Australian Capital Territory

Medicines, Poisons and Therapeutic Goods (Vaccinations by Pharmacists) Direction 2017 (No 1)

Disallowable instrument DI2017–116

made under the

Medicines, Poisons and Therapeutic Goods Regulation 2008, section 352 (Authorisation for pharmacist and intern pharmacist to administer vaccine without prescription - Act, s 37 (1)(b))

---

1 Name of instrument

This instrument is the *Medicines, Poisons and Therapeutic Goods (Vaccinations by Pharmacists) Direction 2017 (No1).*

2 Commencement

This instrument commences on the day after notification.

3 Revocation

This instrument revokes *Medicines, Poisons and Therapeutic Goods (Vaccinations by Pharmacists) Direction 2016 (No 3)* [DI2016-248].

4 Direction by Chief Health Officer

A pharmacist or intern pharmacist is authorised to administer vaccines to an adult without a prescription if the administration is performed in accordance with the Pharmacist Vaccination Standards as set out in Schedule 1.

Dr Paul Kelly
Chief Health Officer
19 June 2017

ACT Pharmacist Vaccination Standards

These Pharmacist Vaccination Standards (vaccination standards) are made under the Medicines, Poisons and Therapeutic Goods Regulation 2008 for the purposes of establishing conditions and criteria under which a registered pharmacist may initiate administration of the particular vaccines in the absence of a supply authority (prescription).

These vaccination standards should be read in conjunction with the *Medicines, Poisons and Therapeutic Goods Act 2008*, the Medicines, Poisons and Therapeutic Goods Regulation 2008 (from www.legislation.act.gov.au) to ensure pharmacists are fully aware of their obligations in administering vaccines.

A registered pharmacist is authorised to administer a vaccine described in *Appendix 1 - Approved substances* under his/her own authority to a patient (without a prescription) subject to the conditions described under Parts A - C of this document.

Part A - Pharmacist training requirements

Pharmacists are considered to have appropriate training and competence to administer vaccinations in the ACT if they can demonstrate suitability against **ALL** of the following conditions:

- The pharmacist holds current registration with the Pharmacy Board of Australia under the Australian Health Practitioner Regulation Agency (AHPRA);
- The pharmacist has 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) as delivered by a Registered Training Organisation.
- The pharmacist holds a current anaphylaxis management certificate.
- The pharmacist holds a current first-aid qualification (valid for three years), including a current Cardiopulmonary Resuscitation (CPR) certificate (valid for one year).
- The pharmacist holds appropriate professional indemnity insurance for providing a vaccination service.

Provisionally registered pharmacists (intern pharmacists) who have successfully completed the above *Pharmacist training requirements* may only administer a vaccine under the direct supervision of a pharmacist. A supervising pharmacist must be able to demonstrate suitability against the training requirements specified under Part A of this document.

Note: In this document, 'pharmacist' means a person who holds registration under the *Health Practitioner Regulation National Law (ACT)* to practice in the pharmacy profession (other than a student).

Part B - Practice Standards

1. General administration requirements

The following requirements apply as a condition of a pharmacists' authorisation to administer vaccines without a prescription.

- Only vaccines identified in *Appendix 1 - Approved substances* may be administered by pharmacists.
- Vaccinations must only be administered to patients aged **18 years or older.**
- Pharmacists should only administer vaccines in accordance with the ***Australian Immunisation Handbook (current online version)*** unless otherwise indicated by these vaccination standards***.*** *The Australian Immunisation Handbook is available from www.immunise.health.gov.au.*
- A vaccine should not be administered to a patient with a contraindication or precaution to vaccination as listed in the Australian Immunisation Handbook *(current online version).*
- A pharmacist must obtain **written consent** from the patient prior to administering a vaccine and provide the patient with information about the vaccine.
- Patients who are eligible to receive vaccines at no cost under the National Immunisation Program (NIP) or other ACT Government program, should be made aware of their eligibility to receive the vaccine from their nominated general practitioner (GP) or participating immunisation service.
- Pharmacists are encouraged to adopt or follow professional guidelines:
    - '*Practice guidelines for the provision of immunisation services within pharmacy*' - Pharmaceutical Society of Australia; and/or
    - *'Guidelines for conducting immunisation services within a Community Pharmacy Environment'* - Pharmacy Guild of Australia.

2. When not to vaccinate

A person is considered unsuitable for pharmacist vaccination and should be referred to a GP if they meet any of the following criteria:

a) Meet any contraindications or precautions listed in the *Australian Immunisation Handbook (current online version)* for a vaccine.

b) Have previously had an anaphylactic reaction to any vaccine or vaccine component.

c) Are aged less than 18 years.

d) Are pregnant.

e) The pharmacist considers that the patient would not benefit from the vaccine.[1]

For example a person receiving more than one influenza vaccination during a flu season.

[1] *Pharmacists should refer to the Australian Immunisation Handbook regarding the recommended frequency of administering vaccines. Pharmacists are encouraged to consult the patient, the patient's GP or the Australian Immunisation Register regarding a patient's vaccination history.*

3. Premises, Staffing and Equipment requirements

Authorised pharmacists should only administer vaccines in accordance with the below premises, staffing and equipment requirements:

- That all **sharps and clinical waste are safely disposed** of as per the *Australian Immunisation Handbook (current online version).*
- **Vaccine storage** and temperature control must be consistent with the *National Vaccine Storage Guidelines "Strive for 5" (current online version) - Commonwealth Department of Health*, available from *www.immunise.health.gov.au. A* temperature monitored refrigerator must be used to store vaccines.
- The pharmacist must either observe, or direct an appropriately trained staff member to observe, the patient for 15 minutes post-vaccination to monitor and respond to any adverse events. During vaccination periods, the administering pharmacist's primary responsibility is vaccine administration and post-vaccination observation.
- That an in-date and complete anaphylaxis response kit is readily available at the premises.
- An adverse vaccination emergency response protocol is on display in the administration area.
- That administrating pharmacists have **ready access to relevant professional documents** including the *Australian Immunisation Handbook (current online version)* and *National Vaccine Storage Guidelines "Strive for 5" (current online version).*

4. Administration area requirements

An authorised pharmacist must only administer a vaccine in an appropriate professional services area (administration area). The administration area must:

- Not be visible (during administration) to other persons in the premises (i.e. use of a privacy screen or private consultation room).
- Not be used as a dispensary, storeroom, staff room or retail area.
- Be clear of equipment and allow for adequate space for an adult to fully lie down and for there to be enough space for appropriate medical care to be provided.
- Have a **seat or couch for the patient** to sit in while vaccine is being administered..

The premises must have **hand washing** or **hand sanitisation facilities** readily available and provide a **seating area** for the patient to wait in following administration of a vaccine. This seating area must be able to be easily monitored by a pharmacist who has successfully completed the pharmacist training requirements as specified under Part A of this document.

The pharmacist must advise the patient that he/she must remain on the premises for at least **15 minutes post-vaccination for observation**.

Part C - Record Keeping

1. Record keeping

The administering pharmacist or pharmacy must maintain accurate and up to date records of all conducted vaccinations including:

- the patient's full name, address, gender, date of birth, and contact details;
- the patient's Aboriginal and Torres Strait Islander (ATSI) status;
- evidence of the patient's informed consent;
- the name and contact details of the patient's primary medical practitioner (if known);
- the type, brand, batch number and expiry date of the vaccine;
- the date the vaccine was administered to the patient;
- the name or signature of the administering pharmacist;
- the name and address of the premises where vaccines were administered; and
- a unique identifying number for the administration event.

A record of this information should be kept by the pharmacist or pharmacy for at least seven years after the day the vaccine is administered in accordance with the *Health Records (Privacy and Access) Act 1997*.

It is recommended that pharmacists electronically record each vaccination event on the **Australian Immunisation Register (AIR)**.

2. Reporting of information

For each vaccination event, with the consent of the patient, a record of the patient's vaccination should be provided to their nominated GP **by the pharmacist or pharmacy** including:

- the patient's name and address;
- date, type and brand of vaccine administered; and
- any adverse event observed.

Pharmacists or pharmacies must supply a **record, no less than annually** (including electronic record) to the Chief Health Officer about pharmacist vaccination events including: the number and type of vaccine administered for each patient as well as the patient's date of birth, gender and Aboriginal or Torres Strait Islander status. A template for manually reporting details to the Chief Health Officer is available from www.health.act.gov.au/pharmaceuticalservices.

Pharmacists or pharmacies must also maintain evidence of a pharmacist's ongoing competence to administer vaccines. These records should be retained at the premises and should be made available during inspection at the request of an authorised Medicines and Poisons Inspector under the *Medicines, Poisons and Therapeutic Goods Act 2008*.

3. Written procedures

An authorised pharmacist must ensure that there are written procedures in place for:

- the vaccination process (from patient presentation to post-vaccination);
- dealing with adverse events;
- obtaining and recording patient consent; and
- the reporting of vaccination data to the patient's nominated GP.

If administration occurs at a registered community pharmacy, these written procedures must be retained at the premises. Written procedures must be made available during inspection at the request of an authorised Medicines and Poisons Inspector under the *Medicines, Poisons and Therapeutic Goods Act 2008*.

4. Adverse events

An administering pharmacist must be competent to manage anaphylaxis post vaccination, including the use of adrenaline consistent with the *Australian Immunisation Handbook (current online version).* The pharmacist must ensure that an ambulance is called to attend to the patient in the event of anaphylaxis.

An Adverse Event Following Immunisation (AEFI) is any unwanted or unexpected event following the administration of vaccine(s). AEFI may be caused by the vaccine(s) or they may occur by coincidence (they would have occurred regardless of the vaccination). Adverse events are not limited to an anaphylactic response and may include other physiological responses such as localised bruising or swelling at the site of injection, migraine, or fainting. Common examples of adverse events are included in the Australian Immunisation Handbook (available from www.immunise.health.gov.au).

All AEFIs must be recorded in the patient's vaccination record and reported to the patient's GP and the ACT Health Immunisation Team. The AEFI reporting form is available from www.health.act.gov.au/immunisation or www.health.act.gov.au/pharmaceuticalservices.

Appendix 1 - Approved substances

Table 1 - Approved Substances

Column 1 Approved Substance	**Column 2** Route of administration	**Column 3** Conditions
Influenza vaccine *(Fluvax®, Influvac®, FluQuadri®, Fluarix Tetra®, Agrippal®, Fluarix®, Afluria Quad®)*	Intramuscular injection	Frequency of administration should occur in accordance with the *Australian Immunisation Handbook (current online version).*
Diptheria, tetanus, a-cellular pertussis (dTpa) vaccine *(Boostrix®, Adacel®)*	Intramuscular injection	Frequency of administration should occur in accordance with the *Australian Immunisation Handbook (current online version).*