Australian Capital Territory

Medicines, Poisons and Therapeutic Goods (Vaccinations by Pharmacists) Direction 2021 (No 3)

Disallowable instrument DI2021–207

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 2021 (No 3).*

2 Commencement

This instrument commences on the day after notification.

3 Revocation

This instrument revokes *Medicines, Poisons and Therapeutic Goods (Vaccinations by Pharmacists) Direction 2021 (No 2)* [DI2021-205].

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.

5 Temporary Amendment to Schedule 1, Part A – Pharmacist Training Requirements

A registered pharmacist or intern pharmacist is considered to meet the training requirements of Schedule 1, Part A, Item (4) if they hold a first-aid qualification that has or will expire between 16 March 2020 and 31 August 2021.

A registered pharmacist or intern pharmacist is considered to meet the training requirements of Schedule 1, Part A, Item (5) if they hold a Cardiopulmonary Resuscitation Certificate that has or will expire between 16 March 2020 and 31 August 2021.

6 Expiry – Clause 5 Temporary Amendment to Schedule 1, Part A – Pharmacist Training Requirements

Clause 5 (Temporary Amendment to Schedule 1, Part A – Pharmacist Training Requirements) expires on 1 September 2021.

Dr Kerryn Coleman
Chief Health Officer

13 August 2021

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:

1. The pharmacist holds current registration with the Pharmacy Board of Australia under the Australian Health Practitioner Regulation Agency (AHPRA).
2. 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.
3. The pharmacist holds a current anaphylaxis management certificate.
4. The pharmacist holds a current first-aid qualification (valid for three years).
5. The pharmacist holds a current Cardiopulmonary Resuscitation (CPR) certificate (valid for one year).
6. 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 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.

a) Only vaccines identified in *Appendix 1 - Approved substances* may be administered by pharmacists or intern pharmacists.
b) Vaccines may only be administered to patients:
   - For an influenza vaccine; aged **10 years or older**, or
   - For a COVID-19 vaccine; **of an age that the vaccine is approved or provisionally approved for use** under the *Therapeutic Goods Act 1989* and, where a COVID-19 vaccine is approved for use in persons younger than 10 years of age, **not less than 10 years** of age;
   - for any other vaccine listed in *Appendix 1 - Approved substances;* aged **16 years or older**.

Note: On the date of effect of these Standards, the Therapeutic Goods Administration (TGA) has provisionally approved the Comirnaty (Pfizer) COVID-19 vaccine for use in persons greater than or equal to 12 years of age. Both the chadox1-s (AstraZeneca) and Moderna Spikevax (elasomeran) COVID-19 vaccines are provisionally approved by the TGA for use in persons greater than or equal to 18 years of age.

c) The *covid-19 (chadox1-s) (AstraZeneca) vaccine* must be administered in accordance with *Australian Technical Advisory Group on Immunisation (ATAGI) clinical guidance on use of COVID-19 vaccine in Australia* (current online version) as it relates to patient age.

Note: On the date of effect of these Standards, ATAGI clinical guidance on use of COVID-19 vaccine in Australia states that the Cominarty (Pfizer) vaccine is preferred over the AstraZeneca vaccine for people aged less than 60 years.

d) 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 https://immunisationhandbook.health.gov.au.
e) 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).
f) For a COVID-19 vaccine that is not included in the Australian Immunisation Handbook, a pharmacist should administer the vaccine in accordance with the ATAGI *clinical guidance on use of COVID-19 vaccine in Australia* (current online version).
g) A pharmacist must obtain **written consent** from the patient prior to administering a vaccine and provide the patient with information about the vaccine.

Note: The Australian Government has published Information for health care providers to help consumers make informed decisions *about the COVID-19 AstraZeneca vaccine (current online version). Pharmacists should refer to this resource when explaining the risks and benefits of the AstraZeneca vaccine and are encouraged to use the* Australian Government Consent form for COVID-19 vaccination *(current online version) when obtaining patient consent.*

h) 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.

i) Pharmacists are encouraged to adopt or 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.

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) 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 specified in Part B, 1 (b).

d) 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.

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 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.
- 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.
- The pharmacist must advise the patient that he/she must remain on the premises for at least **15 minutes post-vaccination for observation**.
- A complete and in-date anaphylaxis response kit is readily available at the premises.

[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.*

- An adverse vaccination emergency response protocol is on display in the administration area.
- That administering 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

The vaccine 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 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 patient** to sit in while vaccine is being administered.

Have **hand washing** or **hand sanitisation facilities** readily available and 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.

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 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 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 patient is under 18 years old, for at least until the day the patient turns 25 years old.

Pharmacists must electronically record each vaccination event on the **Australian Immunisation Register (AIR)** as soon as possible following administration.

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

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 and by 30 November each year** (including electronic record) to the Health Protection Service about all pharmacist administered vaccination events over the period 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.

Pharmacists or pharmacies that provide NIP funded vaccines must also supply a record, no less than once every two weeks regarding NIP funded vaccines administered over the period to the Health Protection Service. A Pharmacist Vaccination Record Form template for manually reporting details to the Health Protection Service is available from https://health.act.gov.au/health-professionals/pharmaceutical-services/pharmacist-vaccinations. This form may be used for reporting information about NIP and privately funded vaccines concurrently.

Collated reports from a third party or any other suitable reporting template will also be accepted by the Health Protection Service, provided the report(s) contain all fields within the Pharmacist Vaccination Record Form.

Note: For example, the Health Protection Service will accept collated electronic reports from the Pharmacy Guild of Australia ACT Branch containing information on their behalf of its members.

Pharmacists or pharmacies must also maintain evidence of a pharmacist's ongoing competence to administer vaccines. These records 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.

These written procedures must be retained by the pharmacist or at the premises and must 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*.

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 https://immunisationhandbook.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 ACT AEFI reporting form is available from https://health.act.gov.au/health-professionals/pharmaceutical-services/pharmacist-vaccinations.

Note: AEFIs are Notifiable Conditions under the ACT Public Health Act 1997 and must be reported to the Health Protection Service Immunisation Unit.

Appendix 1 - Approved substances

Table 1 - Approved Substances

Column 1 Approved Substance	**Column 2** Route of administration	**Column 3** Conditions
Influenza vaccine	Intramuscular injection	Frequency of administration should occur in accordance with the *Australian Immunisation Handbook (current online version)*.
Diphtheria, tetanus, a-cellular pertussis (dTpa) vaccine	Intramuscular injection	Frequency of administration should occur in accordance with the *Australian Immunisation Handbook (current online version)*.
Measles-mumps-rubella combination vaccine (MMR)	Intramuscular or subcutaneous injection	Frequency of administration should occur in accordance with the *Australian Immunisation Handbook (current online version)*.
A vaccine for COVID-19 included on the Australian Register of Therapeutic Goods	Intramuscular injection	With evidence of successful completion of the Australian Government COVID-19 vaccination training program. All dealings in accordance with the Australian Government COVID-19 Vaccination Program.