immunisation Register (ACIR) became the Australian Immunisation Register (AIR), a national register that records vaccinations given to people of all ages in Australia.

Pharmacists must register with the AIR as part of 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 are required to contribute information to the AIR for all vaccines administered.

12.7 Complaints

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

- Complaints relating to the pharmacist's professional practice should be directed to the Australian Health Practitioner Regulation Agency.
- Complaints relating to the pharmacy premises should be directed to the Victorian Pharmacy Authority.
- Individuals may also bring a complaint against a pharmacist to the Health Services Commissioner at <<http://www.health.vic.gov.au/hsc/patient/complaint.htm>>.

13. Questions

If you have any questions regarding the Victorian Pharmacist-Administered Vaccination Program or these guidelines, please contact the Immunisation unit, Department of Health and Human Services on 1300 882 008 or email <immunisation@dhhs.vic.gov.au>.

Attachment 1

Record keeping and reporting template (print version)

This template should be completed in addition to pre-vaccination screening checklist in the Australian Immunisation Handbook (current edition).

Individual Information	
Surname:	Other names:
Medicare number:	Concession/Pension card number:
Address:	
Phone Number:	
Carer details (if applicable):	
Name of GP/family doctor:	Contact information:
Name of other relevant medical professionals (e.g. obstetrician):	Contact information:
Notes	
Immuniser Details	
Pharmacist name:	Contact number:
Pharmacy name and address:	Date:
Signature:	
Turn page over	
Please fill in all details on all pages and keep in the pharmacy as an immunisation record	

Information on this page is de-identified to facilitate data collection for the purposes of ongoing evaluation conducted by the Victorian Department of Health and Human Services

Date of birth:	Gender:
At the time of pre-vaccination screening, is the individual 16 or 17 years of age? O Yes O No	
Aboriginal and/or Torres Strait Islander: O Yes O No	Post Code:
Influenza vaccination history	Current influenza vaccine administration
When did the individual last receive an influenza vaccine? O Last year O 2-3 years O 3-5 years O > 5 years O Never	Date of vaccination:
	Time:
	Name of vaccine (including Brand):
	Dose:
Is the individual at high risk of influenza or complications related to influenza? O Aboriginal/Torres Strait Islander ≥ 15 years O Pregnant O COPD, severe asthma, lung or heart disease, diabetes, low immunity O ≥ 65 years	Injection site: O Right arm O Left arm
	Batch number:
	Date the next vaccination is due (if applicable):
	Was the vaccine provided/supplied through the National Immunisation Program? O Yes O No
Whooping cough vaccination history	Current whooping cough vaccine administration
When did the individual last receive a whooping cough vaccine? _____	Date of vaccination:
	Time:
Does the individual belong to any of the below categories? O Third trimester of pregnancy from 28 weeks gestation. O Partners of women ≥ 28 week pregnant and who have not had a pertussis booster in the past 10 years. O Parents or guardians of babies under 6 months and who have not received a pertussis booster in the past 10 years.	Name of vaccine (including Brand):
	Dose:
	Batch number:
	Injection site: O Right arm O Left arm
	Date the next vaccination is due (if applicable):
	Was the vaccine provided/supplied through the Victorian Government's Partner Whooping Cough Vaccine Program? O Yes O No

Turn page over

Please fill in all details on all pages and keep in the pharmacy as an immunisation record

Measles, mumps and rubella vaccination history		Current measles, mumps and rubella vaccination history	
When did the individual last receive a measles-mumps-rubella vaccine?		Date of vaccination:	
		Time:	
Does the individual belong to any of the below categories?		Name of vaccine (including Brand):	
<input type="radio"/> Individuals aged 16 to 19 years requiring catch-up <input type="radio"/> Refugees and all humanitarian entrants aged 16 years and over <input type="radio"/> Born during or since 1966 <input type="radio"/> Women planning pregnancy or post-partum with low or negative rubella antibody levels		Dose:	
		Batch number:	
		Injection site: <input type="radio"/> Right arm <input type="radio"/> Left arm	
		Date the next vaccination is due (if applicable):	
		Was the vaccine provided/supplied through the Victorian Government's Measles-Mumps-Rubella Adult Vaccine Program? <input type="radio"/> Yes <input type="radio"/> No	
Adverse events			
Was an adverse event observed in the time period the individual remained in the pharmacy post vaccination? <input type="radio"/> Yes <input type="radio"/> No 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://www2.health.vic.gov.au/public-health/immunisation/adverse-events-following-immunisation-reporting			
Continuity of care			
Was the individual's vaccination record sent to the primary care provider and any other relevant medical professional suggested by the individual (e.g. obstetrician)?		<input type="radio"/> Yes	<input type="radio"/> No
Australian Immunisation Register			
Immunisation providers report vaccines administered to the Australian Immunisation Register (AIR). Personal identifying details will be kept confidential. These details are for the purpose of providing targeted improved health services for all Victorians. In addition the details enable tools such as recall and reminder systems to improve vaccination rates. This is important to improve overall immunisation rates. Individuals will have access to their record of all vaccines recorded in the AIR.			

Record keeping and reporting template (electronic version)

This template should be completed in addition to pre-vaccination screening checklist in the Australian Immunisation Handbook (current edition)

Individual Information	
Surname: Click here to enter text.	Other names: Click here to enter text.
Medicare number: Click here to enter text.	Concession/Pension card number: Click here to enter text.
Address: Click here to enter text.	
Phone Number: Click here to enter text.	
Carer details (if applicable): Click here to enter text.	
Name of GP/family doctor: Click here to enter text.	Contact information: Click here to enter text.
Name of other relevant medical professionals (e.g. obstetrician): Click here to enter text.	Contact information: Click here to enter text.
Notes	
Click here to enter text.	
Immuniser Details	
Pharmacist name: Click here to enter text.	Contact number: Click here to enter text.
Pharmacy name and address: Click here to enter text.	Date: Click here to enter text.
Signature:	
<p align="center">Turn page over</p> <p align="center"><i>Please fill in all details on both pages and keep in the pharmacy as an immunisation record</i></p>	

Information on this page is de-identified to facilitate data collection for the purposes of ongoing evaluation conducted by the Victorian Department of Health and Human Services

<p>Date of birth: Click here to enter text.</p> <p>At the time of pre-vaccination screening, is the individual 16 or 17 years of age?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Gender: Click here to enter text.</p>
<p>Aboriginal or Torres Strait Islander:</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Post Code: Click here to enter text.</p>
Influenza vaccination history	Current influenza vaccine administration
<p>When did the individual last receive an influenza vaccine?</p> <p><input type="checkbox"/> Last year <input type="checkbox"/> 2-3 years <input type="checkbox"/> 3-5 years <input type="checkbox"/> > 5 years <input type="checkbox"/> Never</p>	<p>Date of vaccination: Click here to enter text.</p> <p>Time: Click here to enter text.</p> <p>Name of vaccine (including Brand): Click here to enter text.</p> <p>Dose: Click here to enter text.</p>
<p>Is the individual at high risk of influenza or complications related to influenza?</p> <p><input type="checkbox"/> Aboriginal/Torres Strait Islander \geq 15 years</p> <p><input type="checkbox"/> Pregnant</p> <p><input type="checkbox"/> COPD, severe asthma, lung or heart disease, diabetes, low immunity</p> <p><input type="checkbox"/> \geq 65 years</p>	<p>Batch number: Click here to enter text.</p> <p>Injection site: <input type="checkbox"/> Right arm <input type="checkbox"/> Left arm</p> <p>Date the next vaccination is due (if applicable): Click here to enter text.</p> <p>Was the vaccine provided/supplied through the National Immunisation Program? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
Whooping cough vaccination history	Current whooping cough vaccine administration
<p>When did the individual last receive a whooping cough vaccine? Click here to enter text.</p>	<p>Date of vaccination: Click here to enter text.</p> <p>Time: Click here to enter text.</p>
<p>Does the individual belong to any of the below categories?</p> <p><input type="checkbox"/> Third trimester of pregnancy from 28 weeks gestation.</p> <p><input type="checkbox"/> Partners of women \geq 28 week pregnant and who have not had a pertussis booster in the past 10 years.</p> <p><input type="checkbox"/> Parents or guardians of babies under 6 months and who have not received a pertussis booster in the past 10 years.</p>	<p>Name of vaccine (including Brand): Click here to enter text.</p> <p>Dose: Click here to enter text.</p> <p>Batch number: Click here to enter text.</p> <p>Injection site: <input type="checkbox"/> Right arm <input type="checkbox"/> Left arm</p> <p>Date the next vaccination is due (if applicable): Click here to enter text.</p> <p>Was the vaccine provided/supplied through the Victorian Government's Partner Whooping Cough Vaccine Program? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>

Turn page over

Please fill in all details on both pages and keep in the pharmacy as an immunisation record

Measles, mumps and rubella vaccination history	Current measles, mumps and rubella vaccination administration
When did the individual last receive a measles-mumps-rubella vaccine? Click here to enter text.	Date of vaccination: Click here to enter text.
	Time: Click here to enter text.
Does the individual belong to any of the below categories? <input type="checkbox"/> Born during or after 1966 <input type="checkbox"/> Women planning pregnancy or post-partum with low or negative rubella antibody levels	Name of vaccine (including Brand): Click here to enter text.
	Dose: Click here to enter text.
	Batch number: Click here to enter text.
	Injection site: <input type="checkbox"/> Right arm <input type="checkbox"/> Left arm
	Date the next vaccination is due (if applicable): Click here to enter text.
	Was the vaccine provided/supplied through the Victorian Government's Measles-Mumps-Rubella Adult Vaccine Program? <input type="checkbox"/> Yes <input type="checkbox"/> No
Adverse events (if applicable)	
Was an adverse event observed in the time period the individual remained in the pharmacy post-vaccination: <input type="checkbox"/> Yes <input type="checkbox"/> No 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://www2.health.vic.gov.au/public-health/immunisation/adverse-events-following-immunisation-reporting	
Continuity of care	
Was the individual's vaccination record sent to the primary care provider and any other relevant medical professional suggested by the individual (e.g. obstetrician)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Australian Immunisation Register	
Immunisation providers report vaccines administered to the Australian Immunisation Register (AIR). Personal identifying details will be kept confidential. These details are for the purpose of providing targeted improved health services for all Victorians. In addition the details enable tools such as recall and reminder systems to improve vaccination rates. This is important to improve overall immunisation rates. Individuals will have access to their record of all vaccines recorded in the AIR.	