



The Pharmacy  
Guild of Australia  
NSW Branch

# **GUIDELINES FOR CONDUCTING PHARMACIST INITIATED AND ADMINISTERED VACCINATION SERVICE WITHIN A COMMUNITY PHARMACY**

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## **Document Owner**

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The Guild is grateful for the contribution of the Reference Group in the review of Guidelines for Conducting Vaccination Services within a Community Pharmacy.

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## **Disclaimer**

This document is designed to provide guidance to pharmacists on the implementation of pharmacist initiated and administered vaccinations within a community pharmacy setting.

At all times, pharmacists must meet any legislative and regulatory requirements of the State and Territory in which they are practicing and are expected to exercise professional judgment in adapting the guidance provided here to presenting circumstances.

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## Executive Summary

These Guidelines provide pharmacists with the best practice guidance for the delivery of pharmacist initiated and administered vaccination services in NSW community pharmacies.

Immunisation is a safe and effective way to protect against harmful communicable diseases and, at the population level, prevent the spread of these diseases among the community. In Australia, routine immunisation begins at birth and includes vaccines against 17 diseases including measles, mumps, rubella and whooping cough<sup>1</sup>.

The New South Wales Pharmacist-Administered Vaccination Program commenced in early 2015, enabling adults across NSW to receive influenza vaccinations from an appropriately trained, registered pharmacist. This scope was expanded as of 1 January 2019 to include measles-mumps-rubella and diphtheria-tetanus-pertussis vaccinations.

The key objectives of the program are to:

- Improve consumer access to vaccination services;
- Create opportunities for consumer-centred care;
- Reduce or avoid the disease burden associated with influenza, pertussis and measles;
- Maintain the quality and safety of vaccinations provided by pharmacists;
- Increase pharmacist professional services and career pathways<sup>2</sup>.

In Australia under the National Immunisation Program (NIP), high-risk patients are eligible to receive the influenza vaccine for free. Individuals at high risk of developing influenza-related complications include the elderly irrespective of their health status, patients with diabetes, renal dysfunction, cardiovascular conditions and immunosuppression.

There are indications, however, that large numbers of eligible people remain unvaccinated, even though vaccination has demonstrated to reduce hospitalisation and mortality rates<sup>3</sup>.

A 2012 Productivity Commission report on Government Services on vaccination reported that statistics have remained largely unchanged over the years; with the 2009 Annual Vaccination Survey estimating 22.8% of adults (aged 18 -64 years) and 74.6% of Australians aged 65 years and over were vaccinated against seasonal influenza<sup>4</sup>.

Similarly, a 2014 Newspoll Omnibus survey estimated 39% of adults had received their seasonal influenza vaccine by mid-June 2014; 73% of those aged 65 years and over had received their vaccination, and 63% of those classified as high-risk had also received their vaccination<sup>5</sup>.

It has long been recognised that the impact of influenza is often substantially under-estimated. From 2006-2013 (excluding the 2009 pandemic year), an annual average of 100 deaths and approximately 5,100 hospitalisation due to influenza occurred annually in Australia. In the 2017 influenza season, the highest levels of activity since the pandemic of 2009, over 1000 deaths were reported nationally among notified cases of laboratory-confirmed influenza. However, a mathematical modelling study estimated that influenza is likely to be associated with over 3000 deaths and 13,500 hospitalisation each year in Australia, in the target group of people aged 50 years and over<sup>6</sup>.

Multiple studies have demonstrated the significant effectiveness of the influenza vaccine amongst high-risk populations during peak virus circulation for 'epidemic influenza' and 'influenza-like illness'.

Studies have demonstrated significant reduced infection rates and resultant decreased morbidity and mortality<sup>7,8,9</sup>.

The Influenza Specialist Group (ISG) consisting of medical and scientific specialists from Australia and New Zealand reports that 'each year, an estimated 3,500 Australians die from influenza and its complications and it is estimated that influenza annually causes 18,000 hospitalisations and over 300,000 GP consultations'<sup>10</sup>.

The economic loss suffered by industry and individuals is also significant, with a 1996 study calculating the economic burden of influenza resulting in an estimated 1.5 million work days lost annually in Australia<sup>11,12</sup>. There is evidence that the influenza vaccine can decrease the total winter absenteeism in the workplace by 36%<sup>13</sup>.

Therefore, there is strong evidence for community pharmacy to be actively providing vaccination services; filling existing gaps, reducing health risks to the individual and the community, decreasing hospital administration and reducing the economic burden to the finance sector.

There are a number of potential existing barriers that may act as a disincentive for patients being vaccinated that can be addressed by community pharmacy, including;

- the time involved in making an appointment and attending the GP practice;
- the cost involved in visiting a GP. In NSW, approximately 8% of people aged 15 years old and over defer or do not visit a GP due to cost considerations alone<sup>1</sup>; and
- the multi-step process and costs for patients not eligible under the National Immunisation Program who need to attend both a community pharmacy for dispensing of the prescription and a GP on separate occasions for its prescribing and for its administration.

These disincentives are, in large measure, addressed by having vaccines supplied and administered in a pharmacy setting which offers savings and convenience.

Community Pharmacy delivers the most accessibility across all health professionals through a network of over 1,800 pharmacies in urban, regional and rural NSW. Many community pharmacies offer extended trading hours including weekends and public holidays, providing easy access for the community.

In a recent 2018 study of vaccination services in Victoria, at least 96% of consumers rated their experience as 'very satisfied' or 'extremely satisfied' with both regional and metropolitan consumers reporting similar satisfaction levels (95% and 96% respectively)<sup>2</sup>. 87% of consumers reported that it was 'acceptable' or 'very acceptable' to receive vaccinations from a pharmacist when compared to another health professional from whom they had received vaccinations<sup>2</sup>.

By providing vaccination services, community pharmacy may also generate increased opportunistic vaccination, particularly for people who do not visit GP's, regardless if they are from high risk population groups or not. The benefits of increased vaccination coverage include increased protection for the public at large via limited spread of the virus; reduced morbidity, treatments, hospitalisation and reduced work absenteeism, and better access to the vaccine for those at risk of influenza complications. Furthermore, vaccination services by pharmacists may generate additional benefits, including reduction of workloads and waiting times at GP surgeries; reduction in Medicare spending on consultations and hospitalisation; an increased capacity to address future pandemics, and support public health immunisation initiatives that educate and counsel patients, while addressing their concerns and immunisation needs.

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## Abbreviations and Terminology

<b>AEFI</b>	Adverse Event Following Immunisation – an unwanted reaction following administration of a vaccine, which may or may not be caused by the vaccine.
<b>AHPRA</b>	Australian Health Practitioner Regulation Agency
<b>AIR</b>	Australian Immunisation Register – a national register that records vaccines given to people of all ages in Australia
<b>Anaphylaxis Response Kit</b>	Anaphylaxis response equipment as described in the current edition of the <i>Australian Immunisation Handbook</i> .
<b>ASCIA</b>	Australasian Society of Clinical Immunology and Allergy
<b>Australian Immunisation Handbook</b>	The <i>Australian Immunisation Handbook</i> is accessible online for free: <a href="https://immunisationhandbook.health.gov.au/">https://immunisationhandbook.health.gov.au/</a> The print version has now been phased out of publication, at the time of reviewing this guideline.
<b>CMI</b>	Consumer Medicines Information
<b>CPR</b>	Cardiopulmonary Resuscitation
<b>GP</b>	General Practitioner
<b>Guidelines</b>	This document: <i>Guidelines for Conducting Pharmacist Initiated and Administered Vaccinations</i>
<b>GuildCare</b>	GuildCare provides community pharmacy the a range of in-pharmacy professional services and patient support programs on a digital platform
<b>Immunisation</b>	The process of inducing immunity to an infectious agent by administering a vaccine.
<b>Immunity</b>	The ability of the body to fight off certain infections as a result of vaccination or previous infection.
<b>Nurse Immuniser</b>	A registered nurse who is certified to deliver vaccinations in accordance with State or Territory regulations
<b>PGA</b>	The Pharmacy Guild of Australia
<b>Pharmacy</b>	A business premise containing a dispensary approved to prepare, preserve, compound and dispense medicines
<b>Pharmacist Vaccinator</b>	An appropriately trained and registered pharmacist certified to provide vaccination services in accordance with State or Territory regulations
<b>Pharmacy Vaccination Service</b>	Any vaccination service delivered in a pharmacy by a vaccinator.
<b>Pharmacy Staff</b>	Any person who works in the pharmacy, including pharmacist.
<b>Primary Healthcare Provider</b>	Primary healthcare professional responsible for the consumer’s care.
<b>PSA</b>	The Pharmaceutical Society of Australia
<b>QCPP</b>	The Quality Care Pharmacy Program
<b>TGA</b>	Therapeutic Goods Administration
<b>Third-party provider</b>	A vaccinator delivering vaccination services within a community pharmacy under a contract arrangement.
<b>Vaccination</b>	The administration of a vaccine. If vaccination is successful, it results in immunity to a pathogen.
<b>Vaccinator</b>	An appropriately trained and registered health practitioner certified to provide vaccination services in accordance with State or Territory regulations.

<b>Vaccine</b>	The material used for vaccination, including extracts of killed viruses or bacteria, or live weakened strains of viruses or bacteria.
<b>WHS</b>	Work, Health & Safety

## Section 1 - Introduction

### 1.1 Community Pharmacy - An Ideal Setting for Vaccination Services

Pharmacists are one of the most trusted and accessible health care professionals<sup>14</sup>. By law, every pharmacy must have an AHPRA registered pharmacist on duty at all times during hours of trade<sup>15</sup>. Community pharmacies are an integral component of the health system, with over 5,300 well- distributed community pharmacies throughout Australia, and many operating with extended trading hours; approximately 20% of these located in regional and remote areas<sup>16</sup>.

The high standards and accessibility of service delivery provided by community pharmacists is reflected in the Menzies-Nous Australian Health Survey 2012, which found that Australian pharmacies were visited by 94% of the population (one of the most highly used health care services in the country) with 89% of the consumers who used the pharmacist's services rating the level of service provided as *good/excellent*, the highest of all health care professionals<sup>17</sup>.

### 1.2 International Experience of Pharmacist Administered Vaccination Services

Pharmacist administered vaccinations have been adopted into international practice for many years. Vaccination services in community pharmacy are a proven service in the USA, the UK, Ireland and New Zealand.

Across the USA, there is extensive experience in the administration of vaccines through community pharmacy. Since 2009, pharmacists have been authorised to administer vaccinations in all 50 US states<sup>18</sup> in accordance with state-specific arrangements such as written or verbal prescriptions, standing orders, protocols or collaborative agreements.

In the UK, community pharmacists have offered influenza vaccinations as a privately-funded service for numerous years. From 2015-2016, all community pharmacies were eligible to vaccinate patients of at-risk groups under the 5<sup>th</sup> Advanced Service in the English Community Pharmacy Contractual Framework (CPCF)<sup>19</sup>. All UK pharmacists providing influenza vaccination services must complete practical face-to-face training for injection technique and basic life support every 3 years<sup>19</sup>.

In Ireland following legislative updates in October 2011, pharmacists are eligible to provide the seasonal influenza vaccination service. Their scope was further expanded in 2015 to include the pneumococcal polysaccharide and herpes zoster vaccine<sup>20</sup>.

In New Zealand, pharmacists were initially eligible to administer influenza and dTpa vaccines upon having completed an approved training course. In 2013, the herpes zoster and meningococcal vaccines were added to the scope for community pharmacists<sup>21</sup>.

### 1.3 Australian Developments

As the community pharmacy model evolved to meet the changing needs of the public, community pharmacies introduced vaccination services utilising nurse vaccinators. Building on this evolution and given the international trends, much work has been done to pave the way for pharmacist initiated and administered vaccinations in Australia.

In December 2013, the Pharmacy Board of Australia advised that vaccination is within the current scope of practice of a pharmacist, subject to the provision of appropriate training and standards<sup>22</sup>. Australian states and territories have thus amended their regulations to allow appropriately trained pharmacists to conduct vaccination services.

In 2014, a Queensland trial of pharmacist-administered vaccinations saw over 10,000 influenza vaccinations delivered. The success of this trial resulted in its extension, with coverage of other vaccinations including measles/mumps/rubella and whooping cough for adults<sup>22</sup>.

Following on from the success of the QLD trials, pharmacist-initiated vaccination services were slowly introduced from 2015 to South Australia and Western Australia, followed by all other states and territories in 2016<sup>22</sup>.

In 2016 NSW and ACT allowed appropriately trained pharmacists to administer the influenza vaccination to adults over the age of 18 years. The strong demand for timely access to vaccination services and to encourage the uptake of vaccines in the community, accredited NSW pharmacists had their scope expanded to include diphtheria-tetanus-pertussis (dTpa) and measles-mumps-rubella (MMR) for people aged 16 years and over, as of January 2019<sup>23</sup>.

## 1.4 Quality Assurance in Community Pharmacy

Community pharmacies provide high quality and consistent professional services to the public. Over 92% of Australian community pharmacies are accredited under the Quality Care Pharmacy Program (QCPP), a structured quality management system (Australian Standard 85000:2011)<sup>24</sup>. The program aims to ensure a uniform approach when delivering professional services and customer care within community pharmacies, with accredited pharmacies externally audited for compliance by a licensed assessor every 2 years<sup>24</sup>.

It is important to remember that QCPP-accredited pharmacies that satisfy *T3M Hosting Vaccination Services in Pharmacy Checklist Action 6.1* may need to modify their practices to ensure they comply with the requirements and standards set by their relevant state or territory.

The level of the requirements set in the *T3M Hosting Vaccination Services in Pharmacy Checklist* and the *NSW Vaccination Standards* may also differ. An important example of this difference is the professional service area. The *NSW Vaccination Standards* state that the area where the vaccination service is to be conducted (the vaccination service room, consulting room or another area of the pharmacy premises) must:

- Have sufficient floor area, clear of equipment and furniture, to accommodate the person receiving the vaccination and an accompanying person, and to allow the pharmacist adequate space to manoeuvre
- Have sufficient bench space (with an impervious surface), a chair and a first aid couch (or similar)
- Not permit the vaccination to be visible or audible to other persons in the pharmacy<sup>24</sup>.

However, the QCPP checklist further state that facilities to support the vaccination service there must be at least 4 square metres to ensure that if required in an emergency, a patient could lie down on the ground. Additionally, QCPP requirements state that there must be a dedicated area to enable the vaccination service to be provided. This includes either a screened area to ensure patient privacy and to lie down if required or a consultation room<sup>25</sup>.

As QCPP reminds its accredited pharmacies, local jurisdictional legislation and regulations take precedence.

## 1.5 Scope

This document provides practice guidelines for the delivery of pharmacist initiated and administered vaccination services within a community pharmacy. The Guidelines should be read in conjunction with:

- The Australian Vaccination Handbook (current edition) - Australian Government Department of Health; and
- National Vaccine Storage Guidelines - Strive for 5 (current edition) - Australian Government Department of Health.

Legislation and regulations permitting pharmacist-administered vaccinations vary between state and territory jurisdictions. It is important to remember these guidelines are tailored to NSW legislation and regulations; pharmacists practising in other jurisdictions must refer to their relevant equivalent standards and regulations.

Pharmacist vaccinators must ensure they are aware of the National Immunisation Program (NIP), a series of immunisations given at specific times throughout someone life.

On the NIP, the Influenza vaccines is free to patients who fall into the following categories<sup>26</sup>:

- People aged 65 years and over;
- Aboriginal and Torres Strait Islander people from 6 months and over;
- Pregnant women;
- Influenza vaccine is free to people six months and over who has:
  - Heart disease
  - Chronic lung conditions or severe asthma

- Diabetes
- Have another chronic illness, including multiple sclerosis and seizure disorder
- Impaired immunity, including HIV infection

If the patient is eligible for the NIP, the pharmacist is advised to refer the individual to their GP or specialist.

The PGA has developed a template *Vaccination Referral form for General Practitioner* (Appendix A).

## **Section 2 - Vaccination Training Requirements**

To implement a vaccination service within a pharmacy, all pharmacists participating in the service must successfully complete a training course accredited in accordance with the Australian Pharmacy Council *Standards for the Accreditation of Programs to Support Pharmacist Administration of Vaccines* (current version), including all required pre-learning and assessments; and must maintain up-to-date qualifications and requirements determined by their state or territory legislation. The training course must be conducted by an accredited Continuing Professional Development Accrediting Organisation.

Pharmacists participating in a vaccination service within a pharmacy must also:

1. Have current registration as a pharmacist with the Australian Health Practitioner Regulation Agency (AHPRA). Provisionally registered pharmacists are eligible to complete the vaccination training course, and may initiate and administer vaccines only when under the supervision of a pharmacist who holds general registration, has completed an accredited vaccination training course and has determined the vaccination is appropriate for the individual. Proof of registration should be included as part of a pharmacist's training record<sup>23</sup>.
2. Successfully complete the Australasian Society of Clinical Immunology and Allergy (ASCIA) online anaphylaxis training for pharmacists. A certificate of completion should be included as a part of a pharmacist's training record.
3. Hold a current HLTAID003 Provide First Aid and HLTAID001 Provide CPR Statement of Attainment. A pharmacist's training record in the operations manual should include certificates that provide proof of currency of First Aid and/or CPR training.
  - A valid and current HLTAID003 Provide First Aid: Pharmacists delivering vaccinations are required to renew their first aid certificate every 3 years.
  - A valid and current HLTAID001 Provide Cardio-Pulmonary Resuscitation: Pharmacists delivering vaccinations are required to renew their CPR certification every 12 months<sup>23</sup>.

### **2.1 Pharmacist Training**

#### **Pharmacist Administration of Vaccines**

The Pharmacy Guild of Australia offers immunisation training, accredited by the Australian College of Pharmacy, to provide pharmacists with a range of knowledge and skills, to safely and competently provide vaccinations to people within the community pharmacy environment.

Pharmacists wishing to complete the course must show valid currency for all requested requirements prior to attending the practical workshop. These pre-requirements include:

- AHPRA registration certificate;
- HLTAID003 Provide First Aid;
- HLTAID001 Provide CPR;
- ASCIA Anaphylaxis: Anaphylaxis for Pharmacists;
- Successful completion of pre-learning for Pharmacy Guild Immunisation Course.

On successful completion of accredited training, a Statement of Completion will be issued by The Pharmacy Guild of Australia. While regulatory and jurisdictional requirements are not precise on the display of the accreditation certificate, it is considered best practice to do so within the vaccination service area.

## 2.2 Pharmacy Staff Training

To ensure consistent service delivery, all staff assisting in the delivery of vaccination services within a community pharmacy must be appropriately trained according to best practice<sup>26</sup>.

Areas of training to be covered include:

- Relevant policies and procedures;
- How to access all relevant resources, references and forms;
- Roles and responsibilities of staff involved in vaccination service;
- Information about vaccines provided under the vaccination service;
- Monitoring requirements for the vaccination service;
- Adverse events that may occur from a vaccination;
- Roles and responsibilities during an emergency situation arising from a vaccination;
- Privacy and confidentiality requirements of vaccination programmes;
- Consent requirements.

Additionally, it is recommended that staff assisting the pharmacist vaccinator complete the relevant anaphylaxis, CPR and/or First Aid course, to help in the management of any adverse events.

Pharmacists practising in other jurisdictions should refer to the relevant standards and regulations of those jurisdictions.

## Section 3 - Ongoing Certification Requirements for Pharmacist Vaccinators

Upon successfully meeting all requirements for initial immunisation training as outlined in Section 2.1 of this guideline, the pharmacist vaccinator is responsible for completing any on-going certification requirements.

At the time of writing, there is no legislative requirement for the pharmacist vaccinator to undertake any ongoing reaccreditation after the initial accredited training has been completed, other than continuing to be an AHPRA registered pharmacist, and maintain up-to-date qualifications in First Aid and CPR.

- CPR qualifications require renewal every **twelve months**;
- First Aid qualifications require renewal every **three years**.

### 3.1 Australian Immunisation Record

As of 2019, it is a requirement that all vaccinations administered by a pharmacist be recorded onto the Australian Immunisation Register (AIR)<sup>26</sup>. A pharmacy must first register with the Commonwealth Department of Human Services to be approved as a vaccination site provider; upon acceptance a unique AIR number will be provided for the pharmacy to access and upload vaccination records onto the AIR. Additionally, as of 1 January 2019, all vaccinating pharmacists must be registered and approved by the NSW Ministry of Health as a vaccination provider<sup>29</sup>. It is the individual pharmacist's responsibility to declare themselves to the NSW Ministry of Health prior to administering vaccines to individuals.

Pharmacists practising in jurisdictions other than NSW should refer to the relevant standards and regulations of those jurisdictions.

## Section 4 - Policies and Procedures

Pharmacies implementing a vaccination service must maintain a vaccination-specific Operations Folder, available within the vaccination service room, consulting room or vaccination area of the pharmacy premises.

### 4.1 Privacy and Confidentiality

Any information collected about a consumer must only be used for the purpose for which it was intended.

The collection of personal information must be consistent with Australian Privacy Act 1998 and a pharmacy's Confidentiality Policy. Information collected must be securely stored.

It is recommended that all documentation be retained by the pharmacy, as well as be protected against flood, fire, pests and any other external factors.

The *NSW Pharmacist Vaccination Standards* require that vaccination records must be kept for 7 (seven) years (refer to [Section 6.2 Recording Vaccine Use](#) for further information)<sup>26</sup>. Pharmacists practising in jurisdictions other than NSW should refer to the relevant standards and regulations of each state and territory.

#### 4.2 Recommended Vaccination Service Folder Contents

<b>Policies and procedures</b>	<b>Resource</b>
1. Establishing a pharmacist-administered vaccination service (see Appendix B)	<i>Guidelines*</i>
2. Vaccination service outline (see Appendix C)	<i>Guidelines*</i>
3. Delivering a pharmacist-administered vaccination service (see Appendix D)	<i>Guidelines*</i>
4. Maintaining and monitoring a pharmacist-administered vaccination service (see Appendix E)	<i>Guidelines*</i>
5. Staff training procedure	<i>Quality Care Pharmacy Program (QCPP) P15A</i>
6. Infection control guideline - including hand hygiene, needle stick injuries and waste management (See Appendix F)	<i>Guidelines*</i>
7. Sharps Waste Disposal (see Appendix G)	<i>Guidelines*</i>
8. Emergency response protocol	<i>QCPP P17F</i>
9. Vaccine management protocol	<i>Strive for 5 and QCPP P5A</i>
10. Confidentiality policy	<i>QCPPP P1A</i>
11. Inter-professional collaboration guideline	<i>QCPP P2I</i>
12. Incident reporting procedure	<i>QCPP P7D</i>

<b>Forms and templates</b>	
Vaccination Referral form for General Practitioner (see Appendix A)	<i>Guidelines*</i>
Information for Consumers on Influenza Vaccination	<i>Vaccination Resources on the PGA website (MyGuild log-in required)</i>
Information for Consumers on MMR Vaccination	<i>Vaccination Resources on the PGA website (MyGuild log-in required)</i>
Information for Consumers on Pertussis Vaccination	<i>Vaccination Resources on the PGA website (MyGuild log-in required)</i>
Vaccination notification letter for General Practitioner	<i>Vaccination Resources on the PGA website (MyGuild log-in required)</i>

Patient Vaccination Pre-Screening/Consent Recording Form	Vaccination Resources on the PGA website (MyGuild log-in required)
<b>Forms and templates</b>	
Patient After-Care Card	Vaccination Resources on the PGA website (MyGuild log-in required)
<b>Vaccination training record checklist</b>	
see Appendix K	Guidelines*

\* *Guidelines for Conducting Pharmacist Initiated and Administered Vaccination Service within a NSW Community Pharmacy*

## Section 5 - Vaccination Service Area and Equipment

### 5.1 Vaccination Service Area

Pharmacies delivering a vaccination service must be equipped with facilities and resources that are appropriate for the delivery of that service. The pharmacy premise providing the vaccination service must have:

- A temperature-monitored fridge which has been manufactured (either exclusively or principally) for the purpose of storage of vaccines (refer to [Section 6: Procurement and Storage](#)).
- A suitable area for conducting vaccination service, with adequate stock of resources and equipment required to deliver vaccinations and manage waste appropriately.

This area is not to be used as a dispensary, storeroom, and staff room or retail area. The vaccination area must also:

- Not permit the vaccination to be visible or audible to other persons in the pharmacy;
- Have adequate lighting;
- Be maintained at a comfortable ambient temperature;
- Have a hand sanitisation facility;
- Have ready access to a hand washing facility;
- Have sufficient floor area, clear of equipment and furniture, to accommodate the person receiving the vaccination as well as an accompanying person, and to allow the pharmacist adequate space to manoeuvre; and
- Have sufficient bench space (with an impervious surface), a chair and a first aid couch (or similar)<sup>25</sup>.
- An in-date anaphylaxis response kit consistent with the *Australian Immunisation Handbook* (current edition);
- An emergency response protocol, laminated and on display in the vaccination service area;
- Access to *The Australian Immunisation Handbook*: current online edition is recommended;
- Access to the *National Vaccine Storage Guidelines – Strive for 5*: current online edition is recommended;
- A policies and procedures manual for the vaccination service;
- A process to regularly monitor digital updates to *The Australian Immunisation Handbook* and the *National Vaccine Storage Guidelines*, including prior to administering any vaccine.

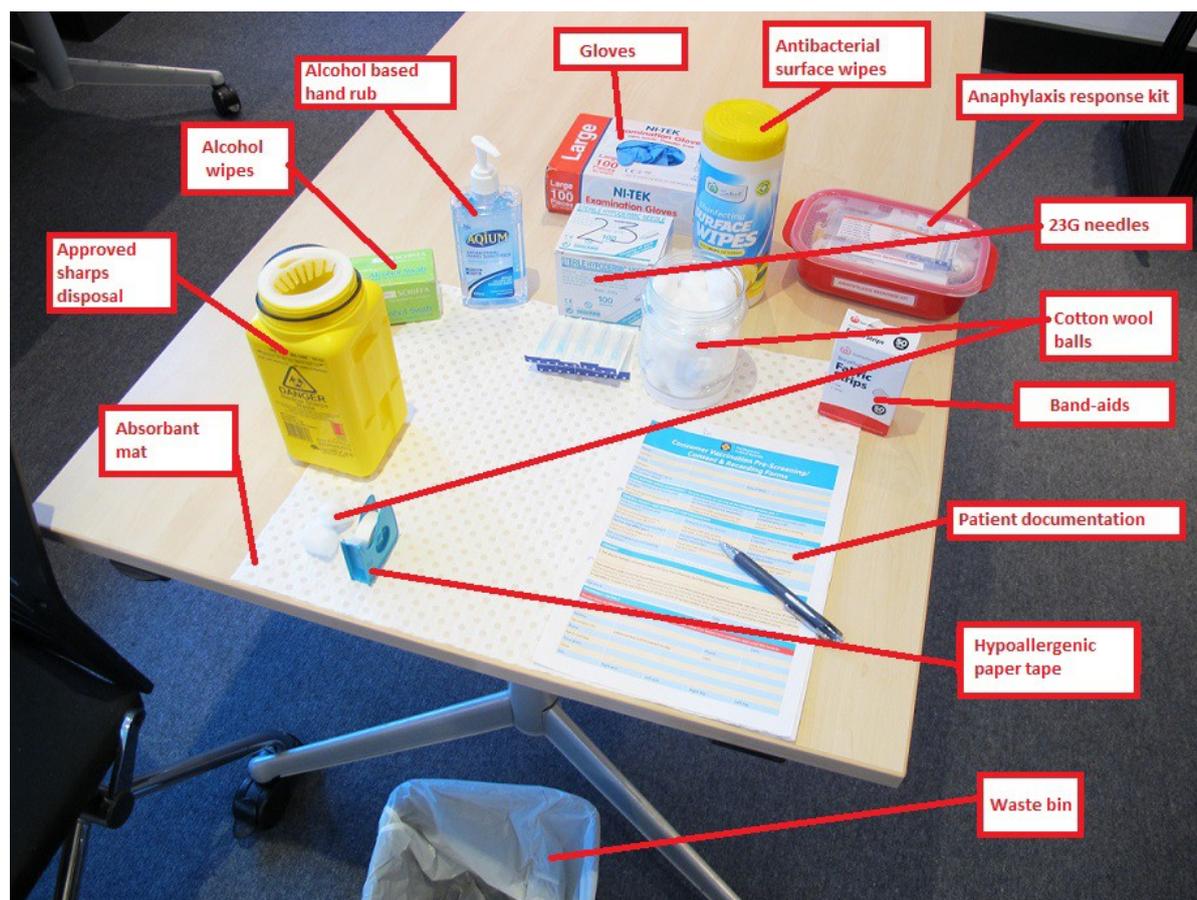


Figure 1: Example of Vaccination Service Area

## 5.2 General Equipment

Appropriate equipment should be available within the vaccination service area, including:

**Chairs** - a minimum of two chairs, one each for the consumer and vaccinator, with an impervious surface (e.g. plastic).

**Bench or Table** - free from unnecessary clutter and with an impervious surface (e.g. stainless steel)

**Storage facility** - an easily accessible storage facility should be used to accommodate required equipment, including:

- Cotton wool balls;
- Gloves (*see below*);
- Anaphylaxis Response Kit (*see Section 5.3: Anaphylaxis Response Kit for Vaccination Services*);
- Anaphylaxis management card and posters;
- Adrenaline dosage cards and poster;
- Approved Australian Standard Sharps Container;
- Kidney dish;
- Medical waste bin;
- Hypoallergenic tape;
- Clinical table mats;
- Anti-bacterial wipes to clean work area;
- Liquid hand soap or alcohol-based hand sanitiser;
- *The Australian Immunisation Handbook* (current edition);
- *'National Vaccine Storage Guidelines – Strive for 5'* (current edition);
- A process to regularly monitor digital updates to *The Australian Immunisation Handbook* and the *National Vaccine Storage Guidelines*, including prior to administering any vaccine;

- Laminated CPR Chart (on display);
- Laminated Emergency Response protocol (on display), including 000 and street address for emergency services;
- Emergency contact doctor information.

**Gloves** - A vaccinator may wear gloves where there is an identified risk from coming into contact with body fluids, or the vaccinator has open lesions on their hands.

**Gloves are not routinely recommended for vaccination.**

### 5.3 Anaphylaxis Response Kit for Vaccination Services

If signs or symptoms of anaphylaxis are evident, recommended dosage of adrenaline should be immediately delivered.

Pharmacists conducting vaccination services within a community pharmacy environment must ensure that an Anaphylaxis Response Kit is available at **ALL** times within the vaccination service area.

#### **IMPORTANT INFORMATION**

The availability of protocols, equipment and drugs necessary for the management of anaphylaxis should be checked before each vaccination session. An Anaphylaxis Response Kit must be on hand at all times and should contain:

- Adrenaline 1:1000 (minimum three ampoules – check expiry dates)
- Minimum of three 1 mL syringes and 23 gauge 25mm length needles (for intramuscular [IM] injection)
- Cotton wool swabs
- Pen and paper to record time of administration of adrenaline
- Laminated copy of adrenaline doses (see Table 1 following)
- Laminated copy of 'Recognition and treatment of anaphylaxis' (see Table 1 following)

### 5.4 Use of Adrenaline Auto injectors in Anaphylaxis Response Kits

Adrenaline auto injectors (EpiPen®) are devices that administer a single, pre-measured dose of adrenaline and are designed for use by any person, whether medically trained or not. Clear instructions on correct use are provided on the barrel and in the packaging of these devices and they are designed to be administered in the mid-outer thigh.

Auto injectors are not recommended for inclusion in Anaphylaxis Response Kits as outlined in the Australian Vaccination Handbook (current edition) because they are single use only. Since they are dose-specific, multiple pens would be required to allow for repeat dosing and varying ages/weights of patients, and the shelf-life is generally limited to one- to-two years maximum.

Since the audience for vaccinations by a pharmacist is restricted to people aged over 16 years (in NSW), auto-injectors may be used. If pharmacies offering influenza vaccinations choose to hold additional adrenaline auto-injectors, they must have at least 2 auto-injectors with the prepared anaphylaxis kit located in the vaccination service room. Expiry dates must be noted and checked at regular intervals.

**Table 1: Recognition and Treatment of Anaphylaxis**

<b>Signs of Anaphylaxis</b>	
<p>Anaphylaxis causes respiratory and/or cardiovascular signs or symptoms AND involves other organ systems, such as the skin or gastrointestinal tract, with:</p> <ul style="list-style-type: none"> <li>• Signs of airway obstruction, such as cough, wheeze, hoarseness, stridor or signs of respiratory distress (e.g. tachypnoea, cyanosis, rib recession)</li> <li>• Upper airway swelling (lip, tongue, throat, uvula or larynx)</li> <li>• Tachycardia, weak/absent carotid pulse</li> <li>• Hypotension that is sustained and with no improvement without specific treatment (Note: in infants and young children, limpness and pallor are signs of hypotension)</li> <li>• Loss of consciousness with no improvement once supine or in head-down position</li> <li>• 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)</li> <li>• Abdominal cramps, diarrhoea, nausea and/or vomiting</li> <li>• Sense of severe anxiety or distress</li> </ul>	
<b>Management of Anaphylaxis</b>	
<ul style="list-style-type: none"> <li>• If the patient is unconscious, lay him/her on the left side and position to keep the airway clear. If the patient is conscious, lie supine in 'head-down and feet-up' position (unless this results in breathing difficulties).</li> <li>• Give adrenaline by intramuscular injection (see below for dosage) if there are any signs of anaphylaxis with respiratory and/or cardiovascular symptoms or signs. Although adrenaline is not required for generalised non-anaphylactic reactions (such as skin rash without other signs or symptoms), administration of intramuscular adrenaline is safe.</li> <li>• Call for assistance. Never leave the patient alone.</li> <li>• If oxygen is available, administer by facemask at a high flow rate.</li> <li>• If there is no improvement in the patient's condition within 5 minutes, repeat doses of adrenaline every 5 minutes, until improvement occurs.</li> <li>• Check breathing; if absent, commence basic life support or appropriate cardiopulmonary resuscitation (CPR) as per the Australian Resuscitation Council guideline (<a href="http://www.resus.org.au/policy/guidelines">www.resus.org.au/policy/guidelines</a>).</li> <li>• Transfer all cases to hospital for further observation and treatment.</li> <li>• Complete full documentation of the event, including the time and dose(s) of adrenaline given.</li> </ul> <p>Experienced practitioners may choose to use an oral airway, if the appropriate size is available, but its use is not routinely recommended, unless the patient is unconscious.</p> <p>Antihistamines and/or hydrocortisone are not recommended for the emergency management of anaphylaxis.</p>	
<b>Adrenaline Dosage</b>	
<p>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 or 0.5 mg, given by deep intramuscular injection into the anterolateral thigh. Adrenaline 1:1 000 <i>must not</i> be administered intravenously.</p> <p>The use of 1:1000 adrenaline is recommended because it is universally available. Adrenaline 1:1000 contains 1 mg of adrenaline per mL of solution in a 1 mL glass vial. Use a 1 mL syringe to improve the accuracy of measurement when drawing up small doses.</p>	
<b>Doses of 1:1000 (one in one thousand) adrenaline:</b>	
<b>&gt;12 years and adult (over 50kg)</b>	0.5 mL

Pharmacists practising in jurisdictions other than NSW should refer to the relevant equivalent standards and regulations in those jurisdictions in the treatment of possible anaphylaxis reactions.

## Section 6 - Procurement and Storage

Pharmacies must ensure that vaccine procurement and storage procedures are consistent with the *National Vaccine Storage Guidelines – Strive for 5* (current edition).

Vaccines are susceptible to temperature changes and correct procedure for the transport and handling of vaccines is vital. 'Strive for 5' refers to strive for 5 degrees Celsius (°C) – that is, the point midway between +2°C and +8°C, which is the temperature range recommended for vaccine storage. Many vaccines are damaged or destroyed at temperatures outside this range.

'Cold Chain' refers to the protocol of safely transporting and storing vaccines and medicines from the place of manufacture to the point of administration, to ensure patients receive a viable vaccine or medication that has not been affected by temperature changes.

Purpose-built vaccine refrigerators are best practice and are the recommended vaccine storage option. There is currently no Australian Standard for vaccine refrigerators. A recommended list of approved refrigerators is available from the PGA NSW Branch<sup>29</sup>.

**Domestic refrigerators, including bar refrigerators, are unsuitable for vaccine storage and not recommended.**

A pharmacy procuring vaccines for the delivery of a pharmacy vaccination service must do so in accordance with legislation and regulations in the relevant state or territory.

### 6.1 Vaccine Management Protocol

Every pharmacy conducting a vaccination service must have a vaccine management protocol, which should include written instructions on the following:

- **Equipment:** temperature monitoring and the monitors used to do so, maintenance of both the refrigerator and monitors, cleaning the refrigerator, freezer storage for ice/gel packs in case of power failure or outreach vaccination.
- **Vaccines:** ordering and receiving, rotating stock, calculating vaccine requirements, storage of vaccines and diluents.
- **Vaccine Transport:** managing power failures, packing a cooler, conditioning ice/gel packs.
- **Action and Communication:** reporting a cold chain breach, action to take if the refrigerator temperature goes outside the recommended range, communication with other all staff involved in handling vaccines, ongoing vaccine management education.

Furthermore, pharmacies conducting vaccination services should ensure the following are in place:

- A trained, designated staff member who is responsible for vaccine storage and implementation of protocols;
- A trained backup staff member is available to relieve the designated person, when required;
- Orientation and education on safe and effective vaccine management for all staff members who may be involved in vaccine storage at any stage;
- Contact names and numbers for reporting cold chain breaches, refrigerator and/or data logger maintenance issues, power failures;
- Backup vaccine storage options.

It is important that the pharmacist must ensure when administering vaccines that at least one other appropriately trained pharmacy staff member is present<sup>26</sup>.

For more information on vaccine management, storage and cold chain protocols, refer to the 'National Vaccine Storage Guidelines – Strive for 5' (current edition).

### 6.2 Recording Vaccine Use

When a vaccine is used in the vaccination service of a pharmacy, the record must be retained for seven (7) years from the date of vaccination. Capture of the recording electronically in dispensing software is acceptable, or in specific recording software such as the GuildCare Vaccination Recording program. However, it is important to note that a copy of the patient-signed consent form must be retained by the pharmacy and stored in a secure place (see [Section 4.2: Recommended Vaccination Service Folder Contents](#)), regardless of whether other

vaccination information is stored electronically.

In accordance with the *NSW Pharmacist Vaccination Standards*<sup>26</sup>, the following information must be recorded:

**Patient information:**

- Patient's name;
- Patient's address;
- Patient's date of birth;
- Patient's contact details;
- Name and contact details of patient's primary GP;
- Location on body to which the vaccine was administered;
- Date of injection administration.

**Pharmacist information:**

- Name of the pharmacist who initiated and administered the vaccine;
- The address and contact number of the pharmacist who initiated and administered the vaccine;
- The accreditation certificate number of the pharmacist who initiated and administered the vaccine;
- The unique identifying/reference number allocated to administration of the vaccine by the pharmacist.

**Vaccine information:**

- Brand;
- Batch number;
- Expiry date;

It is the pharmacist's responsibility to confirm and check an individual's vaccination status on the AIR prior to administering a vaccine and subsequently record any vaccines they administer<sup>26</sup>.

Pharmacists practising in other jurisdictions should refer to the relevant standards and regulations regarding recording of vaccinations of those jurisdictions.

*The Pharmacy Guild of Australia has developed a template 'Pre-Screening and Consent form' to aid recording vaccinations; to access this form please sign-in to MyGuild under the Vaccination Resources.*

## **Section 7 - Pre-vaccination Procedures**

### **7.1 Pre-Screening and Valid Consent**

Pre-vaccination screening is used to identify individuals who may be at an increased risk of adverse events associated with vaccination. This may require special consideration, or alterations to the standard vaccination recommendations to reduce the risk of adverse effects and to optimise an individual's response to vaccination. Pre-screening may also identify households that require enhanced protection against vaccine-preventable diseases.

When conducting a pre-vaccination screening assessment, the pharmacist vaccinator should ensure that all questions are answered properly and take reasonable steps to be satisfied that the responses provided are accurate.

Valid consent must be obtained from the individual by a vaccination provider before a vaccine can be administered. A record of their consent must be kept as a part of an individual's vaccination record. Valid consent obtained in the community pharmacy should include:

- Outlining the risk and benefits of vaccination in an honest, objective and scientifically valid manner
- Informing individuals of any costs associated with the vaccination service
- Obtaining the details of the individual's primary health care provider and asking consent to provide the primary health care provider with notification of vaccination to ensure continuity of care.

Careful assessment must be made of a patient's capacity to provide valid consent. Where the patient lacks capacity to provide consent, the vaccinator should refer the patient to his/her GP or a specialist vaccination clinic.

Pharmacists practising in states other than NSW should follow the relevant standards and regulations of each state and territory regarding obtaining valid consent for vaccinations.

## 7.2 Patient Information

To support informed consent, all risks and benefits must be outlined to the patient and the pharmacist vaccinator must ensure the patient understands these risks and benefits. This information may be provided through the following:

- Vaccine-specific Consumer Medicines Information (CMI) hand-outs;
- A Consumer Information Card: this can be a useful tool for supporting the consumer in understanding the benefits and risks of the vaccination.

*The PGA has developed a resource for consumers on influenza, diphtheria-tetanus-pertussis (dTpa) and measles-mumps-rubella (MMR) vaccinations; to access please log-onto 'Vaccination Resources' with your MyGuild account details.*

Any information about the vaccine that is given to the patient should be in a language that they understand. Where information cannot be provided in a language that the patient can understand, the vaccination should not take place. The pharmacist vaccinator should provide adequate time for the patient to read the information and to ask questions, if any.

Pharmacists practising in states other than NSW should refer to the relevant standards and regulations of each state and territory regarding patient information.

## Section 8 - Vaccination Delivery

Only appropriately trained pharmacists certified under relevant state or territory regulations may administer vaccines.

*The PGA has developed a 'Vaccination Service Business Support Guide', 'Designing your Vaccination Service Workbook' and 'Vaccination Service Checklist'; to access please log-onto 'Vaccination Resources' with your MyGuild account details.*

Prior to administration, the pharmacist vaccinator must re-confirm that:

- The details on the patient screening and consent form match the person to be vaccinated; and
- The person being vaccinated is aged over 16 years.

Pharmacists practising in states other than NSW should follow the relevant standards and regulations of each State and Territory regarding age restrictions.

### 8.1 Post-Vaccination Care

Following vaccination delivery, the patient must be appropriately counselled on post-vaccination care and must be provided with:

- (a) **Contact information** of the pharmacy and the name of the pharmacist vaccinator who performed the vaccination;
- (b) **Care instructions** for the injection site;
- (c) **What to expect** for the next 24 hours after the injection has taken place;
- (d) **Vaccine information** (brand of vaccine, batch number, expiry number).

*The PGA has developed an 'After-care Information Card' template; to access please log-onto 'Vaccination Resources' with your MyGuild account details.*

The pharmacist vaccinator must advise the patient to remain on the pharmacy premises for a minimum fifteen (15) minutes post vaccination and must advise the patient of possible risks in leaving earlier than fifteen minutes<sup>26</sup>.

The pharmacist must either observe, or direct an appropriately trained pharmacy staff member to observe, the patient for fifteen (15) minutes post vaccination, to monitor for acute adverse events or anaphylaxis. The pharmacist must make notes in the record of vaccination when a patient leaves the pharmacy premises earlier than fifteen (15) minutes post-vaccination.

*The Pharmacy Guild of Australia have developed 'Consumer Release Form' (Appendix I) which may be used where a consumer leaves within the required 15-minute monitoring period post-vaccination; to access please log-onto 'Vaccination Resources' with your MyGuild account details.*

Pharmacists practising in states other than NSW should follow the relevant standards and regulations of each state and territory regarding post-vaccination care.

## **8.2 Maintaining Continuity of Care**

All vaccinations provided by a pharmacist must have the details uploaded onto the Australian Immunisation Register (AIR)<sup>25</sup>.

Pharmacists practising in states other than NSW should follow the relevant standards and regulations of each State and Territory regarding continuity of care.

## **Section 9 - Management of Adverse Events**

Most adverse events associated with vaccination are minor, such as a mild fever or pain and swelling at the injection site. These should be anticipated and generally require no treatment.

Pre-screening is used to identify those individuals who may be at increased risk of adverse events following vaccination. Pharmacies providing vaccination services must have appropriate procedures in place to inform individuals about the risks associated with vaccination prior to delivery. They will also need to be prepared to provide appropriate advice regarding adverse effects or, in the case of a severe adverse effect, be prepared to manage the patient until further medical help is available.

Pharmacists practising in states other than NSW should follow the relevant standards and regulations of each state and territory regarding management of adverse events.

### **9.1 Emergency Procedures**

In the case of an anaphylactic reaction, pharmacists should be prepared to follow the Emergency Response Protocol (which is to be displayed in the vaccination service area).

The Emergency Response Protocol must be consistent with the Australian Vaccination Handbook for management of the following adverse events:

- Anaphylaxis;
- Allergic reaction;
- Syncope;
- Vasovagal episode.

The vaccination service area must clearly display all the emergency procedures for management of adverse events.

## 9.2 Reporting Adverse Events

Adverse events must be reported to the Immunisation Section of the local Public Health Unit. In NSW call **1300 066 055** to contact your local Public Health Unit.

The **Adverse Medicine Events Line** allows consumers to report minor adverse events by calling **1300 134 237** from anywhere in Australia. The Adverse Medicines Events Line is not for emergencies.

The pharmacist vaccinator should also:

- Record the occurrence on the consumer's as part of the pharmacist's reporting protocol; and
- Report the occurrence to the Therapeutic Goods Administration (TGA), which can be done online at <http://www.tga.gov.au/reporting-problems> or by downloading an Adverse Events Following Immunisation (AEFI) form, available here: <http://www.tga.gov.au/form/national-adverse-events-following-immunisation-ae-fi-reporting-form>

### **AEFI forms can be submitted to the TGA via:**

Email: [adr.reports@tga.gov.au](mailto:adr.reports@tga.gov.au)  
Fax: +61 2 6232 8392  
Mail: Therapeutic Goods Administration  
PO Box 100  
Woden ACT 2606  
Australia

Pharmacists with access to the GuildCare suite of programs may also report adverse events to the TGA via the Adverse Events Recording Service.

Pharmacists practising in states other than NSW should report to recommended bodies as outlined in the relevant standards and regulations of each state and territory.

## Section 10 - Use of a Third-Party Vaccinator Qualified Pharmacist

A community pharmacy that contracts a third party pharmacist vaccinator must ensure that the contracted vaccinator delivers the vaccination service according to the *NSW Pharmacist Vaccination Standards*. The community pharmacy must retain evidence of the third party vaccinator's suitability, including:

- Current AHPRA Pharmacist Registration;
- Current certification having successfully completed a training course accredited in accordance with the Australian Pharmacy Council 'Standards for the Accreditation of Programs to Support Pharmacist Administration of Vaccines' (current version);
- Current HLTAID003 Provide First Aid Statement of Attainment;
- Current HLTAID001 Provide Cardio-Pulmonary Resuscitation Statement of Attainment;
- Current ASCIA Anaphylaxis Training certificate;
- Current Professional Indemnity Insurance;
- Registered and approved by NSW Ministry of Health as a vaccination provider.

## Appendix A - Vaccination Referral form for General Practitioner

The following letter should be used to notify consumer's GP of their eligibility for the National Immunisation Program (NIP).

[Pharmacy Name]  
[Pharmacy Address]  
[Pharmacy contact number]

[Doctor's Name]  
[Surgery Address]

Date:

Dear Dr \_\_\_\_\_,

I am writing to you about [PATIENT NAME] [D.O.B] of [PATIENT ADDRESS].

[PATIENT NAME] is eligible to receive the annual influenza vaccine free of charge as he falls within the NIP eligibility criteria:

- People aged 65 years and over
- Pregnant women
- Aboriginal and Torres Strait Islander people aged 6 years and over
- Aged 6 months and over who has a chronic condition placing them at increased risk of complications from influenza:
  - Have heart disease
  - Have lung disease or asthma
  - Have another chronic illness, including diabetes and renal failure
  - Have chronic neurological condition, including multiple sclerosis and seizure disorders
  - Have an immune compromising condition, including HIV infection

As such, he was not vaccinated at [PHARMACY NAME].

Regards,

[DATE]

(NAME and SIGNATURE OF PHARMACIST)

## Appendix B- Establishing a pharmacist-administered vaccination service procedure

Step	Complete
<p>1. Be familiar with relevant State or Territory legislation, regulations, standards and protocols relating to the pharmacist-administered pharmacy vaccination services and where they can be accessed. <i>Complete sections 1 &amp; 2 in the Vaccination Service Outline</i></p>	<input type="checkbox"/>
<p>2. Ensure appropriate pharmacy indemnity insurance is in place.</p>	<input type="checkbox"/>
<p>3. Ensure staff involved in the provision of the vaccination service is trained as per the pharmacy's <u>Staff Training Procedure</u>. Appropriate staff training for the vaccination service includes:</p> <ol style="list-style-type: none"> <li>a. For all staff involved – must be trained in the pharmacy's procedures (use <u>Vaccination Operations Manual</u>)</li> <li>b. For pharmacist vaccinators - must be permitted to administer vaccines within their jurisdiction and completed an approved course of study and maintains currency of practice to administer vaccines, as well has current First Aid, CPR and Anaphylaxis qualifications</li> <li>c. For pharmacy support staff – must be trained in the pharmacy's procedures, including responding to a medical emergency (anaphylaxis training, First aid and/or CPR qualifications where appropriate).</li> </ol>	<input type="checkbox"/>
<p>4. Establish an appropriate vaccination service room, consulting room or vaccination area within the pharmacy premises. Minimum requirements of the facilities include:</p> <ol style="list-style-type: none"> <li>a. Not permitting the vaccination to be visible or audible to other persons in the pharmacy, ensuring that the patient receives appropriate privacy and confidentiality</li> <li>b. Sufficient space to accommodate the individual, carer (if appropriate), pharmacist vaccinator and all necessary equipment during the service;</li> <li>c. A surface with sufficient space to lay the individual down to safely manage adverse events (if required);</li> <li>d. Seating for the individual and carer (if appropriate) during the vaccination service, and</li> <li>e. Equipment that facilitates the appropriate disposal of sharps and medical waste.</li> </ol> <p><i>Note: A dispensary area, store room, staff room or retail area may not be used as a vaccination service area.</i></p>	<input type="checkbox"/>
<p>5. Ensure the pharmacy premises has:</p> <ol style="list-style-type: none"> <li>a. Hand washing facilities to adequately conduct hand hygiene procedures in accordance with the pharmacy's <u>Infection Control Guideline</u>;</li> <li>b. An area with sufficient seating where an individual may be observed for 15 minutes post-vaccination for adverse events</li> </ol>	<input type="checkbox"/>
<p>6. Ensure the pharmacy has an emergency response protocol, and is displayed within the vaccination service area.</p>	<input type="checkbox"/>
<p>7. Ensure the pharmacy's vaccine refrigerator is compliant with the <u>National Storage Guidelines – Strive for 5</u>. Ensure the pharmacy has a <u>Vaccine management protocol</u> in place, consistent with the <u>National Storage Guidelines – Strive for 5</u>.</p>	<input type="checkbox"/>
<p>8. Procure required equipment to deliver the vaccination service, including:</p> <ol style="list-style-type: none"> <li>a. An anaphylaxis response kit containing: <ul style="list-style-type: none"> <li>• Adrenaline 1:1000 (minimum of three ampoules – check expiry dates);</li> <li>• Minimum of three 1ml syringes and 25mm length needles (for intramuscular injection);</li> </ul> </li> </ol>	<input type="checkbox"/>

Step	Complete
<ul style="list-style-type: none"> <li>• Minimum of 2 (in date) EPI-PEN auto-injector for adults;</li> <li>• Cotton wool swabs;</li> <li>• Pen and paper to record time of administration of adrenaline;</li> <li>• Laminated copy adrenaline doses;</li> <li>• Laminated copy of 'Recognition and treatment of anaphylaxis';</li> </ul> <p>b. Consumables such as (not exhaustive):</p> <ul style="list-style-type: none"> <li>• Antibacterial surface wipes;</li> <li>• Medical waste (sharps) container;</li> <li>• Injection equipment (if appropriate);</li> <li>• Clean cotton wool and hypoallergenic tape;</li> <li>• Soap or hand sanitiser;</li> <li>• Alcohol swabs;</li> <li>• Immunise service identifiers (e.g. stickers);</li> </ul> <p>c. Vaccines – must be procured in accordance with the NSW Poisons and Therapeutic Good Regulation 2008 or other relevant jurisdictional regulations via the Australian pharmacy wholesaler network</p> <p><b>Note: Refer to jurisdictional requirements of each State or Territory</b></p>	
<p>9. Establish an appropriate system to record and store vaccination records for a minimum of seven years; administered vaccinations must be recorded onto the Australian Immunisation Register (AIR). All record keeping must comply with the <u>Australian Privacy Principles</u> and be consistent with the pharmacy's <u>Confidentiality Policy</u> and <u>Inter-Professional Collaboration Guideline</u>. e.g. paper-based system or GuildCare. Records to be stored include:</p> <ul style="list-style-type: none"> <li>• Vaccination record (including pre-screening, consent &amp; record ); <ul style="list-style-type: none"> <li>- Details of notifications;</li> <li>- Details of patient counselling; and</li> <li>- Details of adverse events (if applicable).</li> </ul> </li> <li>• Statement of vaccination; <i>Complete Section 3 in the Vaccination Service Outline</i></li> </ul>	<input type="checkbox"/>
<p>10. Ensure reference material is available, including:</p> <ol style="list-style-type: none"> <li>a. The Australian Immunisation Handbook (current edition);</li> <li>b. National Vaccine Storage Guidelines – Strive for 5;</li> <li>c. Myths and Realities – responding to arguments against vaccination: A guide for health providers;</li> <li>d. PGA – Guidelines for Conducting Pharmacist Initiated and Administered Vaccination Services within Community Pharmacy ;</li> <li>e. PSA – Practice Guidelines for the Provision of Vaccination Services within Pharmacy;</li> <li>f. NSW Pharmacist Vaccination Standards (or Standards relevant to the State or Territory the service is taking place).</li> </ol> <p><i>Complete Section 4 in the Vaccination Service Outline</i></p>	<input type="checkbox"/>
<p>11. Ensure the pharmacy maintains and follows relevant policies and procedures</p> <ol style="list-style-type: none"> <li>a. Incident reporting procedure</li> <li>b. Medical emergency response procedure</li> <li>c. Infection control guideline</li> </ol>	<input type="checkbox"/>

Step	Complete
12. Determine the days and hours of trade the vaccination service will be available to the public, with consideration for additional staffing requirements. <i>Complete Section 5 in the <u>Vaccination Service Outline</u></i>	<input type="checkbox"/>
13. Determine the professional service fee the pharmacy will charge individuals, with consideration for required expenditure. <i>Complete Section 5 in the <u>Vaccination Service Outline</u></i>	<input type="checkbox"/>
14. Promote the vaccination service within the pharmacy, include details of availability. <i>Complete Section 6 in the <u>Vaccination Service Outline</u></i>	<input type="checkbox"/>

## Appendix C - Vaccination Service Outline

Vaccination service outline for \_\_\_\_\_

### Section 1: Aim

The aim of the service is to increase \_\_\_\_\_ vaccination rates in the \_\_\_\_\_ community.

### Section 2 - Legal framework

Vaccine available: \_\_\_\_\_

Exclusions: \_\_\_\_\_

Legislation: \_\_\_\_\_

Regulation: \_\_\_\_\_

Standard: \_\_\_\_\_

### Section 3 - Pharmacy vaccination record system:

*Provide details of record system to be used, including how vaccination records will be stored securely and backed up (in the case of electronic records)*

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

### Section 4 - Reference material

*Provide details of how reference materials can be accessed:*

\_\_\_\_\_  
\_\_\_\_\_

### Section 5 - Service details:

*Service fee:* \_\_\_\_\_

*Provide details of when and how the vaccination service will be conducted:*

*Staff roster:*

\_\_\_\_\_  
\_\_\_\_\_

*Pharmacist vaccinator :* \_\_\_\_\_

*Pharmacist on duty (during vaccination service):* \_\_\_\_\_

*Staff member in charge of bookings:* \_\_\_\_\_

*Additional staff member with CPR and First Aid qualifications:* \_\_\_\_\_

### Section 6 - Promotion/advertising:

*Provide details of how the service will be promoted*

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## Appendix D- Delivering a pharmacist-administered vaccination service

### Identifying and initiating a pharmacist-administered vaccination service

1. Identify individuals who may benefit from an in-pharmacy vaccination service.
2. Discuss the vaccination service, including risks and benefits of the vaccination to be provided, possible adverse events, and requirement to remain within the pharmacy premises for 15 minutes post vaccine administration. *Note: Influenza information leaflets may be used to guide discussions.*
3. If the service is not being offered at the time of identification, make a record of the appointment, complete a booking form and advise individual of date and time of appointment.
4. Provide the individual with a *Vaccination Record Form*; the individual should complete the pre-screening and consent components.
5. Check the individual's eligibility for the service by reviewing the completed *Vaccination Record Form* and vaccination history (where possible).
  - a. If the individual is not eligible, refer to their medical practitioner or primary health care provider using the *Vaccination Referral Form (Appendix A)*
  - b. If the individual is eligible for the service, proceed with the vaccine administration.

### Delivering a pharmacist-administered vaccination service (within the vaccination service area):

6. Ensure the vaccination service area is clean and presentable.
7. Perform hand hygiene as per the pharmacy's *Infection Control Guideline*.
8. Assemble all required equipment.  
**Note:** Do not remove vaccine from refrigerator until immediately before administering the vaccine.
9. Reconfirm the individual's identify and vaccine to be administered against the *Vaccination Record Form*. Answer any final questions the individual may have regarding the service.
10. Determine the appropriate vaccine injection site and clean skin if necessary.
11. Remove the vaccine from the refrigerator and prepare the vaccine for administration (check expiry date and physical appearance of vaccine).
12. Administer the vaccine to the individual and dispose of used equipment according to the pharmacy's *Infection Control Guideline (including management of medical waste, sharps disposal and needle stick injuries)*.
13. Complete the Pharmacy vaccination record section of the individual's *Vaccination Record Form* including:
  - a. The individual's name, address, date of birth and contact details;
  - b. The name and contact details of the person's primary medical practitioner;
  - c. The vaccine, brand name, batch number and expiry date of the vaccine;
  - d. The site of injection;
  - e. The pharmacist's name and contact details and his or her certificate of accreditation number;
  - f. The address of the pharmacy at which the vaccination was administered, and
  - g. A unique reference number for the supply and administration.

*Note: Vaccination Record Form must be retained for a minimum of seven years.*

14. Provide immediate post-vaccination care:
  - a. Counsel the individual on post-vaccination care, including possible adverse events following vaccination.  
**Note:** *Information leaflets may be used to guide discussions.*

- b. Advise the individual to remain within pharmacy premises for 15 minutes for observation.  
**Note:** *Information leaflets may be used to guide discussions.*
  - c. Use discreet vaccination service identifiers (e.g. sticker) to support quick identification of individual within the pharmacy premises who may require immediate attention.
  - d. If the individual wishes to leave the pharmacy premises early, counsel individual on possible risks and make appropriate notes within the individual's vaccination record and use The PGAs 'Consumer Monitoring Early Release Form' (Appendix I).
15. If an adverse event occurs:
- a. Provide acute management within scope of competence and professional knowledge.  
**Note:** *Laminated Emergency Response Protocol must be displayed in the vaccination area.*
  - b. If appropriate, refer to a medical practitioner for ongoing management
  - c. After the adverse event is appropriately managed:
    - Record details of adverse event in the individual's vaccination record.
    - Notify the local NSW Public Health Unit on **1300 066 055**
    - Report the incident to the TGA via email to [adr.reports@tga.gov.au](mailto:adr.reports@tga.gov.au) or fax +61 2 6232 8392
16. Complete a post-vaccination information form (e.g.: the PGAs 'After Care Card') and provide to the patient
17. All details of the vaccination must be recorded onto the Australian Immunisation Register
18. Store records of relevant vaccination documentation as per the pharmacy vaccination record system for minimum 7 years

## Appendix E - Maintaining and monitoring a pharmacist-administered vaccination service

Step	Date							
1. Clean the vaccination service area daily, ensuring the area remains free from stock and is presentable.								
2. Ensure the pharmacy's <u>Vaccine Management Protocol</u> is adhered to, and the pharmacy's vaccine refrigerator temperature is recorded twice daily.								
3. Ensure the pharmacy's vaccine refrigerator is maintained, which may include: <ol style="list-style-type: none"> <li>a. Having the vaccine refrigerator tested yearly via the PGA Cold Chain Testing Centre</li> <li>b. Having the refrigerator serviced every 12 months</li> <li>c. Conducting a self-audit at least every 12 months.</li> </ol>								
4. Replenish consumables as required, including expired adrenaline injections.								
5. Check currency of pharmacist vaccinator certification/qualifications on a yearly basis using the vaccination training record checklist. If qualifications have lapsed, facilitate required training to maintain certification as per the pharmacy's <u>Staff Training Procedure</u> .								
6. Check references and resources are current on a yearly basis; replace superseded references with current versions.								
7. Review all relevant policies, procedures, forms and templates within the Vaccination Service Operations Manual on an annual basis for quality assurance purposes.								

## Appendix F - Needle stick Injury procedure Example

To be included the Policies and Procedures manual for the Vaccination Service.

### Immediate actions for a needle stick injury or exposure

- Stay calm.
- Immediately after a needle stick injury or blood/body substance exposure, take the following action:
  - If the skin is penetrated, wash the area well with soap and running water (alcohol-based hand rubs or wipes can be used when soap and water are not available);
  - If blood contacts the skin, irrespective of whether there are cuts or abrasions, wash well with soap and water;
  - If the eyes are contaminated, rinse the area gently with water or normal saline solution while the eyes are still open;
  - If blood gets into the mouth, spit it out and then rinse the mouth with water several times.
- Pat-dry the area around a skin penetration injury and apply a sterile adhesive dressing.
- Ensure the needle/syringe involved in the injury is safely collected in a secure container using established procedures.
- Report the injury immediately to the Pharmacist in Charge or WHS Officer. In all instances where the skin is penetrated or blood or body substances enter the mouth, nose, eyes or any cuts or abrasions, the affected person is to receive medical advice from a registered health professional as soon as possible.
- Complete the appropriate workplace injury form.

### Reducing risks after exposure

The Pharmacist in Charge or WHS Officer should quickly act to:

- Ensure that the exposed area has been washed thoroughly.
- Ensure that the needle, syringe, or other sharp that caused the needle stick injury has been safely placed into a sharps container for appropriate disposal.
- Ensure that the employee is provided with immediate medical advice by a registered health professional. Advice and appropriate risk exposure counselling/treatment may be obtained through the Accident and Emergency department of a local hospital, the employee's own doctor, or the pharmacy's nominated doctor.
- Reassure the employee.
- Offer support and trauma counselling through the appropriate agencies.
- Investigate the circumstances of the accident or incident.
- Take measures to prevent recurrence. This may include changes to work practices, changes to equipment, and/or training. It is important that the confidentiality of the employee and details of the type of exposure be maintained.
- Ensure that the appropriate workplace injury form has been completed in the time required<sup>30</sup>.

## Appendix G - Sharps Waste Disposal Policy

To be included in the Policies and Procedures manual for the Vaccination Service.

A pharmacy conducting a vaccination service is legally responsible for the safe disposal of all sharps generated in the provision of the service. Sharps waste must be collected from the pharmacy and disposed of by a company licensed to handle the safe removal and destruction of sharps.

The immunising pharmacy must use sharps containers that comply with *AS 4031-1992 Non-reusable containers for the collection of sharp medical items used in health care areas*.

Pharmacies conducting a vaccination service must comply with Clause 25 and Clause 27 of the Public Health Regulation 2012.

### Clause 25: Premises must have sharps containers and supply of sterile disposable needles

- (1) If skin penetration procedures that involve the use of sharps are carried out at the premises, there must be an appropriate sharps container at the premises.
- (2) If skin penetration procedures that involve the use of needles are carried out at the premises, there must be an adequate supply of sterile disposable needles at the premises.
- (3) In this clause **'appropriate sharps container'** means:
  - (a) If skin penetration procedures that involve the use of reusable sharps are carried out at the premises-a sharps container that complies with *AS/NZS 4261:1994 Reusable containers for the collection of sharp items used in human and animal medical applications*; or
  - (b) If skin penetration procedures that involve the use of non-reusable sharps are carried out at the premises-a sharps container that complies with *AS 4031-1992 Non-reusable containers for the collection of sharp medical items used in health care areas* .

### Clause 27: Use of needles, sharps and other articles

- (1) A person who carries out a skin penetration procedure must not use a needle that has previously been used in a skin penetration procedure.
- (2) A person who uses a needle in a skin penetration procedure must dispose of the needle in the appropriate sharps container immediately after completing the procedure.
- (3) A person who uses any article in a skin penetration procedure that is manufactured for a single use only must dispose of the article immediately after completing the procedure.
- (4) A person who uses a non-reusable sharp in a skin penetration procedure must dispose of the sharp in the appropriate sharps container immediately after completing the procedure.
- (5) A person must not use an article that may penetrate the skin of a person in a skin penetration procedure unless it is clean and has been sterilised and kept in a sterile environment.
- (6) A person must not use an article in a skin penetration procedure if the article has previously been used in a skin penetration procedure but did not penetrate the skin of the person undergoing the previous procedure unless the article has been cleaned and kept in a clean condition.
- (7) In this clause, **'appropriate sharps container'** means a sharps container that complies with *AS 4031-1992 Non-reusable containers for the collection of sharp medical items used in health care areas*.

## Appendix H - Staff Training Record

This form can be used to ensure that all pharmacists who provide the vaccination service are properly trained and have the required qualifications in accordance with these guidelines.

Pharmacists							
Staff Member	AHPRA Registration Number	Registration Expiry	Accredited Training Course Number and Date of Completion	First Aid Certificate Provider/Certificate Number/Date Completed	CPR certificate provider/certificate number/date completed	Anaphylaxis certificate provider/certificate number/date completed	

Staff				
Staff Member's Name	Position	Trained to Assist Completion of Screening/Consent form (date)	First Aid Certificate provider/certificate number/date completed	CPR certificate provider/certificate number/date completed

## Appendix I - Consumer Monitoring Release form

The following form may be used where a consumer leaves within the required 15-minute monitoring period post-vaccination.

### VACCINATION MONITORING RELEASE FORM

Dear [CONSUMER NAME]

We would like to thank you for having your vaccination at our pharmacy with our pharmacist vaccinator.

As you are aware, this pharmacy requires you to remain within the vicinity of the vaccination room for a period of 15 minutes for monitoring of any possible adverse events that may occur after your vaccination.

You have advised our vaccinator that you are unable to remain within the vicinity of the vaccination room and that you need to leave the pharmacy.

Prior to leaving our pharmacy today, please complete the following and hand back to your vaccinator.

I, *(insert name of patient AND patient address)* \_\_\_\_\_

---

Confirm that I have been asked to remain within the vicinity of the vaccination room by the vaccinator and have had the reasons explained why this should occur, and I confirm that I am unable to do so.

I confirm that I have been provided the following information in relation to the vaccination I have received today. I have received:

- (a) An after care card providing information about my vaccination today, how to care for the site of my vaccination and what to expect in the next 24 hours
- (b) Contact information for the TGA self-reporting hotline for adverse events that may occur from the vaccination I have received today
- (c) Advice as to where to obtain further information about the vaccination I have received today
- (d) Advice that if a severe adverse event occurs to contact 000 immediately

I confirm that I feel well and that I do not currently have any signs or symptoms of an adverse event from the vaccination I have received today.

**Consumer Name [PRINT]:**

**Consumer Signature:**

Date: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

#### Pharmacist vaccinator use only

I, the pharmacist vaccinator, confirm that \_\_\_ [NAME OF PATIENT] has received a vaccination today and has left the vicinity of the vaccination room during the 15 minute observation period, against professional advice.

**Vaccinator Name [PRINT]:**

**Vaccinator Signature:**

Date: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

## Other Useful Information

### Health Authorities within Australia

The following table should be used to report any adverse events occurring after a vaccination by a pharmacist.

State/Territory	Report adverse events to	Contact information
ACT	ACT Health	02 6205 2300
NSW	NSW Public Health units	1300 066 055 (For connection to local public health unit)
VIC	SAFEVIC	03 9345 4143
QLD	Queensland Health or complete AEFI initial report on Queensland Health website	07 3328 9888
TAS	TGA	1800 044 114
NT	NT Department of Health	08 8922 8044
SA	Immunisation Section, Department of Health	1300 232 272
WA	WAVSSS	08 9321 1312

### State/Territory Communicable Disease Control

State/Territory	Contact Information
ACT	Health Protection Service: 02 9205 2155 After Hours : 02 9962 4155
NSW	Local public health unit: 1300 066 055
VIC	Health Department: 03 1300 651 160
QLD	Communicable Disease Centre: 07 3328 9724 07 3328 9728 Email: <a href="mailto:cdu.online@health.qld.gov.au">cdu.online@health.qld.gov.au</a>
TAS	03 6222 7666 or 1800 671 738
NT	Communicable Disease Centre: Darwin – 08 8922 8044 Alice Springs – 08 8951 6906 Katherine – 08 8973 9049 Barkly – 08 8962 4259 East Arnhem – 08 8987 0357
SA	Communicable Disease Control Branch (24 hour line): 1300 232 272
WA	Communicable Disease Control Directorate: 08 9222 0255 After Hours Emergency Phone: 08 9328 0553 Email: <a href="mailto:cdc@health.wa.gov.au">cdc@health.wa.gov.au</a>

## State and Territory Drugs and Poisons Legislation

The following should be used to ensure that pharmacies are up to date with correct drugs and poisons legislation. All staff working within the vaccination service should be aware of how to utilise this information.

State/ Territory	Act	Regulation
ACT	Medicines, Poisons and Therapeutic Goods Act 2008 <a href="http://www.legislation.act.gov.au">www.legislation.act.gov.au</a>	Medicines, Poisons and Therapeutic Goods Regulation 2008 <a href="http://www.legislation.act.gov.au">www.legislation.act.gov.au</a>
NSW	Poisons and Therapeutic Goods Act 1966 <a href="https://www.legislation.nsw.gov.au/#/view/act/1966/31">https://www.legislation.nsw.gov.au/#/view/act/1966/31</a>	Poisons and Therapeutic Goods Regulation 2008 <a href="https://www.legislation.nsw.gov.au/#/view/regulation/2008/392/full">https://www.legislation.nsw.gov.au/#/view/regulation/2008/392/full</a>
VIC	Drugs, Poisons and Controlled Substances Act 1981 <a href="https://www2.health.vic.gov.au/alcohol-and-drugs/aod-policy-research-legislation/aod-legislation/drugs-and-poisons-act">https://www2.health.vic.gov.au/alcohol-and-drugs/aod-policy-research-legislation/aod-legislation/drugs-and-poisons-act</a>	Drugs, Poisons and Controlled Substances Regulations 2017 <a href="http://www.legislation.vic.gov.au/Domino/Web_Notes/LDMS/PubStatbook.nsf/b05145073fa2a882ca256da4001bc4e7/C3217A0343C6A914CA25812200151801/\$FILE/17-029sra%20authorised.pdf">http://www.legislation.vic.gov.au/Domino/Web_Notes/LDMS/PubStatbook.nsf/b05145073fa2a882ca256da4001bc4e7/C3217A0343C6A914CA25812200151801/\$FILE/17-029sra%20authorised.pdf</a>
QLD	Health Act 1937 <a href="https://www.legislation.qld.gov.au/view/html/inforce/current/act-1937-031">https://www.legislation.qld.gov.au/view/html/inforce/current/act-1937-031</a>	Health (Drugs and Poisons) Regulation 1996 <a href="https://www.legislation.qld.gov.au/view/pdf/2017-10-01/sl-1996-0414">https://www.legislation.qld.gov.au/view/pdf/2017-10-01/sl-1996-0414</a>
TAS	Poisons Act 1971 <a href="https://www.legislation.tas.gov.au/view/html/inforce/current/act-1971-081">https://www.legislation.tas.gov.au/view/html/inforce/current/act-1971-081</a>	Poisons Regulations 2008 <a href="https://www.legislation.tas.gov.au/view/html/inforce/current/sr-2018-079">https://www.legislation.tas.gov.au/view/html/inforce/current/sr-2018-079</a>
NT	Medicines, Poisons and Therapeutic Goods Act 2012 <a href="https://legislation.nt.gov.au/en/legislation/medicines-poisons-and-therapeutic-goods-act-2012">https://legislation.nt.gov.au/en/legislation/medicines-poisons-and-therapeutic-goods-act-2012</a>	Medicines, Poisons and Therapeutic Goods Regulations 2014 <a href="https://legislation.nt.gov.au/Legislation/MEDICINES-POISONS-AND-THERAPEUTIC-GOODS-REGULATIONS-2014">https://legislation.nt.gov.au/Legislation/MEDICINES-POISONS-AND-THERAPEUTIC-GOODS-REGULATIONS-2014</a>
SA	Controlled substances ACT 1984 <a href="https://www.legislation.sa.gov.au/LZ/C/A/CONTROLLED%20SUBSTANCES%20ACT%201984.aspx">https://www.legislation.sa.gov.au/LZ/C/A/CONTROLLED%20SUBSTANCES%20ACT%201984.aspx</a>	Controlled Substances (Poisons) Regulations 2011 <a href="https://www.legislation.sa.gov.au/LZ/C/R/Controlled%20Substances%20(Poisons)%20Regulations%202011.aspx">https://www.legislation.sa.gov.au/LZ/C/R/Controlled%20Substances%20(Poisons)%20Regulations%202011.aspx</a>
WA	Medicines and Poisons Act 2014 <a href="https://www.legislation.wa.gov.au/legislation/statutes.nsf/law_a147008_currencies.html">https://www.legislation.wa.gov.au/legislation/statutes.nsf/law_a147008_currencies.html</a>	Western Australia Poisons Regulation 2016 <a href="https://www.legislation.wa.gov.au/legislation/statutes.nsf/main_mrtitle_13861_homepage.html">https://www.legislation.wa.gov.au/legislation/statutes.nsf/main_mrtitle_13861_homepage.html</a>

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