Australian Capital Territory

Medicines, Poisons and Therapeutic Goods (Vaccinations by Pharmacists) Direction 2016 (No 2)

Disallowable instrument DI2016– 21

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 2016 (No 2).*

2 Commencement

This instrument commences on the day after its notification day.

3 Revocation

This instrument revokes DI2016-12, being the Medicines, Poisons and Therapeutic Goods (Vaccinations by Pharmacists) Direction 2016 (No 1), dated 1 March 2016.

4 Direction by Chief Health Officer

In accordance with section 352 of the Medicines, Poisons and Therapeutic Goods Regulation 2008, to be authorised to administer vaccines pharmacists and intern pharmacists must comply with the Pharmacist Vaccination Standards set out in Schedule 1.

Dr Paul Kelly
Chief Health Officer

15 March 2016

Schedule 1

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 seasonal influenza vaccine 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 and Poisons and Therapeutic Goods Regulation 2008 (from www.legislation.act.gov.au) to ensure pharmacists are fully aware of their obligations in administering vaccinations.

Vaccination standards

A registered pharmacist may initiate administration of the seasonal influenza vaccine under his/her own authority to a patient (without a prescription) subject to compliance with the following three components:

A. Completion of appropriate training to administer vaccinations;
B. Conduct vaccinations in accordance with any practice standards outlined in the '*ACT Pharmacist Vaccination Standards*' (this document); and
C. Maintain appropriate records of each vaccination event.

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:
    - that complies with the Australian Pharmacy Council's (APC) '*Standards for the Accreditation of Programs to Support Pharmacist Administration of Vaccines'* (current version); and
    - that is delivered by a Registered Training Organisation.
- The pharmacist holds a current certificate for the Australasian Society of Clinical Immunology and Allergy (ASCIA) anaphylaxis e-training for pharmacists or equivalent issued within the last year.
- 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 vaccinations.

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

In administering vaccinations to patients without a prescription, pharmacists must practice in accordance with the below practice standards.

General administration requirements

- Pharmacists should only administer vaccinations in accordance with the ***Australian Immunisation Handbook (current version)*** unless otherwise indicated by these vaccination standards**.**
- Vaccines should not be administered to a patient with a contra-indication or precaution to vaccination as listed in the *Australian Immunisation Handbook (current version).*
- An administering pharmacist must obtain **written consent** from the patient prior to vaccination.
- Only the seasonal **influenza vaccine** can be administered to patients who are aged **18 years** or older.
    - Patients with contraindications or precautions to vaccination as listed in the *Australian Immunisation Handbook (current version)* are to be considered unsuitable for pharmacist vaccination and should be referred to a general practitioner (GP).
    - Patients who have previously had an anaphylactic reaction to any vaccine or vaccine component are to be considered unsuitable for pharmacist vaccination and should be referred to a GP.
    - Patients who are pregnant are to be considered unsuitable for pharmacist vaccination and should be referred to a GP.
    - Patients who are eligible to receive the flu vaccine under the National Immunisation Program (NIP) should be made aware of their eligibility to receive the vaccine free of charge from their nominated GP.
- **Provisionally registered pharmacists** (intern pharmacists) who have successfully completed the pharmacist training requirements as specified under Part A of this document may only administer the flu vaccine under the direct supervision of a pharmacist. This supervising pharmacist must have general registration and must have successfully completed the pharmacist training requirements as specified under Part A of this document.
- 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.

Premises, Staffing and Equipment requirements

- Pharmacists must ensure the **safe disposal of sharps and clinical waste** as per the *Australian Immunisation Handbook (current version).*
- **Vaccine storage** and temperature control must be consistent with the *Vaccine Storage Guidelines 2013 "Strive for 5" (current version) - Commonwealth Department of Health.*
- A temperature monitored refrigerator (manufactured for the purpose of storing vaccines) and used exclusively for vaccines and other pharmaceutical products.
- **Ensure sufficient staffing** to ensure that patients can be monitored post-

vaccination and respond to any adverse events. During vaccination periods, the administering pharmacist's primary responsibility is vaccination administration and post-vaccination observation.

- An in-date and complete anaphylaxis response kit should be readily available at the premises.
- An emergency response protocol that is on display in the administration area.
- Premises to have **ready access to relevant professional documents** including the *Australian Immunisation Handbook (current version) and Vaccine Storage Guidelines 2013 "Strive for 5" (current version).*
- Display **consumer information about a consumer's right to make a complaint** about a health service provider in accordance with the *Human Rights Commission Act 2005*.

Administration area requirements

Ensure the **area (during administration) is not visible to other persons** in the premises (i.e. use of a privacy screen or private consultation room).

- The administration area must not be used as a dispensary, storeroom, staff room or retail area.
- The premises must have **hand washing** or **hand sanitisation facilities** readily available.
- Must have a dedicated **vaccine administration area with at least 4m^2 of free floor space** (clear of equipment) to provide sufficient room for the pharmacist and patient (and an accompanying person if applicable) to manoeuvre or allow the patient to lie down as required.
- Administration area must have a **seat or couch for the patient** to sit in while vaccine is being administered (to account for any syncope response).
- The pharmacist must advise the patient that he/she must remain on the premises for at least **15 minutes post-vaccination for observation**.
- Provide a **seating area** for the patient to wait in following administration. 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

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;
- evidence of the patient's informed consent;
- the name and contact details of the recipient's primary medical practitioner;
- the type, brand, batch number and expiry date of the vaccine;
- the date the vaccine was administered to the patient;
- the name/signature of the administering pharmacist;
- The name and address of the premises where vaccination occurred;
- 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*.

Information about an administered vaccine must be provided to the patient.

Reporting of information

For each vaccination event, a copy of the patient's record of vaccination must be provided to the patient's 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 CHO with the number of vaccines administered to patients, by pharmacists. A template for manually reporting details to the CHO is available from 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*.

Written procedures

The administering pharmacist or pharmacy must ensure that there are written procedures in place for:

- the vaccination process (from patient presentation in the pharmacy to post-vaccination);
- dealing with adverse events;
- obtaining and recording patient consent; and
- sending vaccination records back to the patient's nominated GP.

These written procedures must be retained at the premises. These written procedures 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*.

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 edition).* The pharmacist must ensure that an ambulance is called to attend to the patient in the event of an anaphylaxis.

Any adverse event following immunisation (AEFI) 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 health.act.gov.au/pharmaceuticalservices.