Australian Capital Territory

Medicines, Poisons and Therapeutic Goods (Vaccinations by Pharmacists) Direction 2023 (No 1)

Disallowable instrument DI2023–20

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))

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1 Name of instrument

This instrument is the *Medicines, Poisons and Therapeutic Goods (Vaccinations by Pharmacists) Direction 2023 (No 1).*

2 Commencement

This instrument commences on 17 March 2023.

3 Revocation

This instrument revokes *Medicines, Poisons and Therapeutic Goods (Vaccinations by Pharmacists) Direction 2022 (No 1)* [DI2022-77].

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 Sally Singleton
A/g Chief Health Officer

02 March 2023

ACT Pharmacist Vaccination Standards

Introduction

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.

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**; and
- Any prescribed training, administration and record keeping requirements are met (as described by Parts A – C of this document)

[#] 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 a training course that complies with the Australian Pharmacy Council (APC) 'Standards for the Accreditation of Programs to support Pharmacist Administration of Vaccines', and provided by an APC-accredited pharmacy education provider.
c) The pharmacist must hold a certificate confirming completion of an accredited training program for all authorised vaccines that they intend to administer.
d) The pharmacist holds a current anaphylaxis management certificate.
e) The pharmacist holds a current first-aid qualification (valid for three years).
f) The pharmacist holds a current Cardiopulmonary Resuscitation (CPR) certificate (valid for one year).
g) 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 certification to vaccinate for the specific vaccine administered.

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 nominated medical practitioner or participating 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.

When not to vaccinate

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

a) Have any contraindications or precautions listed in the *Australian Immunisation Handbook* (current online version) or subsequently published ATAGI clinical guidance for a vaccine.
b) Have previously had an anaphylactic reaction to any vaccine or vaccine component.
c) Is of an age less than the age prescribed in column 3 'Person age' of *Appendix 1 - Approved vaccines*.
d) The pharmacist considers that the person would not benefit from the vaccine e.g. a person receiving more than one influenza vaccination during an influenza season.

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.
- Vaccine storage and temperature control for **a COVID-19 vaccine** must be in accordance with the Australian Government COVID-19 vaccination training program.
- A complete and in-date anaphylaxis response kit, as per *Australian Immunisation Handbook* requirements, is readily available at the premises.
- 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 premises (i.e. through use of a privacy screen or private consultation room).
- Not be used as a dispensary, storeroom, staff room or retail area.
- Have adequate lighting and a comfortable temperature
- Be clear of equipment and allow for adequate space for an adult or child 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 person** to sit in while 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 conducted vaccinations 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 and their certificate of accreditation number,
- 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.

Written procedures

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

- the vaccination process (from person presentation to post-vaccination);
- dealing with adverse events;
- the reporting of vaccination outcomes to the person's nominated medical practitioner in the event of an adverse event

Written procedures must be retained at the premises and be made available during an inspection at the request of an authorised Medicines and Poisons Inspector under the *Medicines, Poisons and Therapeutic Goods Act 2008*.

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 Unit. 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 Unit, by telephone on (02) 5124 9800 or by completing an online adverse event reporting form. 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** Conditions	**Column 3** Person age
A vaccine for COVID-19 included on the Australian Register of Therapeutic Goods[§]	In accordance with Therapeutic Goods Administration (TGA) approved Product Information and Australian Technical Advisory Group on Immunisation (ATAGI) recommendations[#] Must have evidence of successful completion of the Australian Government COVID-19 vaccination training program	Of an age that the vaccine is approved or provisionally approved for use under the *Therapeutic Goods Act 1989* for persons aged over five years. Where a COVID-19 vaccine is approved for use in persons younger than five years of age, not less than five years of age.
Diphtheria, tetanus, a-cellular pertussis (dTpa) vaccine[†]		12 years or older
Hepatitis A (Hep A) vaccine[†]		Five years or older
Hepatitis B (Hep B) vaccine[†]		Five years or older
Human papillomavirus (HPV) vaccine[†]		12 years or older
Influenza vaccine[†]		Five years or older
Measles-mumps-rubella combination vaccine (MMR) [†]		12 years or older
Meningococcal vaccine (ACWY only) (quadrivalent) conjugate vaccine[†]		14 years or older
Inactivated poliomyelitis vaccine[†]		Five years or older
Typhoid vaccine[†]	Intramuscular injection (IMI) formulation only	Five years or older
Zoster vaccine[†] Recombinant Varicella zoster virus glycoprotein e antigen vaccine	Shingrix recombinant vaccine brand only.	50 years or older

§ ATAGI advice in regard to medical contraindications, precautions, vaccine administration in pregnancy, use of vaccines and vaccine use as a booster dose/s must be adhered to. A person with any precaution or contraindication (other than the person on anti-coagulation therapy) to a vaccine must be referred to a medical practitioner.

†Vaccination recommendations for individuals, schedules and administration processes must be in accordance with the digital edition of the Australian Immunisation Handbook.

Where the TGA approved Product Information and ATAGI recommendations differ, the advice of ATAGI must be followed.