

Queensland Pharmacist Vaccination Standard

April 2020

Introduction

The Queensland Pharmacist Vaccination Standard (QPV standard) is an adjunct document that details the requirements for a pharmacist who wants to participate in the pharmacist vaccination program in Queensland in accordance with the *Health (Drugs and Poisons) Regulation 1996* (HDPR) and the Drug Therapy Protocol – Pharmacist Vaccination Program.

Pharmacist Requirements

‘Pharmacist’ means a person registered under the *Health Practitioner Regulation National Law (Queensland)* in the pharmacy profession.

‘Trainee pharmacist’ is defined in the HDPR to mean a person who:

- is undergoing a course of training, the successful completion of which would qualify the person to hold an approved qualification for the pharmacy profession under the Health Practitioner Regulation National Law; or
- is undertaking a period of supervised practice required for registration as a pharmacist under the Health Practitioner Regulation National Law.

Trainee pharmacists may provide vaccinations provided they have undertaken appropriate training as outlined below, and, are observed and directly supervised by a registered pharmacist who is also lawfully allowed to vaccinate. It is particularly important that the supervising pharmacist confirms the decision to vaccinate (e.g. such as reviewing the pre-vaccination screening tool) and observes the administration of the vaccine. The Pharmacy Board of Australia clearly indicate that the final legal responsibility lies with the supervising pharmacist for activities undertaken by the trainee pharmacist.

Pharmacists authorised to administer vaccines and adrenaline under the HDPR Drug Therapy Protocol – Pharmacist Vaccination Program must:

- be registered with the Australian Health Practitioner Regulation Agency (AHPRA) without any registration conditions or undertakings associated with vaccination practices or dealing with vaccines
- have successfully completed either of the following training programs:
 - prior to 31 March 2016, the training program for the Queensland Pharmacist Immunisation Pilot I and II (QPIP I & II); or
 - from 1 April 2016 a training program accredited to meet the standards set by the Australian Pharmacy Council’s ‘Standards for the accreditation of programs to support Pharmacist Administration of vaccines’ (<https://www.pharmacycouncil.org.au/standards/>)

- hold appropriate professional indemnity insurance for administering and managing vaccinations. For public sector health service pharmacists, contact the department's Insurance Services Team
- hold a **current** Australian recognised qualification in first aid which includes Cardiopulmonary Resuscitation (CPR) and anaphylaxis management; or hold a current first aid certificate and a certificate in anaphylaxis management.
 - during the declared public health emergency related to COVID-19, pharmacists who have completed first aid training since October 2016 and CPR training since October 2018 will be considered to hold a current Australian recognised qualification in first aid.
 - pharmacists who have completed an accredited vaccination training program, but are unable to complete first aid training themselves due to the restrictions related to COVID-19, must ensure that there is at least one other member of staff on the premises who has completed first aid training since October 2016 before undertaking a vaccination.

Consumers must be able to assure themselves that the pharmacist or trainee pharmacist who will vaccinate them has successfully completed the required training. This may be achieved in a number of ways, for example, displaying a copy of a certificate of training completion in the consulting room, or including a statement of training as part of the information materials provided to consumers at the time of obtaining their consent to be vaccinated.

Pharmacists must ensure that they maintain competency in the skills required to undertake vaccination. This includes undertaking yearly Continuing Professional Development (CPD) in the area of immunisation to ensure they are up to date in their practice and practical application of skills and can demonstrate they meet the Australian Pharmacy Council's *Competencies for administration of vaccines by pharmacists*.

Where the time elapsed since initial practical training is more than 12 months and where a pharmacist has not administered at least two (2) vaccines in the preceding 12 months via either the intramuscular or subcutaneous routes, practical refreshment of the unpractised injection techniques (intramuscular, subcutaneous or both) **must** be undertaken as part of the CPD. In monitoring compliance with this QPV standard, officers authorised under the Queensland *Health Act 1937* may request evidence that CPD requirements are met and that first aid, CPR and anaphylaxis qualifications are current.

Consumer Requirements

The HDPR allows for administration of the vaccines described in Appendix 1 of the Drug Therapy Protocol (DTP) – Pharmacist Vaccination Program. The DTP also allows for administration of adrenaline to manage anaphylaxis.

Pharmacists are only to vaccinate those consumers who meet the criteria detailed in the DTP and within the scope of a pharmacist's practice, professional knowledge and expertise.

Consumers with contraindications or cautions relevant to vaccination as listed in the current online edition of the [Australian Immunisation Handbook](#)¹ are to be considered unsuitable for pharmacist vaccination and should be referred to their local medical practitioner.

Patients who qualify for the National Immunisation Program (NIP) must be advised of the cost to them of the service (if any) and offered referral to their local General Practitioner or other participating NIP service if necessary.

Equipment requirements

Pharmacist vaccination providers must have access to minimum equipment that allow for safe vaccination including:

- monitored refrigerated storage facilities – consistent with the current online edition of the *National Vaccine Storage Guidelines Strive for 5*
- the most current online editions of the [Australian Immunisation Handbook](#) and the [National Vaccine Storage Guidelines Strive for 5](#)
- as per recommendations in the current online edition of the *Australian Immunisation Handbook*, including:
 - all necessary consumables required for vaccine administration
 - equipment to allow for appropriate disposal of sharps and clinical waste
 - an in-date and complete anaphylaxis response kit. The kit should include at least one adrenaline auto-injector for the immediate treatment of an anaphylactic reaction.
Note: Consider stocking additional adrenaline auto-injectors as backups; alternative forms of injectable adrenaline (e.g. prefilled syringes, ampoules) may be used but pharmacists must ensure that they are confident and competent in administration of these forms of adrenaline
- an emergency response protocol on display
- appropriate record management storage.

Written Procedures

Pharmacy business owners and pharmacists in charge of public hospital pharmacy departments must maintain up-to-date written policies and procedures for:

- storage and handling of vaccine, including cold chain monitoring
- pre-vaccination suitability screening and consumer exclusion
- referral to a General Practitioner or other NIP service if necessary
- consumer education and counselling
- obtaining and documenting consumer consent
- vaccine administration

¹ Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook, Australian Government Department of Health, Canberra, 2018, immunisationhandbook.health.gov.au, *Australian Immunisation Handbook*

- handling of sharps and maintaining infection control including management of needle stick injury and exposure to blood or bodily fluids
- disposal of sharps and clinical waste
- post-vaccination consumer monitoring
- response to emergencies, specifically anaphylaxis
- adverse event management and reporting
- documentation and clinical record keeping including recording of all vaccine administration encounters on the Australian Immunisation Register (AIR)
- quality assurance of service
- management of staff training records.

Note: If these written procedures are part of other accreditation/assurance programs they can be used rather than having separate documents to comply with this QPV standard.

Infection Control Management Plan

In addition to the written policies and procedures described above, Chapter 4 of the *Public Health Act 2005* (Qld) places obligations on owners or operators of a health care facility at which vaccination services are provided in relation to an infection control management plan. Owners of a community pharmacy, for example, must ensure that there is a compliant plan, that it is followed, and that the effectiveness and implementation of the plan is reviewed at least yearly.

Vaccine Storage

Vaccines are to be stored securely to prevent access by unauthorised persons and to ensure they remain viable. Storage and transport should be in accordance with the current online edition of the *National Vaccine Storage Guidelines Strive for 5*.

Consent

The pharmacist must obtain informed consent to administer any vaccination in accordance with requirements of the the current online edition of the *Australian Immunisation Handbook*. The pharmacist must record that informed consent was given and retain this information as part of the documentation for the vaccination.

Adverse Events

Consumers who are administered vaccines must be directly observed for 15 minutes post-vaccination to monitor any acute adverse events or anaphylaxis. Consumers must be advised to remain on the premises during the observation period.

If as a result of the social distancing requirements related to the COVID-19 public health emergency it is not practicable for consumers to remain on the premises for 15 minutes, pharmacists must use other appropriate mechanisms to ensure that any acute adverse

events or anaphylaxis can be dealt with. Those mechanisms may include such things as requesting the consumer to wait outside the premises or providing the consumer with the pharmacy's telephone number and instructing them to remain in the immediate vicinity for 15 minutes. In any instance, the consumer should be directly observed on the premises for as close to the 15 minutes as possible before the alternate mechanisms are applied.

Consumers who choose to leave early are to be counselled on the possible risks of not being monitored and appropriate notes should be made in the clinical record that they left the premises before the post-vaccination period ended.

If an adverse event following immunisation occurs, the pharmacist must provide acute management within their scope of competence and professional knowledge.

Pharmacists should notify the Queensland Ambulance Service immediately to assist in ongoing management of anaphylaxis.

All vaccine reactions are to be notified to Queensland Health via the Adverse Event Following Immunisation (AEFI) reporting form available on the Queensland Health website:

www.health.qld.gov.au/publications/clinical-practice/guidelines-procedures/aefi-reporting-form.pdf

Records

The pharmacist must make a record of every occasion on which a vaccine is administered..

If the vaccine is administered at a public hospital, the records must be retained in accordance with the *Public Records Act 2002* (Qld) Health Sector (Clinical Records) Retention and Disposal Schedule. In a community pharmacy, the record must be kept for seven (7) years from the date on which the vaccine was administered and may be kept manually or electronically, provided the software meets industry standards for security and privacy.

The record must include the following information:

- brand, batch number and expiry date of the vaccine(s) provided
- name, address, date of birth, contact details and gender of the consumer
- date on which the vaccine was given
- pharmacist's name
- pharmacist's signature (if records are kept manually)

The pharmacist is to make all reasonable efforts to notify any General Practitioner or primary health care provider nominated by the consumer (or their carer) of:

- consumer's name and address
- type of vaccine administered, with vaccine details
- date of vaccination
- any adverse event observed.

Australian Immunisation Register reporting

All vaccine administration encounters should be recorded by the pharmacist on the Australian Immunisation Register (AIR) at the time of vaccination.

Pharmacies must seek the approval of the Queensland Department of Health to register as a vaccination provider with AIR by:

- completing the AIR Application to register as a provider form
- providing certified evidence of successful completion of a training program that meets the QPV standard
- emailing both documents to QHIP-ADMIN@health.qld.gov.au to approve and provide to AIR.

Once AIR has registered your approved application, the AIR will send a unique AIR registration number. This may take a number of weeks. The registration number will need to be used on each occasion of recording immunisation data to the AIR.

Please refer to the [Australian Government, Department of Human Services](#) website at for further information about “how to access AIR” once your registration is completed.

Pharmacy Premises Requirements

Vaccine administration by pharmacists is only to be conducted at a pharmacy premise or public hospital that provides an appropriate area for clinical care.

Pharmacy premises must have the following minimum facilities and staffing resources:

- A screened or private consulting room that ensures privacy and confidentiality, including during verbal discussions with:
 - sufficient space to allow for:
 - the consumer
 - a carer if necessary
 - the vaccinating, pharmacist
 - any consumables, equipment and documentation
 - seating for the consumer and their carer during the vaccination
 - sufficient space and appropriate surfaces for the consumer to lie down in the event of an adverse reaction and for staff to safely perform resuscitation procedures
 - an area that provides for direct visual observation with sufficient seating where consumers can wait for at least 15 minutes following the vaccination
 - hand washing facilities/hand sanitising products available to allow for the performance of appropriate hand hygiene before and after vaccine administration.
- If as a result of the COVID-19 public health emergency, a significant risk is identified associated with the consumer entering the pharmacy premises, then the pharmacist may administer an influenza vaccine to the consumer in another location in the immediate vicinity of the pharmacy that poses a lesser risk (e.g. to a person in their seventies whilst they are sitting in a parked car outside the pharmacy).

- Sufficient appropriately trained pharmacy staff to ensure the consumer’s safety during post-vaccination monitoring and any adverse event management. Ideally the pharmacy should have two pharmacists available at any one time – one to act as the dedicated vaccinator and the other to manage the general business of the dispensary. Pharmacies with only one pharmacist on duty **must** assess their workflows to ensure they are able to provide **uninterrupted** care to an individual consumer when vaccinating and have staff on-site with current training in first aid (including CPR and management of anaphylaxis) that can assist in providing after-vaccination care or managing an emergency situation.

Approved by:

Dr Jeannette Young PSM

Chief Health Officer and Deputy Director-General, Queensland Health

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Further information

Any questions in relation to this standard should be directed to:

Healthcare Approvals and Regulation Unit
Chief Medical Officer and Healthcare Regulation Branch
Email: HARU@health.qld.gov.au