Australian Capital Territory

Medicines, Poisons and Therapeutic goods (Vaccinations by Pharmacists) Direction 2024

Disallowable instrument DI2024–109

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 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.

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*.

This instrument omits the word 'current' from the requirement that a pharmacist holds an anaphylaxis management certificate. The accredited provider of the certificate, the Australian Society of Clinical Immunology and Allergy has confirmed that certificates do not have an expiry, nor does it recommend repeated training periods. As such, the word "current" is omitted to make clear the requirement that the pharmacist has completed an anaphylaxis management course.

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).

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 pharmacists may supply and administer to include vaccines for Respiratory Syncytial Virus (RSV). Vaccines to prevent RSV are new to the market, with two vaccines recently registered by the Therapeutic Goods Administration (TGA) for use in Australia. These vaccines have been registered for use in individuals aged 60 years and over.

Pharmacists must follow the Australian Technical Advisory Group on Immunisation (ATAGI) recommendations and TGA advice when supplying and administering RSV vaccines. RSV vaccines are not currently included in the Australian Immunisation Handbook (AIH), once included pharmacists must supply and administer them in accordance with the AIH.

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 RSV vaccines. Severe RSV presents a danger to adults with chronic lung or heart disease, older adults, and children under five. Enabling pharmacists to administer RSV vaccines will increase the options available to patients and reduce 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, where pharmacists are authorised to administer RSV vaccines.

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 is particularly important for the groups most affected by severe RSV and RSV-related complications, people over the age of 60. 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* (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.