

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))

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) as determined 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 the 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 (AIH).

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 have been amended to confirm that a pharmacist must complete an accredited training course that complies with the Australian Pharmacy Council 'Standards for the Accreditation of Programs to support Pharmacist Administration of Vaccines'.

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

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).

The written procedures section of part C have been removed from the Vaccination Standards as this content is now covered in the AIH, which pharmacists are required to comply with.

The adverse event reporting section of part C was updated to include a link to the online adverse event reporting form.

Minor changes were made to the Vaccination Standards to reflect the change of name of the ACT Immunisation Unit to the ACT Health Immunisation Section.

Appendix 1 outlines the vaccines approved for administration by pharmacists and associated administration conditions including patient age.

This instrument updates the list of vaccines that pharmacists may supply and administer to include the following vaccines:

- Japanese Encephalitis Virus (JEV) vaccine to pharmacists who complete an additional training module (newly added)
- Mpox vaccine (in settings authorised by the Operational Protocol for the Supply and Administration of JYNNEOS® Vaccine (JYNNEOS® protocol)) (newly added)
- Pneumococcal conjugate vaccines to Aboriginal people aged 50 years and over and non-Aboriginal people aged 70 years and older (newly added)
- Rabies vaccine as pre-exposure prophylaxis to non-immunocompromised people and to educate patients on the need to seek medical assessment after exposure regardless of vaccination (newly added)

- Respiratory syncytial virus (RSV) vaccine Abrysvo® to pregnant people between 28 to 36 weeks gestation (previously limited to those aged 60 years and older)
- Shingrix vaccine (for protection against shingles (herpes zoster) infection) to people 18 years or older (previously limited to those 50 years and older).

Including these vaccines aims to improve community access to vaccines both privately, under the National Immunisation Program and ACT vaccine programs, and promotes consistency with pharmacist scope of practice in New South Wales.

This instrument also removes the previous requirement to follow the Australian Technical Advisory Group on Immunisation (ATAGI) for administration of the Abrysvo® vaccine as it now has been added to the AIH.

In prescribing the vaccines listed above under the Standards, consideration was given to the appropriateness of vaccines for supply and administration by pharmacists at community pharmacies without prior medical practitioner consultation and prescription.

Considering the available information, mitigation strategies have been put in place for each vaccine, including:

- An additional training module is required by pharmacists who wish to administer the JEV vaccine. This is the same requirement as NSW.
- Supply of the mpox vaccine will only be made available to selected pharmacies subject to the JYNNEOS® protocol. Pharmacies will be chosen and authorised by the CHO to ensure targeted access to individuals at higher risk of contracting mpox. The NCRIS risk assessment lists this approach as low risk.
- Pneumococcal vaccines will be limited to the pneumococcal conjugate vaccine. This mirrors the approach in NSW. Communication will be developed to ensure those eligible to receive NIP Pneumovax 23 vaccine are referred to primary care for vaccination.
- Rabies vaccines are limited to pre-exposure prophylaxis for people who are not immunocompromised, and the patient must be educated on first aid and the need to seek medical assessment for exposure to rabies or Australian Bat Lyssavirus, regardless of vaccination status.
- The administration of the RSV vaccine Abrysvo® will be limited to pregnant people between 28 to 36 weeks gestation and people 60 years or older, following National Immunisation Program (NIP) eligibility and ATAGI recommendation.

An additional mitigation is not included for shingrix vaccine for immunocompromised individuals 18 years and older. Vaccination for this cohort is more complex as consideration of the optimal age at which to vaccinate is required and ensure

discussions about other recommended vaccines occurs. The AIH provides this guidance under the 'Vaccination for people who are immunocompromised' chapter.

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 greater access to medicines by allowing pharmacists to administer additional vaccines, increasing the options available to patients and reducing the pressure on hospitals and clinics. Pharmacies are also open on weekends and after hours, providing further access to the vaccines to workers. This will also create better consistency with New South Wales.

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 improves consumer access to vaccination services, this instrument is considered to engage and promote the right to life under the HR Act. Improved access to vaccines helps to reduce the risk of vaccine preventable illnesses.

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* (Cwlth) 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 with or otherwise limit an individual's right to privacy or reputation as described by the HR Act.