

Practice Guidelines for pharmacists providing immunisation services

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Contents

Preface	4
How to use these guidelines	5
Terminology	5
Immunisation in Australia	6
Introduction	7
Pharmacy immunisation services	9
Authorised immunisers	9
Legislative requirements	10
Service agreements	10
Health promotion and risk assessment	10
Procedures and requirements	10
Providing immunisation services	14
Consumer clinical needs assessment	14
Consumer consent	14
Confidentiality and consumer privacy	15
Administration of vaccines	15
Consumer aftercare	15
Consumer vaccination documentation	15
Identification and management of adverse events following immunisation	15
Collaboration with other healthcare providers	16
Providing immunisation services outside the pharmacy setting	16
Immunisation reporting and management	17
Reporting to immunisation registers	17
Reporting adverse events following immunisation	17
Monitoring and auditing of immunisation services	18
Appendices	19
Appendix 1: State and territory drugs and poisons legislation	19
Appendix 2: National Immunisation Program schedule	20
Appendix 3: Consumer information resources	21
Appendix 4: Contact details for Commonwealth and state and territory health authorities and communicable disease control	22
Appendix 5: Immunisation service checklist for pharmacies	23
Appendix 6: Anaphylaxis response protocol	25
Appendix 7: Pre-vaccination screening checklist and informed consent	27
Appendix 8: Post-vaccination procedures checklist	29
Appendix 9: Consumer vaccination statement template	30
References	31



Preface

In Australia, pharmacists have been administering vaccinations since 2014. It is now widely accepted as being within scope of practice for appropriately trained pharmacists across all states and territories.

This document provides guidance to pharmacists on professional issues and obligations relating to pharmacist immunisation services. These guidelines may also be a useful resource for other stakeholders, including service providers or immunisers contracted or employed to administer vaccinations as part of a pharmacy immunisation service.

The Pharmaceutical Society of Australia (PSA) recognises the importance of continuity of care within the healthcare environment.

These guidelines promote specific policies and protocols designed to ensure safe and effective service delivery and communication between healthcare providers.



How to use these guidelines

These guidelines are an educational resource for pharmacists to promote best practice and deliver high-quality immunisation services in pharmacies and by pharmacist immunisers outside the pharmacy setting where jurisdictional regulations allow. Pharmacists are expected to exercise professional judgment in applying the guidance provided to specific presenting circumstances.

Guidelines developed by the PSA are not definitive statements of correct procedure, but usually reflect agreement by experts in the field. PSA guidelines are informed by available clinical evidence and encourage the application of theoretical concepts shown to facilitate the implementation of services. PSA guidelines can be used as a support tool for balanced, professional decision-making in the context of a consumer's needs, beliefs and preferences. They can contribute to quality assurance processes and may also assist in the resolution of legal disputes or ethical dilemmas. They are not intended to provide clinical information. It is the responsibility of individual pharmacists to maintain their clinical skills, knowledge and competence.

Certain aspects of the implementation of pharmacy immunisation services are considered to be outside the scope of these guidelines. Pharmacists must always meet legislative requirements, which may not be detailed in these guidelines.

Pharmacists should refer to the legislation detailing the administration of medicines, poisons and controlled substances in their respective state or territory (refer to **Appendix 1**), or contact their state or territory Department of Health for specific guidance on jurisdictional requirements. Other issues not covered within these guidelines include models of supply or practice, and funding arrangements for pharmacist immunisation services.

These guidelines should be read and considered in conjunction with information and recommendations provided in the current version of the *Australian Immunisation Handbook*.

The *Australian Immunisation Handbook* (the Handbook) is an essential resource for health professionals involved in the delivery of immunisation services in Australia. Recommendations in the Handbook have been developed by the Australian Technical Advisory Group on Immunisation (ATAGI), and endorsed by the National Health and Medical Research Council (NHMRC). The Handbook is regularly updated in line with current best evidence. It is available as a digital version only, and can be accessed at: <https://immunisationhandbook.health.gov.au/>.¹

Pharmacists are encouraged to use this document in conjunction with existing pharmacy operating procedures.²

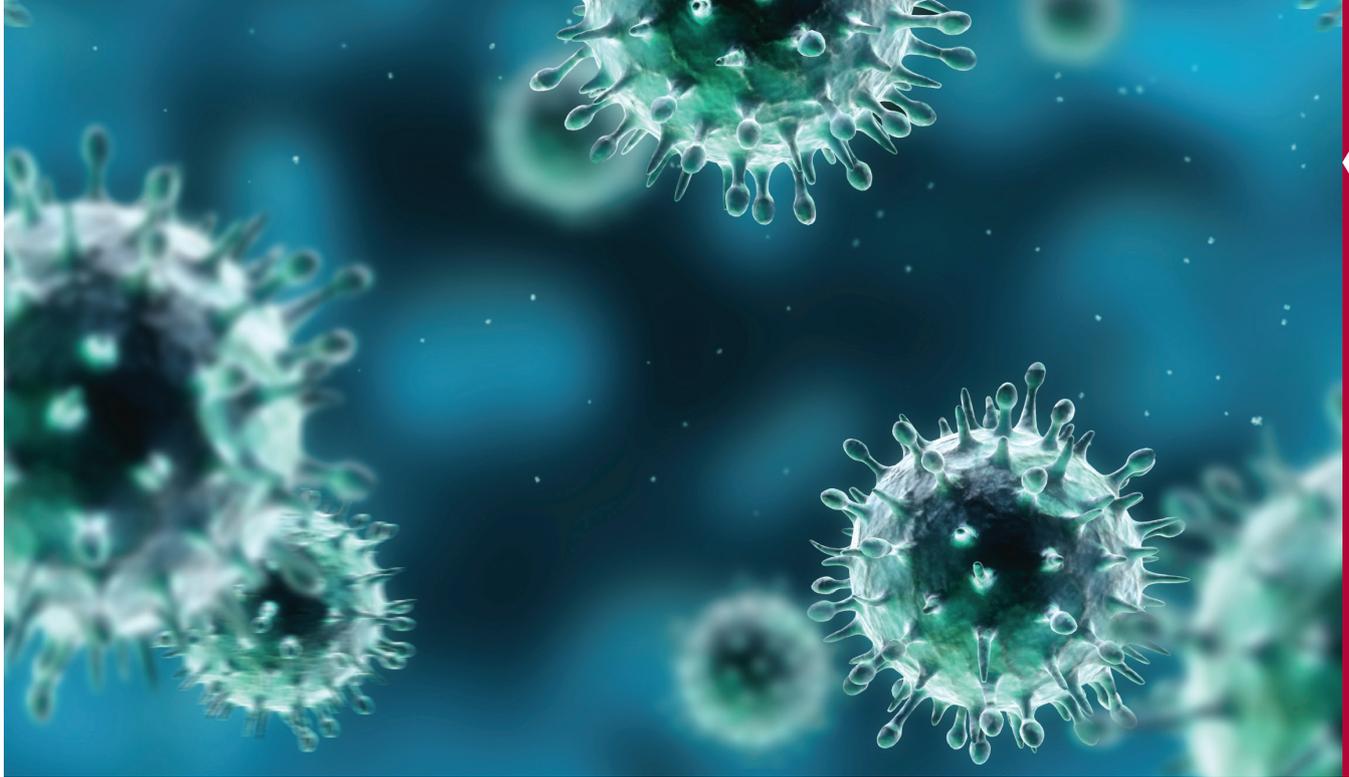
Terminology

TERM	DEFINITION
Adverse event following immunisation (AEFI)	An unwanted reaction following administration of a vaccine, which may or may not be caused by the vaccine
ATAGI	Australian Technical Advisory Group on Immunisation
Australian Immunisation Handbook (the Handbook)	Essential resource for health professionals involved in the delivery of immunisation services. The Australian Immunisation Handbook can be accessed at https://immunisationhandbook.health.gov.au/ or via the Immunisation Handbook mobile app
Australian Immunisation Register (AIR)	The Australian Immunisation Register (AIR) is a national register that records vaccines given to individuals of all ages, living in Australia.
Immunisation	The process of inducing immunity to an infectious agent by administration of a vaccine
Immuniser	A regulated health practitioner who is authorised to supply and/or administer vaccines in accordance with state or territory drugs and poisons legislation, including medical practitioners, nurse immunisers, registered midwives, Aboriginal and Torres Strait Islander health workers/practitioners, and pharmacists. Note: This definition of an immuniser may not be recognised in all jurisdictions.
Immunity	The ability of the body to fight off certain infections as a result of vaccination or previous infection
Pharmacy	A health care destination (usually a business entity) which provides medicines and primary health care
Pharmacist immunisation service	Any immunisation service delivered by trained pharmacist immuniser
Pharmacy staff	Any person who works in or for the pharmacy, including the pharmacist
Pharmacist immuniser	A registered pharmacist who is authorised to deliver vaccinations by the state or territory Department of Health (however named)
Primary healthcare provider	Primary healthcare professional responsible for a consumer's care
Service provider	An entity contracted to deliver immunisation services
Vaccination	The process of administering a vaccine into the body
Vaccine	The material used for immunisation, including extracts of killed or live weakened strains of viruses or bacteria



Immunisation in Australia

Despite a longstanding and expanded immunisation program, immunisation rates can still be improved across some Australian population groups (e.g. at-risk groups, Aboriginal and Torres Strait Islander people) to reduce the risk of vaccine-preventable disease.



Introduction

Vaccination is one of the greatest medical interventions in modern history. It has greatly reduced the burden of infectious diseases.³ The World Health Organization (WHO) estimates that vaccination prevents between two and three million deaths each year.⁴

The protection afforded by immunisation is two-fold. Aside from immunity directly conferred upon the individual through vaccination, when a large proportion of the population is immunised there is a subsequent disease reduction in the unimmunised segment. This phenomenon, known as community (herd) immunity, is an important aim of immunisation programs.⁵ Vaccination against some vaccine preventable diseases may not be considered appropriate in some individuals because of age (e.g. newborns) or medical reasons (e.g. immunocompromised). These individuals are often at a higher risk of complications if they contract the disease. In the instances where they cannot be vaccinated, these individuals rely on community immunity to keep them safe from infection.

The first Australian immunisation programs were established in the 1920s. Since then, Australia has had an excellent record of preventing disease through immunisation. Mass childhood immunisation programs for poliomyelitis, diphtheria, tetanus, pertussis, measles, mumps, rubella, and more recently Haemophilus influenzae type b (Hib) and meningococcal ACWY, have reduced the incidence and associated disease burden of these once common vaccine-preventable diseases.

Immunisation efforts in Australia are supported by the National Immunisation Program (NIP) overseen by the National Immunisation Committee (NIC). Technical advice on the operation of the NIP is provided by the Australian Technical Advisory Group on Immunisation (ATAGI). The NIP⁶ aims to increase immunisation rates across Australia by funding programs administering vaccines recommended in the NIP Schedule.⁷ It also communicates information about immunisation to the general public and provides guidance to healthcare professionals. Despite a longstanding and expanded immunisation program, immunisation rates can still be improved across some population groups (e.g. at-risk groups, Aboriginal and Torres Strait Islander people).

Despite their success, immunisation programs face certain challenges. Firstly, immunisation programs generally target healthy populations. Service providers must be proactive, as healthy consumers will not always seek out vaccinations.⁸ In addition, myths and misconceptions relating to the safety of immunisation persist, leading to a fall in vaccination rates in some areas and among some consumer groups.^{3,8} Finally, a successful immunisation program can lead to complacency



among healthcare professionals and the public. When there is no longer firsthand experience of the serious consequences of disease, immunisation can be undervalued.^{8,9} The public's focus can shift towards the risk of rare adverse events and myths and misconceptions around immunisation.⁸ For these reasons, health promotion and consumer education, as well as increased and ongoing accessibility to immunisation services, are particularly important.

The first National Immunisation Strategy for Australia 2013–2018 published by the Department of Health identified two priority areas—improving immunisation coverage and ensuring an adequately skilled immunisation workforce. The updated National Immunisation Strategy 2019–2024 builds on the initial strategy, and retains these two strategic priority areas.

There are now eight strategic priority areas:

1. Improve immunisation coverage
2. Ensure effective governance of the NIP
3. Ensure secure vaccine supply and efficient use of vaccines for the NIP
4. Continue to enhance vaccine safety and monitoring systems
5. Maintain and ensure community confidence in the NIP
6. Strengthen monitoring and evaluation of the NIP
7. Ensure an adequately skilled immunisation workforce
8. Maintain Australia's strong contribution to the region

The strategic priority areas complement and strengthen the National Immunisation Program and the National Medicines Policy.^{10,11} Services provided by pharmacists support the strategy by increasing accessibility to immunisation services and improving coverage.



Pharmacist immunisation services

Pharmacists have long been involved in the dispensing and distribution of vaccines. More recently however, pharmacists have played a key role in the administration of vaccines.

Authorised immunisers

Any person administering vaccines must be an authorised immuniser. Current authorised immunisers include¹²:

- medical practitioners

and appropriately trained:

- pharmacists
- Aboriginal and Torres Strait Islander health workers / practitioners
- registered and enrolled nurses
- midwives.

An appropriately qualified pharmacist immuniser:

- has current registration with the Pharmacy Board of Australia under the Australian Health Practitioner Regulation Agency (AHPRA)
- has completed a vaccination course accredited by the Australian Pharmacy Council and/or approved by the respective state or territory Department of Health. To be accredited, courses are aligned with the Standards for the Accreditation of Programs to Support Pharmacist Administration of Vaccines¹³
- holds a current first aid certificate (renewal required every three years)

- holds a current cardiopulmonary resuscitation (CPR) certificate (renewal required every 12 months)
- completes appropriate anaphylaxis training (e.g. anaphylaxis e-training for pharmacists by the Australasian Society of Clinical Immunology and Allergy¹⁴)
- has professional indemnity insurance cover appropriate to their immunisation activities
- is permitted to administer vaccines under state or territory legislation
- is authorised by the state or territory Department of Health (however named).

Authorised immunisers (excluding medical practitioners) should provide evidence of completed training, from an authorised registered training organisation (RTO).

Registered pharmacists, Aboriginal and Torres Strait Islander health practitioners, medical practitioners and registered nurses and midwives are listed in the AHPRA registers. However, at present there is no endorsement for authorised immunisers (including pharmacists) on the AHPRA National Register of Practitioners. Authorisation is required and provided by the state or territory Department of Health (however named).

Pharmacist immunisers

Pharmacist immunisers must not be responsible for any other professional activity (including dispensing) when providing vaccinations. When vaccinating, the pharmacist immuniser is accompanied by another appropriately trained person with a current first aid and CPR certificate. This person could assist with after-vaccination care and in the rare event when emergency care is required.

Legislative requirements

Legislative requirements governing the administration of vaccines differ between states and territories. The NIP Schedule details the types of Government-funded vaccines authorised for administration.⁷ Eligibility for authorised immunisers to administer specific NIP vaccines is jurisdiction-specific, as are the requirements and processes for administration of vaccines. Pharmacists should inform eligible people about how to access vaccination as part of the NIP or any other state or territory vaccination program. Refer to **Appendix 2: National Immunisation Program (NIP) schedule**.

The pharmacist-in-charge must ensure the immuniser is authorised to administer the vaccine(s) in the specific state or territory. Immunisation services must not proceed unless all legislative requirements are met. For further information, pharmacists should contact the Department of Health for the relevant jurisdiction. Refer to **Appendix 4: Contact information for Commonwealth and state and territory health authorities and communicable disease control**.

Service agreements

When contracting an external immuniser or service provider, pharmacists are encouraged to develop a service agreement outlining the roles and responsibilities of each party. The service agreement does not replace the need for specific legal advice.

In some jurisdictions, pharmacist immunisers may administer vaccines outside a pharmacy setting.¹⁷ In such instances, a service agreement should be in place between the Service Provider (pharmacist immuniser) and the client (the organisation contracting the immunisation services).¹⁵

Health promotion and risk assessment

Pharmacist immunisation services provide an opportunity to offer immunisation health promotion, education and risk-assessment services to consumers. Providing primary and preventive healthcare is a recognised role of pharmacists.¹⁸

Pharmacists are encouraged to promote and improve public health by educating consumers about immunisation recommendations, assisting consumers identify their vaccination status, and motivating unvaccinated individuals with no contraindications to vaccination to be immunised. Individuals can be identified through health promotion and risk-assessment analysis.

Pharmacists should provide advice to consumers about their immunisation needs, ensuring enough time and resources

are allocated when promoting and explaining the service to consumers and local healthcare professionals. Refer to **Appendix 2: NIP schedule**.⁷

Pharmacists should review local area demographics to inform health promotion campaigns. While pharmacists should encourage vaccination uptake in all unvaccinated individuals, pharmacists should strongly encourage consumers in high-risk populations including infants and children, Aboriginal and Torres Strait Islander people, the elderly, and consumers with chronic disease, to be vaccinated. Specifically, pharmacists should provide consumers identified as being at risk of vaccine-preventable disease (as a result of incomplete immunisation coverage) with appropriate information on 'catch-up' vaccination services. They should be referred to their primary healthcare provider when required.⁷ At all times, pharmacists should only provide advice within the limits of professional knowledge and experience.¹⁸

Pharmacists are encouraged to maintain knowledge of current immunisation policy advice and best scientific evidence.¹⁸ Pharmacists should be able to provide the consumer with appropriate information about vaccination and immunity to help address questions and concerns. Refer to **Appendix 3: Consumer information resources**.

In some jurisdictions, pharmacist immunisers may administer travel vaccines. Pharmacists should consider whether the consumer requires additional travel medicine advice and refer as appropriate such as the Australian Immunisation Handbook. The NIP Schedule may not cover the specific needs of a consumer travelling or residing outside of Australia.¹ Pharmacists not authorised to administer travel vaccines, should refer consumers travelling to areas of considerable risk, or who have chronic diseases placing them at increased risk of disease or illness during their travel, to their primary healthcare provider or dedicated travel medicine centre. For example, if the consumer is travelling to an area requiring a yellow fever vaccine, pharmacists must refer them to an approved provider at an approved yellow fever vaccination centre.¹⁹

Procedures and requirements

Pharmacists must ensure appropriate procedures exist to guarantee resources are available and in-date prior to each vaccination session. Pharmacists providing immunisation services at a site other than a pharmacy should ensure all procedures are in place before commencing those services (e.g. pharmacist hosting an after hours clinic at a community event, pharmacist working in a GP practice or aged care facility). Refer to the section 'Preparing for vaccination' in the *Australian Immunisation Handbook*.²⁰

The following must be available when providing immunisation services including:

- anaphylaxis response kit in accordance with the Australian Immunisation Handbook
- private consultation area, consistent with relevant jurisdictional requirements



- cold-chain management system for vaccines and vaccine products
- disposal system for sharps and medical waste
- policy and procedures manual for the immunisation service
- provision of appropriate training about the immunisation service to all staff
- records management system.

Refer to **Appendix 5: Immunisation service delivery checklist for pharmacies**.^{21,22} Refer to QCPP Vaccination Services in the pharmacy checklist T3M if Quality Care Pharmacy Program (QCPP) accredited.²

When establishing an immunisation service, pharmacy staff should seek assistance with the implementation process. Evidence has shown the benefit over time of targeted, on-site support when preparing for change and building capacity to integrate new professional services.²³⁻²⁵ Established pharmacy immunisation services should undergo regular review to ensure they are congruent with relevant legislation, current practice standards, and guidelines.

Emergency procedures

Pharmacists must ensure appropriate resources are available for responding to emergency situations in the immunisation service area. This includes an anaphylaxis response protocol and an anaphylaxis response kit. The pharmacy should have adequate stock levels of adrenaline appropriate to the volume of the service to provide a desired response to anaphylaxis. This should be either in the form of auto-injectors or ampoules of adrenaline and syringes, consistent with the relevant state or territory requirements. Adrenaline supply should be replenished immediately after use. The standard operating procedure should also include regular checking of expiry dates.

Refer to **Appendix 5: Immunisation service delivery checklist for pharmacies**, and the section 'Preparing an anaphylaxis response kit' in the online *Australian Immunisation Handbook*, for information on how to prepare an anaphylaxis response kit.²⁰

Pharmacist immunisers must have current cardiopulmonary resuscitation (CPR) and first aid certification. Pharmacists should consider first aid, CPR and anaphylaxis training for all staff involved in the immunisation service to enable them to assist in an emergency. All pharmacy staff, including the immuniser, must be familiar with the pharmacy's emergency procedures.

A written protocol outlining the steps for responding to emergencies following the administration of vaccines should be made available and visible in the immunisation service delivery area. All pharmacy staff should be trained to recognise signs and symptoms of adverse events such as anaphylaxis and vasovagal syncope (fainting). A laminated copy of the protocol should be placed in full view for all pharmacy staff.

Refer to **Appendix 6: Anaphylaxis response protocol**, and the document *First Aid for Anaphylaxis*, both published by the Australian Society of Clinical Immunology and Allergy.^{26,27} Also refer to the online version of the *Australian Immunisation Handbook* in the section 'After vaccination'.

Immunisation service area

Immunisation services should be delivered in a private consultation area to protect the privacy and confidentiality of consumers. There should be adequate seating for consumers in the immunisation service area, allowing them to remain in the general vicinity for at least 15 minutes following vaccination.

The immunisation service area should be equipped appropriately to allow consumers to sit or lie when receiving treatment. Pharmacists should ensure the area is of sufficient size and appropriate layout to accommodate efficient workflow, including adequate room for the consumer, their carer and the immuniser, as well as the equipment and documentation required for the service. The immunisation service area should have sufficient space and appropriate surfaces for the immuniser to treat potential adverse events, and hand-washing facilities to meet relevant state or territory health authority requirements.

Cold chain maintenance

Vaccines are fragile biological products. To maintain potency they must be stored at between +2 °C to +8 °C.²⁸ Pharmacist immunisers must ensure that, irrespective of where the immunisation service is being conducted, there is equipment for storing vaccines compliant with cold chain requirements e.g. purpose-built vaccine refrigerator, vaccine cooler i.e. *Eskey*). Pharmacists should monitor and record the minimum/maximum temperature at least twice daily, and ensure there is capacity to store vaccines appropriately. The vaccine storing equipment must be accessible only to people involved in the delivery of the service and used only for storing medicines and vaccines. It must be placed in a secure area, with its power source clearly marked to prevent accidental power cuts.

All cold chain equipment should be placed in the immunisation service area e.g. within the dispensary. Access to vaccines should be restricted, as per the relevant state or territory legislation governing the storage of controlled substances. Pharmacists must be familiar with and adhere to, the *National Vaccine Storage Guidelines: Strive for 5*.²⁸ These Guidelines provide practical advice about maintaining the cold chain and preventing and managing cold chain breaches. The Guidelines detail the importance of storing vaccines at between +2 °C to +8 °C to maintain potency. Protocols for purchasing, transporting, storing, managing and monitoring temperature consistency of vaccines are included in these Guidelines.²⁸

Pharmacists should implement a procedure for dispensing and/or storing vaccines prior to administration, to ensure compliance with cold chain requirements and restrict access to these dispensed medicines. For vaccines provided by the immuniser, pharmacists should be aware of, and respect, the maintenance of cold chain procedures. They should not remove vaccines from the storage environment.

When storing, handling or transporting vaccines, pharmacists must develop a written vaccine management protocol to ensure the cold chain is maintained and auditable. The vaccine management protocol should be included in the policy and procedure manual. The protocol should outline monitoring

processes, adherence to cold chain guidelines including storage and monitoring requirements, identification of persons responsible for ensuring vaccine potency, contingency plans in the event of mechanical or power failure, and reporting processes for cold chain breaches. For audit purposes, pharmacists should ensure pharmacy staff can demonstrate application of, and compliance to, the vaccine management policy or protocol.

The immuniser should have access to the current online versions of *The National Vaccine Storage Guidelines: Strive for 5*.²⁸ and the *Australian Immunisation Handbook*.¹

Refer to the *Australian Pharmaceutical Formulary and Handbook*²⁹ Section A: Cold chain management, QCPP Requirements Manual⁶, and *Australian Immunisation Handbook*¹ section 'Preparing for vaccination'.

Disposal of sharps and medical waste

Pharmacists must ensure that equipment for appropriate disposal of sharps and medical waste is available in the immunisation service area, as outlined in the section 'Preparing for vaccination' in the *Australian Immunisation Handbook*.¹

Refer to state and territory health authorities for management guidelines on the safe disposal of clinical waste, or the National Health and Medical Research Council (NHMRC) *Australian guidelines on the prevention and control of infection in healthcare*.³⁰

Policy and procedures manual

A policy and procedure manual for immunisation services should be developed in collaboration with the immuniser or service provider. If the pharmacy is QCPP accredited, use the QCPP template provided to develop this document. Refer to: QCPP Vaccination services in the pharmacy checklist T3M.²

The immunisation service policy and procedure manual should contain:

- clearly defined aim or purpose of the service
- service checklist or flow chart including how it works and how it is integrated into existing workflows
- clearly defined description of the roles and responsibilities of all people involved in the delivery of the service
- training schedule for all people involved in the delivery of the service including definition of their roles and responsibilities
- vaccine management protocol for ensuring compliance with cold chain storage and monitoring requirements, including identifying persons responsible for ensuring vaccine potency, contingency plans in the event of mechanical or power failure and reporting of cold chain breaches
- process for prevaccination screening including a checklist (see Appendix 7)
- process for obtaining and documenting valid consent policy for communication and provision of service information to local healthcare providers and consumers (including the contact details for the medical officer who has agreed to be contactable during periods in which immunisations are administered, if required by state or territory legislation)

- a protocol for responding to medical emergencies following the administration of vaccines, including the management of anaphylaxis, the use of emergency response equipment, and the roles and responsibilities of pharmacy staff and the authorised immuniser (see **Appendix 6**)
- a procedure for recording and referring consumers for appropriate medical advice and care if presenting with an adverse event following immunisation (AEFI)
- a work health and safety protocol with specific reference to minimising the risk of needle stick injury, exposure to blood and bodily fluids, and the transmission of infectious diseases, including a process for post-exposure prophylaxis
- guidelines and procedures for the development and maintenance of the immunisation service area including (as necessary) information resources, furniture, equipment for storing and administering vaccines, and facilities for sharps and medical waste disposal
- a waste management policy detailing process for the removal of sharps and medical waste from the pharmacy premises
- a process and requirement for documenting immunisation services including the creation and maintenance of consumer records, addition of details to the consumer's electronic health record where possible, and processes for ensuring authorised immunisers review patient history prior to administration and report all vaccinations to the Australian Immunisation Register (AIR)
- a policy for documentation and storage of consumer records (with consumer consent) that ensures consumer confidentiality is maintained
- details of the responsibilities for maintenance of the service and associated documentation (e.g. access, storage, security, backups)
- a process for maintaining access to, and currency of, relevant health information for consumers and healthcare providers
- a process for the development and update of relevant forms and templates (i.e. screening and needs assessment tools, and consumer immunisation history statements)
- a policy for the management of enquiries and complaints about the service, from both consumers and other healthcare providers
- details of an incident reporting and risk management system to document, monitor and address deviations from prescribed protocols and procedures
- details of a monitoring and audit timetable for service review to ensure continuous improvement of the services.

Refer to the PSA Professional Practice Standards, Standard 11: Vaccination Service¹⁸ for further information regarding the development of a policy and procedures manual.

Professional indemnity insurance

Pharmacists must ensure the pharmacy has appropriate insurance cover before hosting immunisation services. The immuniser's professional indemnity insurance does not negate the need for a pharmacy to be covered under its insurance policy. The immuniser must also ensure a professional indemnity insurance cover appropriate to their immunisation activities is in place.



Staff education and training

Pharmacists should ensure all pharmacy staff are trained about integrating immunisation services into the existing pharmacy workload and workflow. Training provided to pharmacy staff should include emergency procedures, alteration to pharmacy layout and other logistical changes, procedures for service delivery in a setting other than the pharmacy, developing relationships with the consumer and other health professionals, remuneration, marketing and obtaining external support.

All pharmacy staff must be informed about their roles and responsibilities within the service, including relevant policies and procedures. Pharmacists should consider delivering staff training in collaboration with an immuniser wherever possible.

All pharmacy staff

Pharmacists should ensure all pharmacy staff are trained in recognising anaphylaxis and vasovagal episodes (temporary fall in blood pressure). All staff should be encouraged to participate in anaphylaxis training. All staff must be aware of their responsibilities in an emergency.

Pharmacists should inform the pharmacy staff about:

- their role in emergency response procedures
- the role and responsibilities of the immuniser
- immunisation service delivery including appointment arrangements, referral of consumer queries, handling of consumer complaints, and post-vaccination monitoring
- policies and procedures for collecting consumer healthcare information including Aboriginal and Torres Strait Islander status and other existing medical conditions
- privacy legislation
- cultural safety and health equity.

Pharmacists

Examples of appropriate educational training for pharmacists include:

- health promotion and immunisation services
- the principles of vaccination and immunity
- knowledge of the NIP schedule⁷ and other government funded vaccination programs
- management of adverse events following immunisation including current CPR, first aid and anaphylaxis training. Refer to PSA Immunisation Update for Pharmacists, published annually
- accredited training courses if becoming an immuniser
- sufficient continuing professional development for pharmacist immunisers, required annually to maintain knowledge and competence. Some immunisers may choose to undertake practical refresher training if they have not immunised for a period of time or not undertaken a particular injection technique.

Work health and safety

Pharmacists must ensure a work health and safety protocol is available, with specific reference to government protocols to minimise the risk of needle stick injury, exposure to blood and bodily fluids, and the transmission of infectious diseases. Any person involved in the provision of immunisation services must be aware of protocols for the handling and disposal of sharps (e.g. needles and syringes) and medical waste, infection control measures (e.g. hand hygiene) and procedures for risk management (e.g. needle stick injury). Pharmacy protocols and procedures should be consistent with the *Australian guidelines for the prevention and control of infection in healthcare*, developed by the NHMRC.³⁰



Providing immunisation services

Consumer clinical needs assessment

The immuniser is responsible for a consumer's clinical needs assessment and pre-vaccination screening. Processes should exist to allow the immuniser to establish consumer immunisation status (refer to the AIR or the consumer's My Health Record) and confirm their immunisation needs. When available, the consumer's record, Aboriginal and Torres Strait Islander status and relevant medical history should be considered as part of the clinical needs assessment. The accuracy of all information must be confirmed verbally with the consumer, or where appropriate, the consumer's carer.

The immuniser must conduct appropriate pre-vaccination screening with each consumer prior to vaccination to identify contraindications or precautions to vaccines to be administered. Immunisers can use the Pre-vaccination screening checklist (see **Appendix 7**) to assist with pre-vaccination screening.

Refer to 'Preparing for vaccination' in the *Australian Immunisation Handbook*¹ for further information about pre-vaccination screening, including valid and false contraindications to immunisation.

Consumer consent

Valid consumer consent must be obtained and documented by the immuniser prior to providing immunisation services. Consent must be obtained before each vaccination, after establishing there are no contraindications to the vaccine or any vaccine component(s) intended to be administered.

As part of the consent process, the consumer or guardian/carer should be:

- provided with appropriate and reliable information (preferably written) about immunisation procedures including the risks and benefits associated with the vaccine(s) to be administered
- informed of any fees associated with the service and consent to such costs
- asked if they have a regular primary healthcare provider, and if in the interest of ensuring continuity of care they consent to providing that provider with a copy of their vaccination statement.

When vaccinating a minor (child/adolescent) in general, a parent or legal guardian has the authority to consent for the vaccination. Some Australian states and territories have legislation specific to the age of consent to medical treatment (vaccination falls under this category) for children and adolescents. Immunisers should be aware of jurisdiction specific legislation and are advised to check with their relevant state or territory health authority if needed. Where appropriate, Gillick competence (i.e. functional ability of minors to make a decision) should be taken into consideration by pharmacist immunisers.

Pharmacists should ensure appropriate processes exist for the immuniser to obtain and document written consumer consent.

Refer to **Appendix 7**: Pre-vaccination screening checklist to obtain and record consumer consent prior to the provision of immunisation services.

For further information regarding valid consent, including how to obtain consent in special populations (i.e. children or people with impaired decision-making ability). Refer to the section 'Preparing for vaccination: Valid consent' in the *Australian Immunisation Handbook*.¹



Confidentiality and consumer privacy

Pharmacists must ensure that any person involved in providing immunisation services understands privacy legislation. Pharmacists must respect and safeguard the consumer's privacy and confidentiality at all times, particularly in relation to information obtained as a result of providing these services.³¹

All consumer information should be stored in a manner that ensures privacy and confidentiality. Access to, and disclosure of, consumer information must comply with the relevant privacy legislation.³¹ Information can only be used for the purpose for which it was collected, unless otherwise authorised by the consumer. In keeping with other professional service programs, all information relating to immunisation services must be retained for a minimum of seven years or in accordance with State and Territory requirements.³² Records can be kept in hard copy or electronically, provided the software meets standards for privacy and security.

Refer to the Australian Privacy Principles³¹ and PSA Professional Practice Standards Standard 1.3: Fundamental Pharmacy Practice¹⁸ for further information about privacy obligations for pharmacists.

Administration of vaccines

Vaccines must be administered in accordance with standards outlined in the section 'Vaccination procedures: Administration of vaccines' in the *Australian Immunisation Handbook*.¹

Pharmacists must ensure that protocols and procedures for the service conform to the standards outlined in the Handbook.

Consumer aftercare

Pharmacy staff should support the immuniser by encouraging consumers to remain in the vicinity following vaccination for at least 15 minutes, during which time the consumer should be closely monitored for the presentation of any adverse reactions.

Consumers should be offered seating near the immunisation service area so assistance and treatment can be provided if necessary.

Pharmacists must ensure there are procedures in place to refer consumers experiencing AEFI for appropriate medical advice and care. Consumers may return to the pharmacy at a later time for advice and treatment to manage delayed adverse events or to confirm information provided by the immuniser. Pharmacists should refer consumers who present with adverse events based on the severity of the adverse event. Pharmacists must also report the adverse event e.g. TGA reporting process, state public health units).

Refer to **Appendix 8**: Post-vaccination procedures checklist, including immediate aftercare procedures.

Consumer vaccination documentation

Appropriate documentation of all vaccinations is a core requirement of any immunisation service.

The following information should be included in the consumer's vaccination records:

- consumer's full name and date of birth
- details of the vaccine given including the dose number, brand name, batch number
- date and time of vaccination
- site of administration
- full name of the immuniser administering the vaccine
- due date of the next vaccination (if appropriate)
- consumer's contact details and the contact details of their primary healthcare provider.

Refer to **Appendix 9**: Consumer vaccination statement template.

Pharmacists should store a copy of the consumer vaccination record and any relevant consumer consent and screening documents for seven years. All documents should be stored in a format and location to allow timely access and easy retrieval. Pharmacists must ensure consumer information is stored in a manner that protects consumer confidentiality, and that access and disclosure processes comply with the relevant privacy legislation. Pharmacists should report the administration of all vaccines to the Australian Immunisation Register, and if the patient consents, to their My Health Record.

Refer to **Appendix 8**: Post-vaccination procedures checklist including documentation procedures.

Identification and management of adverse events following immunisation

Consumers should receive appropriate information regarding potential AEFI from the immuniser as part of the consent process and following vaccination. Pharmacists must ensure that appropriate processes for the provision of information to consumers are in place.

Refer to **Appendix 3**: Consumer information resources: vaccinations and immunity, to support and reinforce information provided by the immuniser.

When vaccination is taking place, pharmacists should know which consumers have been vaccinated and be familiar with common possible AEFIs. Pharmacists may consider processes to discreetly identify consumers who have been vaccinated to enable the provision of appropriate assistance or treatment if required.

Refer to the section 'After vaccination: adverse events following immunisation' in the *Australian Immunisation Handbook*¹, and the product information for specific vaccine products for further information regarding AEFI.

Refer to **Appendix 8**: Post-vaccination procedures checklist, including AEFI procedures.



Collaboration with other healthcare providers

Pharmacists should collaborate with other healthcare providers in the local community when providing immunisation services, particularly local general practitioners, other pharmacists, carers, and community nurses. All communications with other healthcare providers should be documented in the consumer's history. Pharmacists must gain consumer consent before disclosing immunisation information to other healthcare providers (see **Appendix 7**).

Refer to the PSA's Code of Ethics for Pharmacists (the 'Code') Competency Principle 2.³³ Review the relevant Professional Practice Standards Standard 1: Fundamental Pharmacy Practice and Standard 9: Collaborative Care,²⁵ and the relevant National Competency Standards Domain 2: Communication and collaboration.³⁴

Providing immunisation services outside the pharmacy setting

Where jurisdictional regulations allow, pharmacist immunisers may deliver a vaccination service outside a pharmacy setting. In all circumstances, the service must be conducted in accordance with relevant state and territory legislation (see **Appendix 1**). Premises, staffing and equipment requirements are consistent with those expected in an in-pharmacy vaccination service. Specifically, the vaccine administration area must allow for patient privacy, be of sufficient size to accommodate the patient (sitting in a chair or lying down), an accompanying person, and the authorised immuniser. There should be a complete and in-date anaphylaxis response kit, a displayed emergency response protocol that is specific to the practice setting e.g. pharmacists as solo practitioners in mobile/outreach vaccination clinics, equipment for the safe disposal of sharps and clinical waste, a temperature monitored refrigerator, cooler, or Esky (based on practice setting) to store vaccines and ensure cold chain, hand washing facilities, and access to the required resources, *Australian Immunisation Handbook* and *National Vaccine Storage Guidelines: Strive for 5*.²⁸



Immunisation reporting and management

Reporting to immunisation registers

Australian Immunisation Register (AIR)

The Australian Immunisation Register (AIR) is a national whole-of-life register that records vaccinations for Australians. The AIR provides consolidated individual immunisation histories and issues reminders for overdue immunisation with the aim of improving vaccination uptake. Information recorded to the AIR contributes to national, state and local vaccination uptake reports. The information is then used to inform immunisation policies and priority areas. All individuals registered with Medicare have an AIR record.³⁵

In accordance with the Australian Immunisation Act 2015,³⁶ the AIR only accepts immunisation information from recognised immunisation providers. Information cannot be uploaded to the AIR directly from patients or caregivers. Immunisation providers, including pharmacists, should report all vaccines administered to patients to the AIR.

Pharmacists offering a vaccination service must register as a vaccination provider with the AIR using the AIR application form.³⁷ The form will be sent to the state or territory Department of Health. Once approved, the pharmacist will be issued with a unique AIR provider number. This enables pharmacists to view individual immunisation histories and report all vaccination encounters to the AIR.

Vaccinations can be reported directly using the AIR website³⁵ or via practice software that automatically reports vaccinations to the AIR. Note: Although software providers have the functionality to report vaccinations directly to AIR, the pharmacist will still be required to review a patient's history on AIR. Education for vaccine providers on how to use the AIR is also available.³⁸

Reporting adverse events following immunisation

Pharmacists should collaborate with the immuniser to ensure any AEFI are reported to the relevant state or territory Department of Health and any other body as mandated by jurisdictional requirements, to enable the identification of possible local trends in adverse events. State and territory health authorities report all AEFI to the Therapeutic Goods Administration (TGA). Any AEFI may be reported:

- directly to the TGA via the online Australian Adverse Reaction Reporting System (available at: <https://aems.tga.gov.au>)³⁹
- to State and Territory Departments of Health or local public health units⁴¹
- via email, fax or mail using the National Adverse Events Following Immunisation (AEFI) reporting form^{40,41} (available at: www.tga.gov.au/form/national-adverse-events-following-immunisation-ae-fi-reporting-form).

Refer to the TGA for full details on how to report an adverse event.



Monitoring and auditing of immunisation services

Pharmacists should regularly monitor practice against service policies and procedures to identify areas or issues for improvement or change. The monitoring of services may include:

- review of risk management documentation including 'near-miss' reports
- revision of policies
- evaluation of compliance with service protocols
- State and Territory standards.

Immunisation services provided in pharmacies and accredited under QCPP are externally audited as part of the QCPP audit cycle.² Compliance of immunisation services and vaccine management protocols must be demonstrated. Refer to the QCPP Vaccination services in the pharmacy checklist T3M.



Appendices

Appendix 1: State and territory drugs and poisons legislation

STATE	RELEVANT LEGISLATION
ACT	Medicines, Poisons and Therapeutic Goods Act 2008: www.legislation.act.gov.au Medicines, Poisons and Therapeutic Goods Regulation 2008: www.legislation.act.gov.au Medicines, Poisons and Therapeutic Goods (Vaccinations by Pharmacists) Direction 2020 www.legislation.act.gov.au/View/di/2020-88/current/PDF/2020-88.PDF
NSW	Poisons and Therapeutic Goods Act 1966: www.legislation.nsw.gov.au Poisons and Therapeutic Goods Regulation 2008: www.legislation.nsw.gov.au NSW Pharmacist Vaccination Standards: www.health.nsw.gov.au/immunisation/Documents/pharmacist-new-standard.pdf
NT	Medicines, Poisons and Therapeutic Goods Act 2012 https://legislation.nt.gov.au/ Medicines, Poisons and Therapeutic Goods Regulations 2014: https://legislation.nt.gov.au/ Protocol Administration of Vaccine by Pharmacists at Pharmacies in the Northern Territory May 2020: https://health.nt.gov.au Protocol Administration of Vaccines by Pharmacists at places other than pharmacies in the Northern Territory May 2020: https://health.nt.gov.au
QLD	Health Act 1937: www.legislation.qld.gov.au Health (Drugs and Poisons) Regulation 1996: www.legislation.qld.gov.au Queensland Pharmacist Vaccination Standard: www.health.qld.gov.au/__data/assets/pdf_file/0016/444130/standard-pharmacy-vaccination.pdf
SA	Controlled Substances Act 1984: www.legislation.sa.gov.au Controlled Substances (Poisons) Regulations 2011: www.legislation.sa.gov.au Vaccination Administration Code: www.sahealth.sa.gov.au/wps/wcm/connect/
TAS	Poisons Act 1971: www.thelaw.tas.gov.au Poisons Regulations 2018: www.thelaw.tas.gov.au Tasmania Vaccination Program Guidelines www.dhhs.tas.gov.au/__data/assets/pdf_file/0003/340860/Tasmanian_Vaccination_Program_Guidelines_-_September_2019_.pdf
VIC	Drugs, Poisons and Controlled Substances Act 1981: www.austlii.edu.au Drugs, Poisons and Controlled Substances Regulations 2017: www.austlii.edu.au Victorian Pharmacist-Administered Vaccination Program Guidelines: www2.health.vic.gov.au/public-health/immunisation/immunisers-in-victoria/pharmacist-immunisers/guidelines
WA	Medicines and Poisons Act 2014: www.austlii.edu.au Medicines and Poisons Regulations 2016: www.austlii.edu.au SASA Administration of Vaccines by Pharmacists: www2.health.wa.gov.au/Articles/S_T/Structured-Administration-and-Supply-Arrangements



Appendix 2: National Immunisation Program schedule

The National Immunisation Program (NIP) schedule is updated regularly. To learn more about immunisation and the NIP schedule, go to: www.health.gov.au/health-topics/immunisation or contact their information line on 1800 671 811.

The most recent NIP schedule can be accessed at: <https://www.health.gov.au/resources/publications/national-immunisation-program-schedule-portrait>



Appendix 3: Consumer information resources

For consumer information resources on vaccination and immunity for vaccine preventable diseases, refer to Australian Government www.health.gov.au/health-topics/immunisation and the current online version of the Australian Immunisation Handbook at: <https://immunisationhandbook.health.gov.au>.

CONSUMER INFORMATION RESOURCES ON VACCINATION AND IMMUNITY

Immunisation information for parents

- National Centre for Immunisation Research and Surveillance. Sharing knowledge about immunisation. www.talkingaboutimmunisation.org.au
- Australian Academy of Science. The science of immunisation: questions and answers. www.science.org.au/immunisation
- Australian Government Department of Health. Immunisation for children. www.health.gov.au/health-topics/immunisation/immunisation-throughout-life/immunisation-for-children
- Australian Government Department of Health. National Immunisation Program Schedule. www.health.gov.au/health-topics/immunisation/immunisation-throughout-life/national-immunisation-program-schedule
- National Centre for Immunisation Research and Surveillance fact sheets. www.ncirs.edu.au/provider-resources/ncirs-fact-sheets/

Immunisation for adults

- Australian Academy of Science. The science of immunisation: questions and answers. www.science.org.au/immunisation
- National Centre for Immunisation Research and Surveillance fact sheets. www.ncirs.edu.au/provider-resources/ncirs-fact-sheets/

Immunisation for Aboriginal and Torres Strait Islander people

- Australian Government Department of Health. Immunisation for Aboriginal and Torres Strait Islander people. www.health.gov.au/health-topics/immunisation/immunisation-throughout-life/immunisation-for-aboriginal-and-torres-strait-islander-people

Appendix 4: Contact details for Commonwealth and state and territory health authorities and communicable disease control

Note: Refer to the current *Australian Immunisation Handbook*.

AUSTRALIAN GOVERNMENT HEALTH AUTHORITIES	
Australian Government Department of Health	1800 020 103
Australian Immunisation Register (AIR)	1800 653 809 Website: www.humanservices.gov.au

STATE AND TERRITORY GOVERNMENT HEALTH AUTHORITIES	
ACT	Immunisation information line: (02) 5124 9800 www.health.act.gov.au/services/immunisation
NSW	Contact via the state-wide Public Health Unit access line: 1300 066 055 www.health.nsw.gov.au/immunisation/Pages/default.aspx
NT	Immunisation information line: 08 89 228 315 https://nt.gov.au/wellbeing/healthy-living/immunisation
QLD	Phone: 13 432 584 www.qld.gov.au/health/conditions/immunisation
SA	Phone: 1300 232 272 www.sahealth.sa.gov.au
TAS	Public health hotline: 1800 671 738 www.dhhs.tas.gov.au/publichealth/communicable_diseases_prevention_unit/immunisation
VIC	Phone: 1300 882 008 www2.health.vic.gov.au/public-health/immunisation
WA	(08) 9388 4368 or (08) 9328 0553 (after hours Infectious Diseases Emergency) www.healthywa.wa.gov.au/immunisation

COMMUNICABLE DISEASE CONTROL	
ACT	Australian Capital Territory Communicable Disease Control 24-hour line: (02) 6205 2155
NSW	NSW Public Health Unit Phone: 1300 066 055
NT	Northern Territory Centre for Disease Control Phone: 08 8922 8044 (8.30am to 5.00pm) (After hours Royal Darwin Hospital 08 8922 8888 for CDC on-call doctor)
QLD	Queensland Health Communicable Diseases Branch Phone: (07) 3328 9728
SA	South Australia Communicable Disease Control Branch 24-hour line: 1300 232 272
TAS	Communicable Diseases Prevention 24-hour Public Health Hotline: 1800 671 738
VIC	Victoria Communicable Disease Prevention and Control Unit 24-hour line: 1300 651 160
WA	Western Australia Communicable Disease Control Directorate Phone: (08) 9388 4852 After hours line: (08) 9328 0553 (infectious diseases emergency)



Appendix 5: Immunisation service checklist for pharmacist immunisation services

Note: Refer to the current *Australian Immunisation Handbook*

CHECKLIST FOR IMMUNISATION SERVICE DELIVERY	COMPLETED (Y/N)
<p>Ensure the authorised immuniser is either a medical practitioner, or an appropriately qualified and competent registered pharmacist or registered nurse. An appropriately qualified and competent registered pharmacist or registered nurse:</p> <ul style="list-style-type: none"> • has completed an approved course of study and maintained recency of practice to immunise • holds a current statement of proficiency in cardiopulmonary resuscitation (CPR) and first aid • is permitted under state or territory legislation to administer vaccines • is authorised by the state or territory Department of Health (however named) 	
<p>Ensure specific state or territory legislative requirements have been met</p> <p>Contact the health authorities in your relevant state or territory in regard to the legislative requirements</p>	
<p>Ensure insurance policies are appropriate for the delivery of immunisation services</p>	
<p>Sign a service agreement between the pharmacist immuniser and the organisation contracting the immunisation services outlining the roles and responsibilities of each party, if required</p>	
<p>Ensure the immuniser has registered for the AIR and uses the AIR to review the consumer's vaccination history and record the vaccination</p>	
<p>Develop a policy and procedure manual for the service specific to the practice setting and based on state and territory requirements</p>	
<p>Establish a private consultation area that meets the following requirements:</p> <ul style="list-style-type: none"> • area is sufficient to accommodate the consumer (both sitting and lying), their carer if appropriate, and the immuniser, as well as all equipment required to store and administer vaccines • provides appropriate space and furnishings to allow consumers to sit or lie and receive treatment as necessary • allows for space, surfaces and equipment to respond to any adverse events and medical emergencies as necessary • provides equipment for the appropriate disposal of sharps and medical waste • makes available appropriate hand hygiene facilities 	
<p>Ensure adequate seating is available adjacent to the immunisation service area for all consumers and their carers who will be advised to remain in the general area for at least 15 minutes following vaccination</p>	
<p>Ensure appropriate equipment for storing and administering vaccines is available (e.g. a reliable and stable refrigerator or cooler with adequate capacity to store vaccines appropriately)</p>	
<p>Ensure an anaphylaxis response kit is available and in date, whether provided by the immuniser or the organisation contracting the immunisation services</p> <p>An anaphylaxis response kit should be on hand at all times and should contain:</p> <ul style="list-style-type: none"> • adrenaline 1:1000 (minimum of 3 ampoules – check expiry dates) • at least three drawing-up needles, minimum of three 1 mL syringes and 25 mm needles (22 or 23 gauge) for intramuscular injection • cotton wool swabs • pen and paper to record time of administration of adrenaline • laminated copy of <i>adrenaline doses</i> • laminated copy of <i>Recognition and treatment of anaphylaxis</i> 	
<p>Use immunisation service identifiers (i.e. consumer stickers) for quick identification of consumers who have received vaccinations should they require further assistance</p>	
<p>Display an emergency response protocol</p>	
<p>Display <i>adverse events following immunisation information sheet</i></p>	



CHECKLIST FOR IMMUNISATION SERVICE DELIVERY (continued)	COMPLETED (Y/N)
<p>Train all people involved in the delivery of the immunisation service about their roles and responsibilities within the immunisation service so they are familiar with relevant policies and procedures including:</p> <ul style="list-style-type: none">• their role in emergency response procedures• the role and responsibilities of the immuniser• immunisation service delivery including appointment arrangements, referral of consumer queries, and handling of consumer complaints• policies and procedures for collecting consumer healthcare information, including Aboriginal and Torres Strait Islander status• privacy legislation• cultural safety	
<p>Train all pharmacists about the specific aspects of the immunisation service including:</p> <ul style="list-style-type: none">• health promotion and immunisation services• principles of vaccination and immunity• National Immunisation Program Schedule• management of adverse events following immunisation, including current CPR certification	
<p>Ensure systems are developed to document and store consumer immunisation records (with consumer consent)</p>	
<p>Maintain access to, and currency of, relevant health information for consumers</p>	
<p>Ensure a work health and safety protocol with specific reference to minimising the risk of needle stick injury, exposure to blood and bodily fluids and the transmission of infectious diseases is developed and practised</p> <p>Pharmacist immunisation service protocols and procedures should be consistent with the <i>Australian guidelines for the prevention and control of infection in healthcare</i></p>	
<p>Promote an immunisation service to consumers</p>	
<p>Develop a consumer immunisation booking and reminder service</p>	
<p>Ensure the immuniser provides the consumer with immunisation information, including information about the risks of vaccination and of not being vaccinated</p>	
<p>Ensure consumer vaccination consent forms are completed by the immuniser prior to vaccination, and consumer consent is documented</p>	
<p>Ensure pre-immunisation screening is conducted by the immuniser to identify contraindications or precautions to vaccines administered</p> <p>Confirm that pre-immunisation screening is completed and documented (See Appendix 7)</p>	



Appendix 6: Anaphylaxis response protocol

Note: Refer to the current *Australian Immunisation Handbook*.

ANAPHYLAXIS RESPONSE PROTOCOL

SIGNS OF ANAPHYLAXIS

Anaphylaxis causes respiratory and/or cardiovascular signs or symptoms *AND* involves other organ systems, such as the skin or gastrointestinal tract. Signs include:

- signs of airway obstruction, such as cough, wheeze, hoarseness, stridor or signs of respiratory distress
- upper airway swelling (lip, tongue, throat, uvula or larynx)
- tachycardia, weak/absent carotid pulse
- hypotension that is sustained and with no improvement without specific treatment (Note: in infants and young children, limpness and pallor are signs of hypotension)
- loss of consciousness with no improvement once supine or in head-down position
- skin signs, such as pruritus (itchiness), generalised erythema (redness), urticaria (weals) or angioedema (localised or general swelling of the deeper layers of the skin or subcutaneous tissue)
- abdominal cramps, diarrhoea, nausea and/or vomiting
- sense of severe anxiety and distress.

DIFFERENTIATING BETWEEN ANAPHYLAXIS AND A VASOVAGAL EPISODE (adapted from the *Australian Immunisation Handbook*)

	ANAPHYLAXIS	VASOVAGAL EPISODE
ONSET	Usually within 15 minutes but can occur within hours of vaccine administration	Immediate usually within minutes of, or during, vaccine administration
RESPIRATORY	<ul style="list-style-type: none"> • Cough, wheeze, hoarseness, stridor, or signs of respiratory distress (e.g. tachypnoea, cyanosis, rib recession) • Upper airway swelling (lip, tongue, throat, uvula or larynx) 	<ul style="list-style-type: none"> • Normal respiration; may be shallow, but not laboured
CARDIOVASCULAR	<ul style="list-style-type: none"> • Tachycardia, weak/absent carotid pulse • Hypotension—sustained and no improvement without specific treatment (Note: in infants and young children, limpness and pallor are signs of hypotension) • Loss of consciousness—no improvement once supine or in head-down position 	<ul style="list-style-type: none"> • Bradycardia, weak/absent peripheral pulse, strong carotid pulse • Hypotension—usually transient and corrects in supine position • Loss of consciousness—improves once supine or in head-down position
SKIN	<ul style="list-style-type: none"> • Pruritus, generalised skin erythema, urticaria (weals) or angioedema (localised or general swelling of the deeper layers of the skin or subcutaneous tissues) 	<ul style="list-style-type: none"> • Generalised pallor, cool clammy skin
GASTRO-INTESTINAL	<ul style="list-style-type: none"> • Abdominal cramps, diarrhoea, nausea and/or vomiting 	<ul style="list-style-type: none"> • Nausea/vomiting
NEUROLOGICAL	<ul style="list-style-type: none"> • Sense of severe anxiety and distress 	<ul style="list-style-type: none"> • Feels faint, light-headed

MANAGEMENT OF ANAPHYLAXIS

- If patient is unconscious, place them on their left side and position to keep the airway clear.
- If patient is conscious, place them supine in head-down and feet-up position (unless this results in breathing difficulties).
- If any respiratory and/or cardiovascular symptoms or signs of anaphylaxis, give adrenaline by IM injection into the anterolateral thigh (see *Adrenaline use below*). Note: Adrenaline is not required for generalised non-anaphylactic reaction (such as skin rash or angioedema). If in doubt, IM adrenaline should be given. No serious or permanent harm is likely to occur from mistakenly administering adrenaline to an individual who is not experiencing anaphylaxis.
- Call for assistance. Never leave the patient alone.
- If oxygen is available, administer by facemask at a high flow rate.
- If there is no improvement in the patient's condition within 5 minutes, repeat doses of adrenaline every 5 minutes until improvement.
- Check breathing; if absent, commence basic life support or appropriate cardiopulmonary resuscitation (CPR) (See Australian Resuscitation Council guideline).
- In all cases, transfer the person to hospital for further observation and treatment.
- Complete full documentation of the event, including the time and dose(s) of adrenaline given.

ADRENALINE USE

- The recommended dose of 1:1000 adrenaline is 0.01 mL/kg body weight (equivalent to 0.01 mg/kg up to a maximum of 0.5 mL) given by deep intramuscular injection into the thigh (not the deltoid region).
- Adrenaline 1:1000 must not be administered intravenously.
- The dose of 1:1000 (one in one thousand) adrenaline may be repeated every 5 minutes, as necessary, until there is clinical improvement.

DOSES OF 1:1000 (ONE TO ONE THOUSAND) ADRENALINE

AGE	DOSES OF ADRENALINE 1:1000 (one to one thousand)
Less than 1 year (approx. 5–10 kg)	0.05–0.1 mL
1–2 years (approx. 10 kg)	0.1 mL
2–3 years (approx. 15 kg)	0.15 mL
4–6 years (approx. 20 kg)	0.2 mL
7–10 years (approx. 30 kg)	0.3 mL
10–12 years (approx. 40 kg)	0.4 mL
> 12 years and adult (over 50 kg)	0.5 mL

The person who will administer adrenaline is the immuniser. If it is not possible, will administer adrenaline.

The person who will call the ambulance is

The person who will meet and direct the paramedics to the consumer is

They should meet the paramedics at

The person who will provide clinical handover to the paramedics is the immuniser. If this is not possible, will provide the clinical handover.

The person who will record the details of treatment provided, including time and dose of adrenaline administered, is

The person who will report the adverse event following immunisation to the relevant State or Territory health authorities is the immuniser and/or

Appendix 7: Pre-vaccination screening and valid consent checklist

Note: Refer to the current *Australian Immunisation Handbook*

PRE-VACCINATION SCREENING AND CONSENT TOOL FOR PHARMACIST IMMUNISATION SERVICES			
Date:			
CONSUMER DETAILS			
Name of person to be vaccinated:			
Date of birth:	Age today:	Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Other _____	
Identifies as Aboriginal and/or Torres Strait Islander: <input type="checkbox"/> No <input type="checkbox"/> Yes, Aboriginal <input type="checkbox"/> Yes, Torres Strait Islander <input type="checkbox"/> Yes, both Aboriginal and Torres Strait Islander			
Address:		Phone:	
Allergies:		Medicare No:	
Name of person completing this form (if different from above):			
Relationship to person to be vaccinated (if completed by someone else):			
NOMINATED PRIMARY HEALTH CARE PROVIDER (if known)			
Name:			
Address:		Phone:	
Email:			
VACCINATION(S)			
I or the person to be vaccinated (if applicable), expects to be vaccinated with the following vaccine(s) today (list all): _____ _____			
Please indicate if you or the person to be vaccinated (if applicable):		Yes	No
Is unwell today (e.g. fever) If yes, please specify:		<input type="checkbox"/>	<input type="checkbox"/>
Has a disease that lowers immunity (e.g. leukaemia, cancer, HIV/AIDS) or is having treatment that lowers immunity (e.g. oral steroid medicines such as cortisone and prednisone, DMARDs [disease-modifying anti-rheumatic drugs], radiotherapy, chemotherapy) If yes, please specify:		<input type="checkbox"/>	<input type="checkbox"/>
Has had anaphylaxis or any severe reaction following any vaccine If yes, please specify:		<input type="checkbox"/>	<input type="checkbox"/>
Has ever fainted after having an injection		<input type="checkbox"/>	<input type="checkbox"/>
Has a severe allergy to anything If yes, please specify:		<input type="checkbox"/>	<input type="checkbox"/>
Has had a vaccine in the past month If yes, please specify:		<input type="checkbox"/>	<input type="checkbox"/>
Has had an injection of immunoglobulin, or received any blood products or a whole-blood transfusion within the past year		<input type="checkbox"/>	<input type="checkbox"/>
Is pregnant		<input type="checkbox"/>	<input type="checkbox"/>
Is planning a pregnancy or anticipating parenthood		<input type="checkbox"/>	<input type="checkbox"/>

Please indicate if you or the person to be vaccinated (if applicable):	Yes	No
Is a parent, grandparent or carer of a newborn	<input type="checkbox"/>	<input type="checkbox"/>
Has a history of Guillain-Barré syndrome (a rare disorder of the nervous system)	<input type="checkbox"/>	<input type="checkbox"/>
Has a chronic illness (e.g. diabetes, heart or lung disease) If yes, please specify:	<input type="checkbox"/>	<input type="checkbox"/>
Has a severe illness If yes, please specify:	<input type="checkbox"/>	<input type="checkbox"/>
Has a bleeding disorder or is taking medications that prevent blood clots	<input type="checkbox"/>	<input type="checkbox"/>
Does not have a functioning spleen	<input type="checkbox"/>	<input type="checkbox"/>
Lives with someone who has a disease that lowers the immunity (e.g. leukaemia, cancer, HIV/AIDS) or takes treatment that lowers immunity (e.g. oral steroids, DMARDs [disease-modifying anti-rheumatic drugs], radiotherapy, chemotherapy)	<input type="checkbox"/>	<input type="checkbox"/>
Is planning overseas travel	<input type="checkbox"/>	<input type="checkbox"/>
Has occupational or lifestyle factor(s) where vaccination may be needed. If yes, please specify:	<input type="checkbox"/>	<input type="checkbox"/>

CONSENT/AUTHORITY

I, _____ (Print full name) declare that:

- I have been provided with, read, and understood the information given about immunisation including the risks and benefits, and I have been given the opportunity to ask questions.
- The information completed by me on this form is true and correct to the best of my knowledge.
- I am legally authorised to provide consent on behalf of the person being vaccinated.
- I request to have each vaccine or for the person to be vaccinated to have each vaccine (if applicable) and understand that it is completely voluntary.
- I consent to the immuniser collecting my personal information and that of the person to be vaccinated (if applicable) for the purpose of creating and maintaining a vaccination statement and providing a copy of the vaccination statement, including any such personal information contained in the statement, to the Australian Immunisation Register (AIR) and the nominated primary health care provider.
- I am aware that the immuniser will collect, hold and use my personal information including adding it to My Health Record and that of the person to be vaccinated (if applicable) in accordance with relevant privacy laws and its privacy policy, and that I can contact the immuniser at any time for a copy of its privacy policy. I may also contact the immuniser with any concerns I may have about the use of or access to my personal information that it holds.
- I agree to remain within the vicinity of the vaccination service for 15 minutes or for the person to be vaccinated to remain within the vicinity of the vaccination service for 15 minutes (if applicable).
- I have been informed of, and agree to pay, the fees or charges associated with this service.
- I consent to emergency care if required and give permission for the immuniser or pharmacy staff to access medical care on my behalf or on behalf of the person to be vaccinated (if applicable). I understand that I am responsible for any costs associated with any emergency care.

Signature of person consenting: _____ Date: _____

Name of person consenting: _____

Relationship to person to be vaccinated (if applicable): Parent Legal guardian

Authorised immuniser:

Physical location (e.g. location of pharmacy or vaccination premises where vaccine is administered):

Pharmacy stamp (if applicable):



Appendix 8: Post-vaccination procedures checklist

Note: Refer to the current of the *Australian Immunisation Handbook*.

POST-VACCINATION PROCEDURES CHECKLIST	COMPLETED (Y/N)
FOR PHARMACISTS	
Be familiar with the immuniser's post-vaccination care procedures including: <ul style="list-style-type: none"> disposal of used needles, syringes and vaccine vials or ampoules in accordance with standard infection control guidelines provision of comfort and the use of distraction techniques to alleviate any distress and pain felt by the consumer (Note: paracetamol is not used routinely at the time of vaccination but may be recommended as required for fever or pain) provision of appropriate consumer information regarding the vaccination and possible adverse events 	
FOR IMMUNISER	
Provide immunisation information to consumers.	
Inform the vaccinated person and/or their parent or carer about the possible common adverse events following immunisation and how to recognise and manage them. Provide appropriate consumer information on adverse events following immunisation and give advice on when to seek medical attention. See <i>Australian Immunisation Handbook: Adverse events following immunisation</i> .	
Advise the vaccinated person and/or their parent or carer to remain in a nearby area for a minimum of 15 minutes after the vaccination. The area should be close enough to the immuniser so the vaccinated person can be observed and medical treatment can be readily obtained if needed.	
Remind the vaccinated person and/or their parent or carer to promptly report any significant adverse event following immunisation to the authorised immuniser or their primary healthcare provider. An adverse event report can be made to the Therapeutic Goods Administration (TGA), and to the relevant state or territory Department of Health, or any other body as mandated by jurisdictional requirements. TGA Report an adverse event to a vaccine www.tga.gov.au/reporting-problems	
Provide the vaccinated person with a statement of vaccinations received following each appointment (see Appendix 9).	
With the consumer's consent, forward a copy of the consumer's vaccination statement to their nominated healthcare provider.	
Report all National Immunisation Program (NIP) and private vaccinations given to consumers to the Australian Immunisation Register (AIR).	
Store a copy of the vaccinated person vaccination record and any relevant consumer consent and screening documents. If available, note the vaccination details on the consumer's electronic healthcare record.	

Appendix 9: Consumer vaccination statement template

Note: Refer to the current *Australian Immunisation Handbook*

CONSUMER VACCINATION STATEMENT				
CONSUMER DETAILS				
Name		Date of birth		
Phone		Email		
Address		Medicare no.		
AUTHORISED IMMUNISER				
Name		Contact details		
Signed		Date		
VACCINATION(S)				
Vaccine				
Brand name		Dose		
Batch number		Site of administration		
		Right arm	Left arm	Right leg
Date of vaccination	Time	Date of next vaccination (if required)		
Vaccine				
Brand name		Dose		
Batch number		Site of administration		
		Right arm	Left arm	Right leg
Date of vaccination	Time	Date of next vaccination (if required)		
Vaccine				
Brand name		Dose		
Batch number		Site of administration		
		Right arm	Left arm	Right leg
Date of vaccination	Time	Date of next vaccination (if required)		
Vaccine				
Brand name		Dose		
Batch number		Site of administration		
		Right arm	Left arm	Right leg
Date of vaccination	Time	Date of next vaccination (if required)		
PHARMACIST IMMUNISATION SERVICE DETAILS				
Name				
Address				
Phone		Email		

References

1. Australian Government. Department of Health. Australian immunisation handbook. Canberra. Australian Government Department of Health; 2020. At: <https://immunisationhandbook.health.gov.au>
2. Pharmacy Guild of Australia. Quality Care Pharmacy Program: QCPP Requirements. Canberra: Pharmacy Guild of Australia; 2017. At: www.qcpp.com
3. Andre FE, Booy R, Bock HL, et al. Vaccination greatly reduces disease, disability, death and inequity worldwide. *Bull World Health Organ.* 2008;86:140–6.
4. World Health Organisation. 10 facts on immunization. Geneva. World Health Organisation; 2018. At: www.who.int/features/factfiles/immunization/en
5. Australian Government Department of Health. Community (herd) immunity. Canberra. Australian Government Department of Health; 2017. At: <https://campaigns.health.gov.au/immunisationfacts/community-herd-immunity>
6. Australian Government Department of Health. National immunisation program. Canberra. Australian Government Department of Health; 2019. At: www.health.gov.au/initiatives-and-programs/national-immunisation-program
7. Australian Government Department of Health. National immunisation program schedule (NIP). Canberra. Australian Government Department of Health; 2019. At: www.health.gov.au/health-topics/immunisation/immunisation-throughout-life/national-immunisation-program-schedule
8. Elliman D, Moreton J. The district immunisation coordinator. *Archives of disease in childhood.* 2000;82(4):280–2.
9. Plotkin SA. Vaccines: past, present and future. *Nature medicine.* 2005;11(4s):S5.
10. Australian Government Department of Health. National immunisation strategy for Australia 2019–2024. 2018. Canberra. Australian Government Department of Health. At: www.health.gov.au/resources/publications/national-immunisation-strategy-for-australia-2019-to-2024
11. Australian Government Department of Health. Australia's national medicines policy. Canberra. Australian Government Department of Health. 2000. At: www1.health.gov.au/internet/main/publishing.nsf/Content/National+Medicines+Policy-1
12. Immunisation Provider Competency Working Group. The national immunisation education framework for health professionals (the national framework) Canberra, 2017. At: www.health.gov.au/resources/publications/national-immunisation-education-framework-for-health-professionals
13. Australian Pharmacy Council. Standards for the accreditation of programs to support pharmacist administration of vaccines. Canberra. Australian Pharmacy Council; 2019.
14. Australasian Society of Clinical Immunology and Allergy. ASCIA Anaphylaxis e-training for pharmacists version 5.0. Melbourne. Australasian Society of Clinical Immunology and Allergy; 2019. At: <https://etrainingpharm.ascia.org.au/mod/page/view.php?id=59>
15. Pharmaceutical Society of Australia. Immunisation service: service agreement. Canberra: Pharmaceutical Society of Australia; 2019.
16. Pharmacy Board of Australia. Guidelines on practice-specific issues. Canberra, Pharmacy Board of Australia, 2015. At: www.pharmacyboard.gov.au/Codes-Guidelines.aspx
17. Australian Capital Territory Health. Medicines, poisons and therapeutic goods (vaccinations by pharmacists) direction 2020. Canberra: ACT Health; 2020.
18. Pharmaceutical Society of Australia. Professional practice standards. Version 5. Canberra. PSA; 2017. At: www.psa.org.au/wp-content/uploads/2018/08/Professional-Practice-Standards-v5.pdf
19. Australian Government Department of Health. Yellow fever. Canberra. Australian Government Department of Health. 2019. At: www1.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-strateg-communic-factsheets-yellow.htm
20. Australian Government Department of Health. Preparing for vaccination. Canberra. Australian Government Department of Health. 2019. At: <https://immunisationhandbook.health.gov.au/vaccination-procedures/preparing-for-vaccination>
21. Feletto E, Wilson LK, Roberts AS, et al. Building capacity to implement cognitive pharmaceutical services: quantifying the needs of community pharmacies. *Res Social Adm Pharm.* 2010;6(3):163–73.
22. Roberts AS, Benrimoj SJ, Chen TF, et al. Practice change in community pharmacy: quantification of facilitators. *Ann Pharmacother.* 2008;42(6):861–8.
23. Roberts A, Benrimoj S, Dunphy D, et al. Community pharmacy: strategic change management. Sydney. McGraw Hill; 2007.
24. Baker R, Camosso-Stefinovic J, Gillies C, et al. Tailored interventions to overcome identified barriers to change: effects on professional practice and health care outcomes. *Cochrane Database Syst Rev.* 2010(3).
25. Ivers N, Jarntvedt G, Flottorp S, et al. Audit and feedback: effects on professional practice and healthcare outcomes. *Cochrane Database Syst Rev.* 2012(6).
26. Australasian Society of Clinical Immunology and Allergy. ASCIA guidelines: acute management of anaphylaxis. Balgowlah. ASCIA; 2019. At: www.allergy.org.au/hp/papers/acute-management-of-anaphylaxis-guidelines
27. Australasian Society of Clinical Immunology and Allergy. ASCIA First aid plan for anaphylaxis. Balgowlah. ASCIA; 2020. www.allergy.org.au/images/stories/anaphylaxis/2020/ASCIA_First_Aid_Anaphylaxis_Generic_Orange_2020.pdf
28. Australian Government Department of Health. National vaccine storage guidelines 'strive for 5'. Canberra. Australian Government Department of Health; 2019. At: www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5
29. Sansom LN, ed. Australian pharmaceutical formulary and handbook [online]. Canberra: Pharmaceutical Society of Australia; 2019.
30. National Health and Medical Research Council. Australian guidelines for the prevention and control of infection in healthcare. Canberra, NHMRC; 2019. At: <https://www.nhmrc.gov.au/about-us/publications/australian-guidelines-prevention-and-control-infection-healthcare-2019>
31. Office of the Australian Information Commissioner. Privacy Act 1988 (Cth). Canberra. 2019. At: www.legislation.gov.au/Details/C2019C00241
32. Pharmaceutical Society of Australia. Guidelines for pharmacists providing medcheck and diabetes medcheck services. Canberra: PSA; 2017. At: www.ppaonline.com.au/wp-content/uploads/2019/01/PSA-MedsCheck-Guidelines.pdf
33. Pharmaceutical Society of Australia. Code of ethics for pharmacists. Canberra: PSA; 2017. At: www.psa.org.au/wp-content/uploads/2018/07/PSA-Code-of-Ethics-2017.pdf
34. Pharmaceutical Society of Australia. National competency standards framework for pharmacists in Australia. Canberra: PSA; 2016. At: www.psa.org.au/practice-support-industry/national-competency-standards
35. Australian Department of Human Services. Australian immunisation register for health professionals. Canberra. Australian Department of Human Services; 2018. At: www.humanservices.gov.au/organisations/health-professionals/services/medicare/australian-immunisation-register-health-professionals
36. Australian Government. Australian Immunisation Act 2015 (Cth). Canberra: Australian Government; 2015. At: www.legislation.gov.au/Details/C2017C00258
37. Australian Government Department of Human Services. Australian immunisation register (AIR) - application to register as a vaccination provider form (IM004). 2018. At: www.humanservices.gov.au/organisations/health-professionals/forms/im004
38. Australian Government Department of Human Services. AIR education for vaccination providers. 2019. At: www.humanservices.gov.au/organisations/health-professionals/subjects/air-education-vaccination-providers
39. Therapeutic Goods Administration. Adverse event reporting. Canberra: TGA; 2019. At: <https://aems.tga.gov.au>
40. Australian Government. Department of Health. Reporting and managing adverse vaccination events. 2019. At: www.health.gov.au/health-topics/immunisation/health-professionals/reporting-and-managing-adverse-vaccination-events
41. Therapeutic Goods Administration. National adverse events following immunisation (AEFI) reporting form. Canberra: TGA; 2016. At: www.tga.gov.au/form/national-adverse-events-following-immunisation-aeafi-reporting-form

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