

Australian Capital Territory

Medicines, Poisons and Therapeutic goods (Vaccinations by Pharmacists) Direction 2023 (No 2)

Disallowable instrument DI2023–294

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))

EXPLANATORY STATEMENT

PURPOSE AND OUTLINE

Section 352 of the Medicines, Poisons and Therapeutic Goods Regulation 2008 (the MPTG Regulation) provides that the Chief Health Officer (CHO) may, by disallowable instrument, give directions for the administration of a vaccine to a person without prescription by a pharmacist (or intern pharmacist).

This instrument is a direction of the CHO issued under section 352 of the MPTG Regulation. The direction instructs that a pharmacist or intern pharmacist may administer a vaccine without prescription if they comply with the Pharmacist Vaccination Standards (Vaccination Standards) imposed by the CHO at Schedule 1 of this instrument.

These Vaccination Standards are made for the purposes of establishing conditions and criteria under which registered pharmacists may initiate the administration of a vaccine to a person in absence of a supply authority (prescription). A registered pharmacist or intern pharmacist is authorised to supply and administer a vaccine under their own authority to a person provided the vaccine is listed in Appendix 1 of the Vaccination Standards, the pharmacist complies with parts A-C of the Vaccination Standards and the patient meets the approved clinical criteria for the vaccine as per the Australian Immunisation Handbook.

The Vaccination Standards outline the need for administering pharmacists to comply with the following three components:

- Completion of appropriate training to administer an approved vaccine;

- Practice standards; and
- Record keeping requirements.

Part A of the Vaccination Standards specifies the training requirements for pharmacists to be authorised to administer an approved substance (vaccine) in the ACT. These training requirements are considered consistent with the minimum training standards required in other Australian jurisdictions, being the completion of a training course that complies with the Australian Pharmacy Council *Standards for the Accreditation of Programs to Support Pharmacist Administration of Vaccines*.

Part A has been amended to ensure pharmacists have the required knowledge for administering vaccines and hold a certificate confirming completion of an accredited training program. This change is consistent with the NSW Pharmacist Vaccination Standards.

Part B of the Vaccination Standards outlines the general administration; premises, staffing and equipment; and administration area requirements.

Part B of the Vaccination Standards under 'general administration requirements', references eligibility for vaccines under the National Immunisation Program (NIP). From 1 January 2024, the Australian Government has agreed to expand funding for NIP vaccines to include vaccinations provided by pharmacists. In the ACT, community pharmacists will be able to administer the majority of NIP funded vaccines to individuals aged 10 years and over, and influenza vaccine for eligible individuals five years and over, as listed on the ACT Immunisation Schedule.

Catch-up vaccinations that are scheduled for administration prior to 10 years of age are excluded from ACT NIP funded pharmacist vaccinations. This exclusion is due to the low number of catch-up vaccinations required for this age group in the ACT population and the complexity surrounding the schedule of these vaccines. To facilitate this change, the requirement for pharmacists to make patients aware of their eligibility for NIP funded vaccines has been amended to remove 'nominated medical practitioner'. This requirement now states 'participating NIP immunisation provider', which includes medical, nursing and pharmacy NIP providers.

A minor amendment has been made to part B 'under general administration requirements' to add a footnote that clarifies the definition of valid consent. The Vaccination Standards adopt the Australian Immunisation Handbook definition for valid consent.

Part B of the Vaccination Standards 'when not to vaccinate' has been removed as pharmacists are now required to ensure the patient meets the approved clinical criteria for a vaccine as per the Australian Immunisation Handbook.

Part B outlining premises and equipment requirements previously required COVID-19 vaccines to be stored in accordance with the Australian Government

COVID-19 vaccination training. As this training no longer exists, and pharmacies now receive thawed COVID-19 vaccines, this section has been removed.

Part C of the Vaccination Standards sets out record keeping requirements for pharmacists and pharmacies. This section requires pharmacists to consult and record all vaccination events on the Australian Immunisation Register (AIR) consistent with requirements of the *Australian Immunisation Register Act 2015 (Cwlth)*.

Appendix 1 – Approved Vaccines removes the requirement for mandatory training for pharmacists administering COVID-19 vaccines. The Department of Health and Aged Care has advised jurisdictions that as of 1 October 2023, the COVID-19 Vaccine Training Program is no longer mandatory for participation in the COVID-19 Vaccine Program. COVID-19 vaccines are now included in the Australian Immunisation Handbook. As such, the requirement for COVID-19 vaccines to be administered in accordance with the Therapeutic Goods Administration is no longer required. This requirement has been removed from the Vaccination Standards.

Appendix 1 outlines the vaccines approved for administration by pharmacists and associated administration conditions including patient age. This instrument updates the list of approved vaccines that may be supplied and administered by pharmacists. The additional vaccines listed include:

- Haemophilus influenzae vaccine (Hib)
- Meningococcal B
- Meningococcal C
- Varicella vaccine

To align with NSW the minimum age at which a pharmacist can administer most vaccines, the age is now five years of age. ACT pharmacists will be able to administer privately funded vaccines to individuals aged five years and older provided administration is in accordance the Australian Immunisation Handbook.

Vaccines for Hib, Meningococcal B and C are inactivated vaccines and do not contain any live virus. This presents a lower risk of adverse events. Varicella vaccine is a live attenuated (weakened) virus and like many vaccines of this type has a low risk of side effects that generally resolve quickly. Adding these vaccines brings the ACT in line with NSW providing better consistency of vaccinations available through community pharmacies.

Column 2 of the table of approved vaccines previously outlined conditions for the administration of vaccines. These conditions were specific to COVID-19 vaccines, typhoid and Shingrix. This column has now been removed as all conditions have been covered in the Australian Immunisation Handbook and in column 1 of the table. The conditions imposed on COVID-19 vaccines are now covered in the Australian Immunisation Handbook and as a footnote to column 1 of the Approved Vaccines Table. The requirement for typhoid vaccines to be given by intramuscular

injection is also covered in the Australian Immunisation Handbook. The requirement for Shingrix to be the only brand of the Zoster vaccine recombinant has been added to column 1.

Additional information for community pharmacists and the general public will be provided on the ACT Health Pharmacist Vaccination webpage. This will include details regarding the vaccines eligible for NIP funding and any other relevant criteria. This will enable any administrative changes to be updated promptly on the website without updating this instrument.

Regulatory Impact Statement

In accordance with the *Legislation Act 2001*, a regulatory impact statement was not required to be presented with the Vaccination Standards as the amendments do not impose any new appreciable costs or regulatory burden on the community or section of the community.

This instrument enables pharmacists to administer additional vaccines that have been previously excluded from the Vaccination Standards and not funded under the NIP. The instrument also makes minor structural and grammatical updates to assist readers in understanding the Vaccination Standards.

Changes imposed by this instrument create better consistency with other jurisdictions (notably New South Wales), promote consumer access to health services and allow patients to choose their preferred access to health professionals. This instrument does not operate to the disadvantage of any person or impose additional liabilities on a person.

Human rights considerations

During the development of the Vaccination Standards, due regard was given to its compatibility with the *Human Rights Act 2004* (HR Act).

The Vaccination Standards are considered to engage the following HR Act rights:

- Section 9 – Right to life
- Section 12 - Right to Privacy

Right to Life

The right to life is concerned with preventing the arbitrary deprivation of life and is relevant to the delivery of medical treatment, including immunisation services. As this instrument enables consumer access to vaccination services, this instrument is considered to engage and promote the right to life under the HR Act. The Vaccination Standards are not considered to impose any new limitations on an individual's right to life as described by the HR Act.

Right to Privacy

The right to privacy and reputation protects against unlawful or arbitrary interference with personal information.

Part C of the Vaccination Standards require immunising pharmacists to collect and maintain up to date records and patient information regarding administered vaccines and report information about administered vaccines to the AIR. The collection, storage and use of sensitive personal health information, such as vaccine history, medical conditions, and contact details engages the right to privacy. Any engagement with the right to privacy as it relates to health records is already limited by the *Health Records (Privacy and Access) Act 1997*, *Information Privacy Act 2014* and *Australian Immunisation Register Act 2015 (Cwth)* which establish clear rules and limitations on the collection, use and disclosure of personal information, including how a person can access their personal information stored by an immunisation service provider.

Health consumers are also reasonably made aware of their human rights with regard to pharmacy services. In accordance with section 95 of the *Human Rights Commission Act 2005*, all health service providers are required to prominently display information about how complaints may be made to the ACT Human Rights Commission or appropriate regulatory agency.

The Vaccination Standards are therefore considered to engage with the right to privacy under the HRA, but do not operate as to arbitrarily or unlawfully interfere or otherwise limit an individual's right to privacy or reputation as described by the HR Act.