Australian Capital Territory

Medicines, Poisons and Therapeutic Goods (Vaccinations by Pharmacists) Direction 2025 (No 1)

Disallowable instrument DI2025-33

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 2025 (No 1).*

2 Commencement

This instrument commences on the day after notification.

3 Revocation

This instrument revokes *Medicines, Poisons and Therapeutic Goods (Vaccinations by Pharmacists) Direction 2024 (No 1)* [DI2024-109].

4 Direction by Chief Health Officer

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

Dr Kerryn Coleman
Chief Health Officer
26 March 2025

ACT Government | ACT Health

ACT Pharmacist Vaccination Standards

Introduction

The Pharmacist Vaccination Standards (The 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).

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

Authorisation for pharmacists to administer vaccines

A registered pharmacist[#] or registered intern pharmacist may supply and administer a vaccine under their own authority (without a prescription) to a person under the following conditions:

- The vaccine is listed in *Appendix 1 - Approved vaccines**;
- Any prescribed training, administration and record keeping requirements are met (as described by Parts A – C of this document); and
- The patient meets the approved clinical criteria for a vaccine as per the Australian Immunisation handbook.

[#] A Pharmacist is a person who holds registration under the Health Practitioner Regulation National Law (ACT) to practice in the pharmacy profession (other than a student).

** Conditions or limitations may apply to the administration of an approved vaccine. See Appendix 1 - Approved vaccines for further information.*

Part A - Pharmacist training requirements

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

a) The pharmacist holds current registration with the Pharmacy Board of Australia under the Australian Health Practitioner Regulation Agency (AHPRA).
b) The pharmacist has successfully completed an accredited training course that complies with the Australian Pharmacy Council (APC) 'Standards for the Accreditation of Programs to support Pharmacist Administration of Vaccines", and ensure they have the required clinical and administration knowledge for all authorised vaccines they intend to administer.
c) The pharmacist holds an anaphylaxis management certificate.
d) The pharmacist holds a current first-aid qualification (valid for three years).
e) The pharmacist holds a current Cardiopulmonary Resuscitation (CPR) certificate (valid for one year).
f) The pharmacist holds appropriate professional indemnity insurance for providing a vaccination service.

Provisionally registered pharmacists (intern pharmacists) who have successfully completed the above Part A *Pharmacist training requirements* may only administer a vaccine under the supervision of a pharmacist.

A **supervising pharmacist** must be able to demonstrate suitability against the training requirements specified under Part A of this document, including ensuring they have the required knowledge for all vaccines the intern will administer.

Part B - Practice Standards

General administration requirements

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

a) A pharmacist immuniser must ensure they conduct vaccinations in accordance with the Australian Immunisation Handbook (current online version).
b) A pharmacist must provide the person with information about the vaccine and potential side effects, obtain valid **consent** from the person (or authorised parent/guardian) and appropriate medical history prior to administering a vaccine.
c) Appropriate clinical evaluation must occur prior to the administration of any vaccine to determine the need for a pharmacist administered vaccine, and the provision of additional advice or referral.
d) The pharmacist must either observe, or direct an appropriately trained staff member to observe, the person for 15 minutes post-vaccination to monitor and respond to any adverse events.
e) Patients who are eligible to receive vaccines at no cost under the National Immunisation Program (NIP) or other ACT Government funded program, should be made aware of their eligibility to receive the vaccine from their participating NIP immunisation provider.
f) A pharmacist should check a person's vaccination status on the AIR and other available records prior to administering a vaccine.
g) Pharmacists should follow professional guidelines:
    - *'Practice guidelines for the provision of immunisation services'* - Pharmaceutical Society of Australia; and/or
    - *'Guidelines for conducting immunisation services within a Community Pharmacy Environment'* - Pharmacy Guild of Australia.

Note: under the Australian Immunisation Handbook, valid consent is the voluntary agreement by an individual to a proposed procedure, which is given after sufficient, appropriate and reliable information about the procedure, including the potential risks and benefits, has been conveyed to that individual.

Premises and equipment requirements

Authorised pharmacists should only administer vaccines in accordance with the below premises 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 for vaccines requiring storage between +2.0 and +8.0 degrees Celsius must be consistent with the *National Vaccine Storage*

Guidelines 'Strive for 5' (current online version*) - Commonwealth Department of Health, available from https://www.health.gov.au/health-topics/immunisation*. A temperature monitored refrigerator must be used to store vaccines.

- A complete and in-date anaphylaxis response kit, as per *Australian Immunisation Handbook* requirements, is readily available at the place of vaccine administration.
- An adverse vaccination emergency response protocol should be on display in the administration area.

Administration area requirements

The vaccine administration area must:

- Not be visible (during administration) to other persons in the place of vaccine administration (i.e. use of a private consultation room).
- Not be used as a dispensary, storeroom, staff room or retail area.
- Have adequate lighting and a comfortable temperature.
- 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 immuniser adequate space to manoeuvre.
- Have a **seat or medical administration couch for the person** to utilise while the vaccine is being administered.
- Have **hand washing or hand sanitisation facilities** readily available.
- Have a **seating area** for the person to wait in following administration of a vaccine. This seating area must be able to be easily monitored by an appropriately trained pharmacy staff member.

Part C - Record Keeping

Australian Immunisation Register

All vaccines administered by the pharmacist immuniser must be reported to the **Australian Immunisation Register** (AIR), preferably within 24 hours of administration but must be within 10 business days.

Note: Pharmacists will require an ancillary provider number to report on the AIR. The application to be an ancillary provider on AIR is at https://www.humanservices.gov.au/organisations/health-professionals/forms/im004

Vaccination records

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

- The person's name, address, date of birth and contact details,
- The person's Medicare number and/or Individual Healthcare Identifier (IHI),
- A record of the person's valid consent,
- The brand, batch number and expiry date of the vaccine,
- The part of the body to which the vaccine was administered,
- The date on which the vaccine was administered,
- The pharmacist's name and contact details,
- The address of the pharmacy or other vaccination premises at which the vaccination was administered, and
- A unique reference number for the supply and administration.

A record of this information should be kept by the pharmacist or pharmacy in accordance with the *Health Records (Privacy and Access) Act 1997*; that is:

- if the vaccine is administered to an adult, for at least seven years after the day the vaccine is administered, or
- if the vaccine is administered to a person is under 18 years old, for at least until the day the person turns 25 years old.

Adverse event reporting

An adverse event following immunisation (AEFI) is any untoward medical occurrence that follows immunisation. 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.

AEFIs are a Notifiable Condition under the *Public Health Act 1997* and must be reported to the Health Protection Service Immunisation Section. If requested by the person, or in the event of an unexpected or serious AEFI, the pharmacist should also report the AEFI to the person's nominated medical practitioner.

If a pharmacist immuniser becomes aware of an AEFI, the pharmacist immuniser must notify the ACT Health Immunisation Section, by telephone on (02) 5124 9800 or by completing an online adverse event reporting form. The pharmacist should also contact the patient's nominated medical practitioner to advise them of the AEFI, provided the patient has given the pharmacist consent to contact their medical practitioner. Additional information about AEFIs, including pharmacist reporting obligations, is available from the ACT Health website (www.health.act.gov.au/services/immunisation).

Appendix 1 - Approved vaccines

Table 1 - Approved Vaccines

Column 1 Approved Substance	**Column 2** Limitations of use	**Column 3** Person age
SARS-COV-2 (COVID-19) vaccine		5 years and older
Diphtheria toxoid		5 years and older
Haemophilus influenzae vaccine		5 years and older
Hepatitis A (Hep A) vaccine		5 years and older
Hepatitis B (Hep B) vaccine		5 years and older
Human papillomavirus (HPV) vaccine		10 years and older
Influenza vaccine		5 years and older
Japanese Encephalitis Virus (JEV) vaccine	Pharmacists who administer the JEV vaccine must complete the additional training module: Japanese encephalitis – A learning resource for Immunisation providers.	5 years and older
Measles vaccine		5 years and older
Meningococcal vaccine (ACWY) (quadrivalent) conjugate vaccine		5 years and older
Meningococcal B vaccine		5 years and older
Meningococcal C vaccine		5 years and older
Mpox vaccine	Mpox vaccine is to be administered in ACT pharmacy settings only if authorised under the Operational Protocol for the Supply and Administration of JYNNEOS®.	Non-pregnant people aged 16 years and older in accordance with the ACT JYNNEOS protocol.
Mumps vaccine		5 years and older
Pertussis antigen		5 years and older
Pneumococcal	Pneumococcal conjugate vaccine only. Patients who are considered to have identified risk conditions are considered high complexity and should be referred to their GP	Aboriginal people aged 50 years and over. Non-Aboriginal people aged 70 years and over.
Poliovirus		5 years and older
Rabies vaccine	Pharmacists who administer the Rabies vaccine must only do so as pre-exposure prophylaxis for people who are not immunocompromised (refer to AIH) and must educate patients about first aid and the need to seek medical assessment for rabies exposure to rabies or Australian Bat Lyssavirus regardless of having been vaccinated.	5 years and older

Respiratory syncytial virus (RSV) vaccine	Abrysvo® vaccine for pregnant people between 28 to 36 weeks gestation. Abrysvo® or Arexvy® for 60 years and older	Pregnant people between 28 to 36 weeks gestation. 60 years and older
Rubella vaccine		5 years and older
Tetanus toxoid		5 years and older
Typhoid vaccine		5 years and older
Varicella vaccine		5 years and older
Zoster vaccine Recombinant Varicella zoster virus glycoprotein e antigen vaccine (Shingrix recombinant vaccine brand only)		18 years and older

All vaccination recommendations for individuals, schedules and administration processes, including combination vaccines, must be in accordance with the current digital edition of the Australian Immunisation Handbook.

Pharmacists may administer vaccines listed on the ACT Immunisation Schedule that are funded under the National Immunisation Program (NIP) Please refer to the ACT Health Pharmacist Vaccination webpage for further advice on NIP vaccine eligibility.