

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))**

## EXPLANATORY STATEMENT

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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. The Vaccination Standards have a delayed commencement date of 17 March 2023 in order to allow pharmacists and other immunisation providers sufficient time to review and make any necessary changes to their business such as ordering of additional vaccines, updating public communications or ICT systems.

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).

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 to be consistent with the minimum training standards required in other Australian jurisdictions, being the completion of a training course that accords with the Australian Pharmacy Council *Standards for the Accreditation of Programs to Support Pharmacist Administration of Vaccines*. Part B of the Vaccination Standards provides an outline of 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 (Cwth) (AIR Act)*. This instrument updates Part C of the Vaccination Standards to remove the requirement that pharmacists report vaccination records to the CHO. Removal of this requirement decreases regulatory burden on pharmacies in the handling and reporting of health information. The AIR Act and Public Health Regulation 2000 collectively authorise the CHO to access and use data on the AIR when consistent with a defined purpose of the AIR Act, which includes monitoring vaccination coverage across Australia and the effectiveness of vaccination programs. The omission of pharmacist reporting requirements to ACT Health therefore do not adversely impact the collection and use of vaccination data for public health policy or planning purposes.

*Appendix 1 – Approved Vaccines* describes the vaccines approved to be administered by pharmacists and associated administration conditions including patient age, not elsewhere stated in the Vaccination Standards. This instrument updates the list of approved vaccines that may be supplied and administered by pharmacists to include:

- Hepatitis A vaccine
- Hepatitis B vaccine
- Human Papillomavirus vaccine
- Meningococcal vaccine
- Poliomyelitis vaccine
- Typhoid vaccine
- Varicella zoster virus vaccine (Shingrix only)

All additional vaccines added to Appendix 1 are inactivated vaccines, meaning they do not contain any live virus and represent a lower vaccination risk. Inclusion of these vaccines aligns pharmacist vaccination arrangements with NSW Health and promotes equitable cross-border access to immunisation services and choice of service provider. Pharmacists are well placed to provide comprehensive information to patients about vaccine safety including advice on the risks and benefits of vaccination, side-effects and referral to other primary health care providers. Where a person receives a vaccine for travel purposes, pharmacists are also well equipped to provide general information about other related health conditions and may refer people to a medical practitioner as appropriate. Administering pharmacists are required to undertake an appropriate clinical evaluation and provide additional advice and/or referral to people as part of a vaccine consultation.

ACT Health has determined that inclusion of these additional vaccines in the Vaccination Standards do not pose an increased risk to patient safety or public health.

### **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 subsection of the community.

This instrument enables pharmacists to administer additional vaccines that have been previously prohibited. The instrument also makes minor structural and grammatical updates to assist readers in understanding the Vaccination Standards.

Changes imposed by this instrument create greater harmonisation with neighbouring jurisdictions, promotes consumer access to health services and related health service competition. 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 (ACT)*, *Information Privacy Act 2014 (ACT)* 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.

The Vaccination Standards have also removed an obligation that a pharmacist *must* obtain and report on a person's Aboriginal and Torres Strait Islander status as a condition of their authorisation to supply and administer vaccinations without a prescription. While all health service providers are strongly encouraged to ask if a person self-identifies as Aboriginal or Torres Strait Islander in origin, the reporting of this information should remain voluntary and not be linked to a pharmacist's authority to supply and administer vaccines.

Removal of this mandatory record keeping requirement supports a person's right to privacy and right to life under the HRA by ensuring health consumers can access pharmacist-led immunisation services without the need to disclose if they identify as Aboriginal and Torres Strait Islander in origin. ACT Health will continue to promote the voluntary collection of information relating to Aboriginal and Torres Strait Islander health to assist in the delivery of culturally specific and appropriate health, social, emotional and wellbeing services. Immunising pharmacists are also prompted record if patients self-identify as Aboriginal or Torres Strait Islander origin as part of submitting data to the AIR and using pharmacy software systems.

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 (ACT)*, 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.