



The Pharmacy
Guild of Australia

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T R A I N I N G

***Guidelines for Conducting
Pharmacist Initiated and
Administered Vaccination Service
within a New South Wales
Community Pharmacy Environment***

April 2016

Document Owner

This document has been prepared by the Pharmacy Guild of Australia (NSW Branch)

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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 Environment.

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Disclaimer

This document is designed to provide guidance to pharmacists on the implementation of Pharmacist Initiated and Administered Influenza 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.

The Pharmacy Guild of Australia or any person involved with the preparation and development of these *Guidelines* does not accept liability for any loss that users of these *Guidelines* may suffer as a result of the information contained therein. While every effort has been made to ensure all content is accurate and current as at time of writing, please contact the Pharmacy Guild of Australia, NSW Branch if any error is detected.

A message from the NSW Acting Branch President

Dear Pharmacists

It gives me great pleasure to introduce the second edition of The Pharmacy Guild of Australia's *Guidelines for Conducting Pharmacist Initiated and Administered Vaccination Service within a New South Wales Community Pharmacy Environment*.

The first edition of the *Guidelines*, developed in consultation with various local Health Ministries and supported by results from the successful Queensland Pharmacist Immunisation Pilot (QPIP), were more broadly focused than this edition. During 2015 and the first quarter of 2016, a number of Australian jurisdictions granted the right to pharmacists to initiate and administer influenza vaccinations, and this second edition of the *Guidelines* focuses more specifically on New South Wales.

In Australia under the National Immunisation Program, a number of target groups, including those over 65 years of age, are eligible to receive free influenza vaccine. There are indications, however, that large numbers of eligible people remain unvaccinated, even though influenza vaccinations for older people have been demonstrated to reduce hospitalisations and deaths¹.

A Productivity Commission report on Government Services on vaccination published in 2012 reported that statistics have remained largely unchanged over the years and that in 2009, only 74.6% of eligible people were fully vaccinated against influenza², while only 21.1% of people in NSW aged between 18-64 years received a seasonal influenza vaccination in 2009³

Similar indicators were found in the 2004 Influenza Vaccination Survey, which estimated that 79 percent of Australians aged 65 years and over were vaccinated against influenza, however only 42% of Australian adults younger than 65 with high risk conditions were being vaccinated against influenza. If coverage in this group could be increased to a level comparable to the over 65 group, there would be a significant redirection in hospitalisations and deaths due to influenza infection and related complications.⁴ Those suffering from various circulatory, respiratory and immuno-suppressed conditions constitute a group of people at further risk from influenza and its complications. Of these, 49.3% in NSW were vaccinated in 2009. The vaccination rate of those at risk, but not in the target age group for funded vaccine (adults aged 18-64 years old) was only 36.2%.

Influenza vaccination has been shown to reduce hospitalisation and death, particularly among susceptible groups. Multiple studies show that the influenza vaccine decreases the incidence of cardiovascular events by 20-70 percent;⁵ reduces hospitalisations for diabetes by 70 percent during epidemic periods;⁶ and reduces death among those with cystic fibroses and advanced kidney disease.^{7,8}

In NSW in 2009-2010, 0.7 hospital separations per 1,000 people were recorded for vaccine-preventable conditions and nationally, influenza and pneumonia accounted for 73.7 percent of hospital separations for vaccine-preventable conditions⁹.

The Australian Institute of Health and Welfare further reports that over 80 percent of Australian hospital admissions for confirmed or suspected influenza occur in those aged under 65 years.¹⁰

¹ Productivity Commission Report on Government Services 2012 11.67

² Productivity Commission Report on Government Services 2012 – pp11.67

³ Australian Institute of Health and Wellbeing – 2009 Adult Vaccination Survey March 2011 – p12

⁴ Evidence-Practice gaps report Volume 2 National Institute of Clinical Studies 2005 (Source: Guild Road Map)

⁵ Madjid M *et al.* Influenza and atherosclerosis: vaccination for cardiovascular disease prevention. *Expert Opin Biol Ther* 2005;**5**: 91-96

⁶ Nicholson KG, Snacken R, Palace AM. Influenza immunisation policies in Europe and the United States. *Vaccine* 1995; **13**:365-9

⁷ Gross PA, Denning CR, Gaerlan PF *et al.* Benefit of annual influenza immunisation in patients with cystic fibrosis. *Vaccine* 2006; **14**(13):1280-1284

⁸ Kuasz A, Pahari D. The value of vaccination in chronic kidney disease. *Semin Dial* 2004; **17**(1):9-11

⁹ Productivity Commission Report on Government Services 2012 – pp11.70

¹⁰ ISG Media Release 29 March 2010

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.”¹¹

The economic loss suffered by industry and individuals is also significant with a 1996 study indicating that influenza results in an estimated 1.5 million work days lost annually in Australia.¹² The influenza vaccine also has clear economic benefits, with studies showing it can decrease total winter absenteeism in the workplace by 36 percent.¹³

It makes sense for community pharmacy to fill vaccination gaps and to reduce health risks, levels of hospitalisation and economic loss in the community.

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 a doctor’s appointment and attending the GP’s practice;
- the cost involved in visiting a GP. In NSW, about 8% of people over 15 in any year defer or don’t visit a GP due to cost considerations alone¹⁴, 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 flu vaccines supplied and administered in a pharmacy setting which offers savings and convenience.

Community Pharmacy delivers the most accessibility of all health professionals through a network of over 1,800 pharmacies in urban, regional and rural NSW. Many community pharmacies are open after hours and on weekends which provides for ease of access, particularly out of office hours.

In a study of vaccination in pharmacy by Grabestien et al (2001)¹⁵ a survey of respondents compared the pharmacy with other sources of vaccination. Overall:

- 84% thought the pharmacy was easier to get to;
- 68% that the pharmacy was closer than other vaccine providers;
- 70% that the hours of vaccine availability were more convenient than those of other vaccine providers, and
- 24% that the cost was more reasonable.

By providing vaccination services, community pharmacy may also generate increased opportunistic vaccination, particularly for people who do not visit GP’s and whether from high risk population groups or not.

Apart from directly increasing vaccination coverage, vaccination by pharmacists in community pharmacy generates other benefits, including reduction of workloads and waiting times in General Practices; reduction in Medicare spending on consultations and hospitalisation; an increased capacity to address future pandemics, and support of public health immunisation initiatives that educate and counsel patients, while addressing their concerns and immunisation needs.

The benefits of increased vaccination 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.

¹¹ ISG Fact Sheet: Influenza 2012

¹² ISG Fact Sheet: The Impact of Influenza 2012

¹³ Nichol KL, Lind A, Moargolis KL *et al.* the effectiveness of vaccination against influenza in healthy working adults. *New England Journal of Medicine* 1995; 333(14); 889-893, 5 Oct 1995

¹⁴ Productivity Commission Report on Government Services 2012 11.32

¹⁵ http://www.medscape.com/viewarticle/406710_1

Offering a vaccination service in your community pharmacy is an exciting clinical and professional opportunity for all pharmacists in New South Wales and The Pharmacy Guild of Australia is proud to offer its ongoing support of this important Government health initiative.

Sincerely

A handwritten signature in black ink, appearing to read 'Mark Douglass', with a long horizontal flourish extending to the right.

Mark Douglass
Acting President
The Pharmacy Guild of Australia (NSW Branch)

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Abbreviations and Terminology

| | |
|-----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEFI | Adverse Event Following Immunisation – an unwanted reaction following administration of a vaccine, which may or may not be caused by the vaccine. |
| AHPRA | Australian Health Practitioner Regulation Agency |
| Anaphylaxis Response Kit | Anaphylaxis response equipment as described in the current edition of the <i>Australian Immunisation Handbook</i> . |
| ASCIA | Australasian Society of Clinical Immunology and Allergy |
| Australian Immunisation Handbook | The <i>Australian Immunisation Handbook</i> was in its tenth edition at the time of writing. Always refer to the current edition of the handbook, as it may have changed since time of writing. Find the latest edition at www.health.gov.au . |
| CMI | Consumer Medicines Information |
| CPR | Cardiopulmonary resuscitation |
| GP | General Practitioner |
| Guidelines | This document: Guidelines for conducting pharmacist initiated and administered vaccinations |
| Immunisation | The process of inducing immunity to an infectious agent by administering a vaccine. |
| Immunity | The ability of the body to fight off certain infections as a result of vaccination or previous infection. |
| Nurse Immuniser | A registered nurse who is certified to deliver vaccinations in accordance with State or Territory regulations |
| PGA | The Pharmacy Guild of Australia |
| Pharmacy | A business premise containing a dispensary approved to prepare, preserve, compound and dispense medicines |
| Pharmacist Vaccinator | An appropriately trained and registered pharmacist certified to provide vaccination services in accordance with State or Territory regulations |
| Pharmacy Vaccination Service | Any vaccination service delivered in a pharmacy by a vaccinator. |
| Pharmacy Staff | Any person who works in the pharmacy, including pharmacist. |
| Primary Healthcare Provider | Primary healthcare professional responsible for the consumer's care. |
| PSA | The Pharmaceutical Society of Australia |
| QCPP | The Quality Care Pharmacy Program |
| TGA | Therapeutic Goods Administration |
| Third-party provider | A vaccinator delivering vaccination services within a community pharmacy under a contract arrangement. |
| Vaccination | The administration of a vaccine. If vaccination is successful, it results in immunity to a pathogen. |
| Vaccinator | An appropriately trained and registered health practitioner certified to provide vaccination services in accordance with State or Territory regulations. |
| Vaccine | The material used for vaccination, including extracts of killed viruses or bacteria, or live weakened strains of viruses or bacteria. |
| WHS | 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.¹⁶ By law, every Pharmacy must have an AHPRA registered pharmacist on duty at all times during hours of trade.¹⁷ With over 5,300 well-distributed community pharmacies throughout Australia, many operating with extended trading hours and approximately 20% of these located in regional and remote areas, community pharmacies are an integral component of the health system.¹⁸

The high standard 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.¹⁹

This reinforces the value of community pharmacy as the most accessible site to deliver vaccination services.

1.2 International Experience of Pharmacist Administered Vaccination Services

Pharmacist administered vaccinations have long been accepted overseas. Vaccination services in community pharmacy are a proven service in the US, the UK, Ireland, some Canadian provinces and in 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 states²⁰ in accordance with state-specific prescribing arrangement such as written or verbal prescriptions, standing orders, protocols or collaborative agreements. More than 150,000 pharmacists are now trained to administer vaccinations and vaccination training for pharmacists is provided by both the American Pharmacists Association (APhA) and the universities.

Since 2002 pharmacists in the United Kingdom have been authorised to administer certain vaccines, including influenza through a Patient Group Direction (PGD) without the requirement for a patient-specific prescription written by a medical practitioner. In 2010, the NHS in Wales carried out an extensive review of the experience available on the delivery of vaccination services through pharmacies.²¹ It focused on the provision of the seasonal influenza vaccination through pharmacies and demonstrates the service has increased vaccination uptake and has been well received by patients.

In Canada, trained pharmacists in British Columbia, Alberta and New Brunswick are able to administer vaccinations. To ensure competence, registered pharmacists in British Columbia must complete training from a College of Pharmacists' approved, accredited training program and possess current certification in CPR and first-aid from a recognised provider.

In Ireland following changes to legislation in October 2001, pharmacists can participate in the Seasonal Influenza Vaccination Service. Over 1,200 Irish pharmacists are trained to provide an influenza vaccination

¹⁶Pharmacy Guild of Australia, *Public Support for community pharmacy*, February 2014, retrieved from:

<http://www.guild.org.au/docs/default-source/public-documents/issues-and-resources/fact-sheets/public-support-for-community-pharmacy>

¹⁷Pharmacy Council of New South Wales, *The Guide*, August 2014, retrieved from:

<http://www.hpca.nsw.gov.au/Pharmacy-Council/Pharmacies/The-Guide/default.aspx>

¹⁸Pharmacy Guild of Australia, *Rural and Indigenous Health* [webpage], 2015, retrieved from:

<http://www.guild.org.au/issues-resources/rural-and-indigenous-health-policy>

¹⁹Menzies Centre for Health Policy, *The Menzies-Nous Australian health survey 2012*, 23 October 2012, retrieved from:

<http://sydney.edu.au/medicine/public-health/menzies-health-policy/research/Menzies-NousAustralianHealthSurveyReport2012.pdf>

²⁰Traynor K. With Maine on board, pharmacists in all 50 states can vaccinate. *American Journal of Health-System Pharmacy* 2009; 66:1892-94

²¹<http://www.wales.nhs.uk/sitesplus/888/news/17071>

service and as of October 2011 over 400 pharmacists have signed up with the Pharmaceutical Society of Ireland (the pharmacy regulator) to provide the service.²²

The New Zealand Ministry of Health authorised 22 pharmacists as vaccinators in 2012²³ and at the time of writing, its community pharmacy vaccination program has continued to expand.²⁴

1.3 Australian Developments

As community pharmacy models evolved to meet the changing needs of the public, some community pharmacies introduced vaccination services utilising nurse vaccinators.²⁵

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 the practice of a pharmacist, subject to the provision of appropriate training and standards.²⁶ Since that time, Australian states and territories have amended regulations to allow appropriately trained pharmacists to conduct vaccination services in the Northern Territory²⁷, Western Australia²⁸, South Australia²⁹, New South Wales³⁰, Tasmania³¹ and the Australian Capital Territory³².

Progress in Queensland has also been made. In 2014, a trial of pharmacist-administered vaccinations saw over 10,000 influenza vaccinations delivered. 97% of patients evaluated would recommend the service to others and 96% were completely satisfied with the overall vaccination experience.³³ So successful was the trial that in July 2014, the trial was extended to cover other vaccinations including measles/mumps/rubella and whooping cough for adults.³⁴ At the time of writing, the Queensland Pharmacists Immunisation Pilot (QPIP) continues.³⁵

1.4 Quality Assurance in Community Pharmacy

Community pharmacies provide high quality and consistent professional services to the public. Over 90% of Australian community pharmacies are accredited under the Quality Care Pharmacy Program (QCPP), a structured quality management system (Australian Standard 85000:2001).³⁶ 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.³⁷

²²http://www.thepsi.ie/gns/pharmacy-practice/current-developments/Seasonal_Influenza_Vaccination.aspx

²³<http://www.nzdoctor.co.nz/in-print/2011/september-2011/7-september-2011/pharmacy-flu-jab-gig-leaves-gps-puzzled.aspx>

²⁴New Zealand Medicines and Medical Devices Safety Authority 14 January 2016

<http://www.medsafe.govt.nz/profs/class/ReclassificationOfVaccines.asp>

²⁵[http://www.chemmart.com.au/healthservices/in-store-health-services/flu/;](http://www.chemmart.com.au/healthservices/in-store-health-services/flu/)

<http://www.terrywhitechemists.com.au/healthprograms/index/detail/?id=598>

²⁶Pharmacy Board of Australia Communique 5 December 2013 <http://www.pharmacyboard.gov.au/News/Communiqués.aspx>

²⁷ Northern Territory Government, Medicines and Therapeutic Goods Act (NT) s62

http://www5.austlii.edu.au/au/legis/nt/consol_act/mpatga379/s62.html

²⁸ Government of Western Australia, Department of Health *Pharmaceutical Services Branch Information Bulletin December 2014*

http://www2.health.wa.gov.au/Articles/F_I/Information-for-pharmacists-pharmacist-vaccination

²⁹<http://www.sahealth.sa.gov.au/wps/wcm/connect/ea1c9b0040741be0959db7a05d853418/Vaccine+Administration+Code-++January+2015+pdf.pdf?MOD=AJPERES&CACHEID=ea1c9b0040741be0959db7a05d853418>

³⁰NSW Ministry of Health Pharmacist Vaccination Standards 5 June 2015

<http://www.health.nsw.gov.au/pharmaceutical/Documents/pharmacist-vacc-standards.pdf>

³¹ http://www.premier.tas.gov.au/releases/access_to_flu_vaccine

³²http://www.cmd.act.gov.au/open_government/inform/act_government_media_releases/meegan-fitzharris-mla-media-releases/2016/canberra-pharmacists-ready-to-offer-vaccines-this-flu-season

³³ Pharmacy Guild of Australia, *Vaccination in Community Pharmacy*. Retrieved from: <https://www.guild.org.au/docs/default-source/member-documents/issues-and-resources/Policy-and-Position-Statements/20141126-vaccination-in-community-pharmacy.pdf?sfvrsn=0>

³⁴ Queensland Government, Queensland Cabinet and Ministerial Directory, *Pharmacy vaccination trial broadened*, 9 July 2014. Retrieved from: <http://statements.qld.gov.au/Statement/2014/7/9/pharmacy-vaccination-trial-broadened>

³⁵ <http://www.guild.org.au/news-page/2015/12/17/pharmacy-vaccinations-a-quiet-revolution>

³⁶Quality Care Pharmacy Program, *15 Years of Excellence*, 2013. Retrieved from: <http://www.qcpp.com/docs/librariesprovider4/public-documents/about-qcpp/15-years-web-220713.pdf?sfvrsn=0>

³⁷ Quality Care Pharmacy Program, *What is QCPP*, retrieved from: <http://www.qcpp.com/about-qcpp/what-is-qcpp>

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 that they comply with the *NSW Pharmacist Vaccination Standards* or standards set by the relevant state or territory.

In some areas of the *T3M Hosting Vaccination Services in Pharmacy Checklist*, the *NSW Standards* have strengthened requirements. An important example is the area where the vaccination is to be conducted. The *Standards* state that the vaccination service room, consulting room or vaccination 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.

The QCPP checklist states facilities to support the vaccination service must be at least 4 square metres to ensure that if required in an emergency, a patient could lie down on the ground

The *Standards* state that the vaccination service room, consulting room or vaccination area of the pharmacy premises must:

- 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.

The QCPP checklist states pharmacies need to ensure there is 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.

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 vaccination vary between State and Territory jurisdictions and when reading these Guidelines, it should be remembered that they are tailored to *NSW Pharmacist Vaccination Standards*. Pharmacists practising in other jurisdictions should refer to the relevant equivalent standards and regulations in those jurisdictions.

Pharmacist vaccinators must ensure they are aware of the National Vaccination Program (NIP) that provides free vaccines to people who fall into the following categories:

- People aged 65 years and over
- Aboriginal and Torres Strait Islander people from 15 years of age
- Pregnant women
- Influenza vaccine is free to people six months and over who:
 - Have heart disease
 - Have lung disease or asthma
 - Have another chronic illness, including multiple sclerosis and seizure disorders
 - Have an immune compromising condition, including HIV infection

If the patient is eligible for the NIP, refer them to their GP. 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 to accord 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. 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). *Pharmacy interns are able to complete the pharmacist-delivered vaccination training course, but must be supervised by a pharmacist registered by the Pharmacy Board of Australia who has also undertaken and passed the accredited training to administer vaccinations. **Proof of registration should be included as a part of a pharmacist's training record.***
2. Successfully complete the pharmacist's anaphylaxis training course with the Australasian Society of Clinical Immunology and Allergy (ASCIA), available at: <http://etrainingpharm.ascia.org.au/login/index.php>. **A certificate of completion should be included as a part of a pharmacist's training record.**
3. Hold a current first aid and CPR certificate. A pharmacist's training record in the operations manual should include certificates that provide proof of currency of first aid and CPR training:
 - **A current first aid certificate, equivalent to a Senior First Aid (Workplace level 2) or the unit of competency HLTAID003 Provide First Aid:** Pharmacists delivering vaccinations are required to renew their first aid certificate **every 3 years.**
 - **HLTAID001 Provide CPR:** Pharmacists delivering vaccination are required to renew their CPR certification **every 12 months.**

2.1 Pharmacist Training

Pharmacist Administration of Influenza Vaccine

The Pharmacy Guild of Australia offers this course, 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 currency in the following courses prior to attending. Pharmacists must also be currently registered with AHPRA and submit a copy of their registration certificate prior to attending the course.

- **HLTAID003:** Provide First Aid
- **HLTAID001:** Provide CPR (not required if HLTAID003 has been successfully completed within the last twelve months)
- **ASCIA Anaphylaxis:** Anaphylaxis for Pharmacists
- **Course pre-learning** for Pharmacist Administration of Influenza Vaccine

On completion of accredited training, a certificate 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.

Areas of training that should be covered include:

- Relevant policies, procedures
- How to access all relevant resources, references and forms
- Roles and responsibilities of the 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 vaccinator complete the anaphylaxis, CPR and first aid courses, to help in the management of any adverse events. The NSW Health *Pharmacist Vaccination Standards* requires that the pharmacist must ensure that when administering influenza vaccine, an appropriately trained pharmacy staff member is present.

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

Section 3 – Ongoing Certification Requirements for Pharmacist Vaccinators

All pharmacists participating in a vaccination service must successfully complete a training course accredited to accord 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. Up-to-date AHPRA pharmacist registration must be maintained and the pharmacist vaccinator must hold current and valid qualifications in CPR and First Aid.

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 maintaining up-to-date qualifications in First Aid and CPR.

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

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 and pests.

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.) Pharmacists practising in states other than NSW should refer to the relevant standards and regulations of each State and Territory.

4.2 Recommended Vaccination Service Folder Contents

| Policies and procedures | Resource |
|----------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|
| 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>My Guild (log-in required) The PGA Website, NSW Branch and QCPP17F</i> |
| 9. Vaccine management protocol | <i>Strive for 5 and QCPP P5A</i> |
| 10. Confidentiality policy | <i>QCPP P1A</i> |
| 11. Inter-professional collaboration guideline | <i>QCPP P2I</i> |
| 12. Incident reporting procedure | <i>QCPP P7D</i> |

| Forms and templates | |
|---------------------------------------------------------------------|-------------------------------------------------------------------|
| Vaccination Referral form for General Practitioner (see Appendix A) | <i>Guidelines*</i> |
| Information for Consumers on Influenza Vaccination | <i>My Guild (log-in required) The PGA Website, NSW Branch</i> |
| Vaccination referral form for General Practitioner | <i>My Guild (log-in required) The PGA Website, NSW Branch</i> |
| Patient Vaccination Pre-Screening/Consent Recording Form | <i>My Guild (log-in required) The PGA Website, NSW Branch</i> |

| | |
|---------------------------------------------------------------|-------------------------------------------------------------------|
| Forms and templates | |
| Patient After-Care Card | <i>My Guild (log-in required) The PGA Website, NSW Branch</i> |
| Vaccination training record checklist (see Appendix K) | <i>Guidelines*</i> |

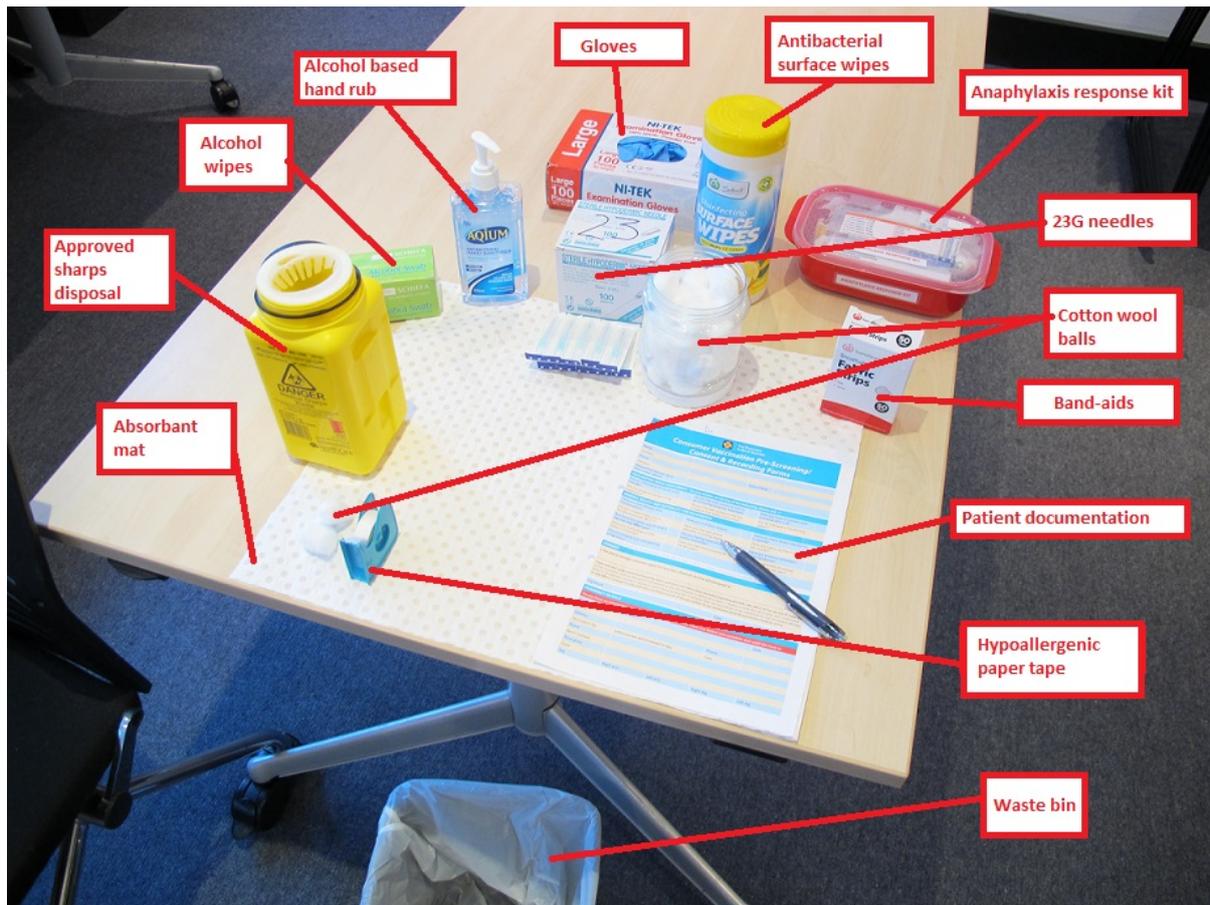
* *Guidelines for Conducting Pharmacist Initiated and Administered Influenza Vaccination Service within a Community Pharmacy*

Section 5 – Vaccination Service Area and Equipment

5.1 Vaccination Service Area

Pharmacies delivering a vaccination service must be equipped with facilities that are appropriate for the delivery of that service. The pharmacy premises 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 services stocked with adequate levels of the equipment required to deliver vaccinations and manage waste. This area is not to be used as a dispensary, storeroom, and staff room or retail area. The vaccination area must:
 - 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).
- 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. *The Pharmacy Guild of Australia has developed a template for 'Emergency Response Protocol', to access this form please sign-in to My Guild on the NSW Branch website.*
- A copy of the *Australian Immunisation Handbook* (current edition)
- A copy of the '*National Vaccine Storage Guidelines — Strive for 5*' (current edition)
- A policies and procedures manual for the vaccination service.



Example of Vaccination Service Area

5.2 General Equipment

Appropriate equipment should be available within the vaccination services area.

This includes:

Chairs – a minimum of two chairs, one each for the consumer and vaccinator, with an impervious service (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 (please see below)
- Anaphylaxis Response Kit (see section 5.3)
- Anaphylaxis management card and posters
- Adrenaline dosage cards and poster
- Approved Australian Standard Sharps Container
- Kidney dish
- Medical waste bin
- Hypoallergenic tape
- Medical table mats
- Anti-bacterial wipes to clean work area
- Liquid hand soap or hand sanitiser

- *The Australian Immunisation Handbook* (current edition) – Retrievable from: <http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home>
- *'National Vaccine Storage Guidelines – Strive for 5'* (current edition) – Retrievable from: <http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/IMM77-cnt>
- A process to regularly monitor on-line updates to *'The Australian Immunisation Handbook'* (current edition), **including prior to administering influenza vaccine.**
- CPR Chart
- 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, immediate administration of adrenaline should be 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 Services 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 should 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 following)
- Laminated copy of 'Recognition and treatment of anaphylaxis' (see table following)

5.4 Use of Adrenaline Auto injectors in Anaphylaxis Response Kits

Adrenaline auto injectors, EpiPen or Anapen, 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 in the Australian Vaccination Handbook (current edition) because they are single use only. As they are dose-specific, multiple pens would be required to allow for repeat dosing and varying ages/weights of patients, and shelf-life is limited to one-to-two years maximum.

Since the audience for influenza vaccinations by pharmacist vaccinator is restricted to people aged over 18 years, auto-injectors can be used. If pharmacies offering influenza vaccinations choose EPI-PEN auto-injector for adults, then they should ensure they have at least 2 auto-injectors in the anaphylaxis kit located in the vaccination service room. Expiry dates must be noted and checked at regular intervals.

Recognition and Treatment of Anaphylaxis

Signs of Anaphylaxis

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

- Signs of airway obstruction, such as cough, wheeze, hoarseness, stridor or signs of respiratory distress (e.g. tachypnoea, cyanosis, rib recession)
- 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 or distress

Management of Anaphylaxis

- 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).
- 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.
- 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 occurs.
- Check breathing; if absent, commence basic life support or appropriate cardiopulmonary resuscitation (CPR) as per the Australian Resuscitation Council guideline (www.resus.org.au/policy/guidelines).
- Transfer all cases to hospital for further observation and treatment.
- Complete full documentation of the event, including the time and dose(s) of adrenaline given.

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.

Antihistamines and/or hydrocortisone are not recommended for the emergency management of anaphylaxis.

Adrenaline Dosage

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 1:1000 *must not* be administered intravenously.

The use of 1:1000 adrenaline is recommended because it is universally available. Adrenaline 1:1000 contains 1 mg or 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.

Doses of 1:1000 (one in one thousand) adrenaline:

| | |
|---------------------------------|--------|
| >12 years and adult (over 50kg) | 0.5 mL |
|---------------------------------|--------|

*Modified from The Brighton Collaboration Case Definition Criteria for Anaphylaxis, and an insert published in Australian Prescriber in August 2011 (available at www.australianprescriber.com/magazine/34/4/article/1210.pdf)

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 medicine 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. To obtain a current list of QCPP-compliant vaccine refrigerators, visit <http://www.qcpp.com/resources/cold-chain-testing>.

Domestic refrigerators, including bar refrigerators, are unsuitable for vaccine storage.

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.

Further, pharmacies conducting a vaccination service should ensure the following are in place:

- A trained, designated person who is responsible for vaccine storage and implementation of protocols.
- A trained backup person 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.

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), regardless of whether other vaccination information is stored electronically.

In accordance with the *NSW Pharmacist Vaccination Standards*, the following information must be recorded:

Patient information:

- Patient's name
- Patient's address
- Patient's date of birth
- Patient's contact details
- Name of contact details of patient's GP
- 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

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 'Patient Screening and Consent form' to aid recording vaccinations, to access this form please sign-in to My Guild on the NSW Branch website.

Section 7 – Pre-vaccination Procedures

7.1 Pre-Screening and Valid Consent

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

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

Valid consent must be obtained from an 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. The NSW Standards state that valid consent obtained in the community pharmacy setting 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 Pharmacy Guild of Australia has developed a template for 'Information for Consumers on Influenza Vaccination', to access this form please sign-in to My Guild on the NSW Branch website.*

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 this 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 pharmacist vaccinators certified under relevant State or Territory regulations may administer vaccines.

The Pharmacy Guild of Australia has developed a 'Vaccination Service Delivery Guide' that is available on the NSW Branch website, accessible by logging into My Guild.

Prior to administration, the vaccinator should reconfirm that:

- The details on the patient screening and consent form match the person to be vaccinated; and
- The person being vaccinated is aged over 18 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, batch, expiry date).

The PGA has developed an 'After-care Information Card' template which can be found on the NSW branch website and accessed via logging in to My Guild.

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

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 monitoring early release form' (Appendix I) which may be used where a consumer leaves within the required 15-minute monitoring period post-vaccination.*

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

A written record of vaccination should be provided directly to the consumer's nominated general practitioner as soon as practicable.

The Pharmacy Guild of Australia has developed a template for 'Influenza Immunisation Patient GP Notification Letter', to access this form please sign-in to My Guild on the NSW Branch website.

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 should have appropriate procedures in place to inform individuals about the risks associated with vaccination before vaccination. 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 (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

An Emergency Response Protocol template developed by the PGA can be found on the NSW branch website, accessed by signing-in to My Guild.

The Vaccination Service Area must clearly display all the emergency procedures for adverse events.

9.2 Reporting Adverse Events

In NSW calling **1300 066 055** to report adverse events following vaccination will direct you to 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 record and GP notification letter 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

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

- Current AHPRA Pharmacist Registration
- Current certification having successfully completed a training course accredited to accord with the Australian Pharmacy Council "Standards for the Accreditation of Programs to Support Pharmacist Administration of Vaccines" (current version)
- Current First Aid certificate
- CPR certificate
- Current ASCIA Anaphylaxis Training certificate
- Current Professional Indemnity Insurance

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 Vaccination Program (NIP).

(Pharmacy Name and Address)

(Doctor's Name and Practice Address)

Date:

Dear Dr _____,

I am writing to you about John Smith, DOB 06/04/1933, of 68 Abc Street, Somerville NSW.

John is eligible to receive the annual influenza vaccine free of charge as he falls within the criteria of:

Groups who are at an increased risk of influenza complications-

- people aged 65 years and over
- pregnant women
- Aboriginal and Torres Strait Islander people aged 15 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 the Pharmacy.

Regards,

(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.</p> <p><i>Complete sections 1 & 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"> a. For all staff involved – must be trained in the pharmacy's procedures (use <u>Vaccination Operations Manual</u>) 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 c. For pharmacy support staff – must be trained in the pharmacy's procedures, including responding to a medical emergency (First aid and CPR qualifications where appropriate). | <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"> 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 b. Sufficient space to accommodate the individual, carer (if appropriate), pharmacist vaccinator and all necessary equipment during the service; c. A surface with sufficient space to lay the individual down to safely manage adverse events (if required); d. Seating for the individual and carer (if appropriate) during the vaccination service, and e. Equipment that facilitates the appropriate disposal of sharps and medical waste. Note: A dispensary area, store room, staff room or retail area may not be used as a vaccination service area. | <input type="checkbox"/> |
| <p>5. Ensure the pharmacy premises has:</p> <ol style="list-style-type: none"> a. Hand washing facilities to adequately conduct hand hygiene procedures in accordance with the pharmacy's <u>Infection Control Guideline</u>; b. An area with sufficient seating where an individual may be observed for 15 minutes post-vaccination for adverse events | <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"> a. An anaphylaxis response kit containing: <ul style="list-style-type: none"> • Adrenaline 1:1000 (minimum of three ampoules – check expiry dates) • Minimum of three 1ml syringes and 25mm length needles (for intramuscular injection) | <input type="checkbox"/> |

| Step | Complete |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| <ul style="list-style-type: none"> • Minimum of 2 (in date) EPI-PEN auto-injector for adults • Cotton wool swabs • Pen and paper to record time of administration of adrenaline • Laminated copy adrenaline doses • Laminated copy of 'Recognition and treatment of anaphylaxis' <p>b. Consumables such as (not exhaustive):</p> <ul style="list-style-type: none"> • Antibacterial surface wipes • Medical waste (sharps) container • Injection equipment (if appropriate) • Clean cotton wool and hypoallergenic tape • Soap or hand sanitiser • Alcohol swabs • Immunise service identifiers (e.g. stickers) <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>Note: Refer to jurisdictional requirements of each State or Territory</p> | |
| <p>9. Establish an appropriate system to record and store vaccinations records for a minimum of seven years, and provide vaccination notifications to primary health care providers and vaccination records that comply with the Australian Privacy Principles and are consistent with the pharmacy's Confidentiality policy and Inter-professional collaboration guideline e.g. paper-based system or GuildCare. Records to be stored include:</p> <ul style="list-style-type: none"> • Vaccination record (including pre-screening, consent & record); <ul style="list-style-type: none"> • Details of notifications; • Details of patient counselling , and • Details of adverse events (if applicable). • Statement of vaccination; <p><i>Complete section 3 in the Vaccination Service Outline</i></p> | <input type="checkbox"/> |
| <p>10. Ensure reference material is available, including:</p> <ol style="list-style-type: none"> a. The Australian Immunisation Handbook (current edition) b. National Vaccine Storage Guidelines – Strive for 5 c. Myths and realities – responding to arguments against vaccination: A guide for health providers d. PGA – Guidelines for conducting Pharmacist Initiated and Administered Vaccination Services within Community Pharmacy setting e. PSA – Practice guidelines for the provision of vaccination services within pharmacy f. NSW Pharmacist Vaccination Standards (or Standards relevant to the State or Territory the service is taking place) <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"> a. Incident reporting procedure b. Medical emergency response procedure c. Infection control guideline | <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"/> |

References

Australian Government National Health and Medical Research Council. *The Australian Vaccination Handbook*, 10th Edition, Canberra, 2014.

The Pharmaceutical Society of Australia, Practice guidelines for the provision of vaccination services within pharmacy

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 the vaccination service will be available

Provide details of how bookings will be made:

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. Nb. 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).
12. Administer the vaccine to the individual and dispose of equipment used 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. Nb. *Information leaflets* may be used to guide discussions.

- b. Advise the individual to remain within pharmacy premises for 15 minutes for observation. Nb. *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 Pharmacy vaccination record and if you choose to, you can 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* should be displayed.
 - 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 Pharmacy 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 or fax +61 2 6232 8392
16. Complete a post-vaccination information form (for example the PGAs '*After Care Card*' available on the NSW Branch website) and provide to the patient
17. Inform the individual's nominated primary health care provider of the vaccination (for example the Pharmacy Guild of Australia's '*Influenza Immunisation GP Notification Letter*' available on the NSW Branch website by logging into My Guild), and
18. Store records of relevant vaccination documentation as per the Pharmacy vaccination record system

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"> a. Having the vaccine refrigerator tested yearly via the Guild Cold Chain Testing Centre b. Having the refrigerator serviced every 12 months c. Conducting a self-audit at least every 12 months. | | | | | | | | |
| 4. Replenish consumables as required, including expired adrenaline injections. | | | | | | | | |
| 5. Check currency of pharmacist vaccinator certification/qualifications a yearly basis using the vaccination training record checklist. If pharmacist vaccinator qualifications have lapsed, facilitate required training to maintain certification as per the pharmacy's <u>Staff training procedure</u> . | | | | | | | | |
| 6. Check references are current on a yearly basis; replace superseded referenced 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.

"Community Sharps Management Guidelines for NSW Councils" © NSW Department of Health 2004

Appendix G – Sharps Waste Disposal Policy

To be included 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 Certificate 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 |
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| 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 |
| | | | | |
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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.

INFLUENZA VACCINATION MONITORING RELEASE FORM

Dear Consumer,

We would like to thank you for having your influenza 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 _____.

(Insert 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.

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.

Your signature:

Your Name:

Date: _____ / _____ / _____

Pharmacist vaccinator use only

I, the vaccinator, confirm that the above received a vaccination today and has left the vicinity of the vaccination room during the 15 minute observation period, against my advice.

Vaccinator signature:

Vaccinator Name:

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 |
|------------------------------|----------------------------------|--------------------------------------------------------|
| Australian Capital Territory | ACT Health | 02 6205 2300 |
| New South Wales | NSW Public Health units | 1300 066 055 (For connection to Public Health Unit) |
| Tasmania | TGA | 1800 044 114 |
| Western Australia | State Health Department - WAVSSS | 08 9321 1312 |

| State/Territory Communicable Disease Control contact information | |
|------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Australia Capital Territory | 24-hour line: 02 6205 2155 |
| New South Wales | State-wide Public Health Unit line: 1300 066 055 |
| Tasmania | 03 6222 7666 or 1800 671 738 |
| Western Australia | Perth Metropolitan area: 08 9388 4852 or 08 9328 0553 (after hours Infectious Diseases Emergency) Outside Perth Metropolitan area: Contact regional population health unit |

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 course this information.

| State/Territory | Act | Regulation |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ACT | Medicines, Poisons and Therapeutic Goods Act 2008 www.legislation.act.gov.au | Medicines, Poisons and Therapeutic Goods Act 2008 www.legislation.act.gov.au |
| NSW | Poisons and Therapeutic Goods Act 1966 www.legislation.nsw.gov.au | Poisons and Therapeutic Goods Act 2008 www.legislation.nsw.gov.au |
| TAS | Tasmania Poisons Act 1971 http://www.dhhs.tas.gov.au/psbtas/legislation_links | Tasmania Poisons Regulations 2008 http://www.dhhs.tas.gov.au/psbtas/legislation_links |
| WA | Western Australia Poisons Act 1964 http://www.slp.wa.gov.au/legislation/statutes.nsf/main_mrtitle_728_homepage.html | Western Australia Poisons Regulation 1965 http://www.slp.wa.gov.au/legislation/statutes.nsf/main_mrtitle_728_homepage.html |

The above website information was correct at time of publication.