

Australian Capital Territory

Medicines, Poisons and Therapeutic Goods (Vaccinations by Pharmacists) Direction 2021 (No 2)

Disallowable instrument DI2021-205

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

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).

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 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 B, section 1 of the Pharmacist Vaccination Standards has been amended to enable pharmacists or intern pharmacists to administer a COVID vaccine in line with the minimum patient age that COVID vaccine is approved or provisionally approved for use by the Therapeutic Goods Administration (TGA) and no less than 10 years of age (where a product is approved for use in persons under the age of 10 years).

This change serves to lower the previously imposed patient age limit of 16 years for pharmacist administration of COVID-19 vaccines. The change is intended to align with TGA approved age restrictions for the Pfizer and Moderna vaccines to support consumer access to these vaccines, which at the time of notification of these Standards are provisionally approved for use in persons aged 12 years of age and older.

The minimum patient age of 10 years for pharmacist administration of COVID vaccines imposed by these Standards is intended to align with the minimum patient age for pharmacist administration of an influenza vaccine in the Vaccination Standards and draws upon the established policy position that pharmacists may administer a subcutaneous vaccine to persons 10 years of age and over. The intent of establishing this age limit is to provide flexibility should a COVID vaccine be approved or provisionally approved for use in children younger than 12 years in the future.

Part B, section 1, sub-clause (c) has been added to this version of the Vaccination Standards to require pharmacists to administer a COVID-19 AstraZeneca vaccine in accordance with the *Australian Technical Advisory Group on Immunisation (ATAGI) clinical guidance on use of COVID-19 vaccine in Australia*, which states the COVID-19 Cominarty (Pfizer) vaccine is preferred over the AstraZeneca vaccine for people aged less than 60 years. The intent is to ensure pharmacists only administer the AstraZeneca vaccine to persons under the age of 60 years following preferential consideration of the use of the Pfizer vaccine and following an explanation by the pharmacist of the risks and benefits of the AstraZeneca vaccine and receiving written informed consent of the patient.

The publication of *Information for health care providers to help consumers make informed decisions about the COVID-19 AstraZeneca vaccine* and supporting *Consent form for COVID-19 vaccination* by the Australian Government at the time of notification of these Standards is expected to support pharmacists administer AstraZeneca vaccines in accordance with ATAGI clinical guidance.

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

The condition which restricted pharmacists and intern pharmacists from administering the COVID-19 AstraZeneca vaccine to people who are 50 years of age or older is removed in this version of the Vaccination Standards. By removing this condition, both pharmacists and intern pharmacists will be able to administer the AstraZeneca

vaccine subject to requirements to follow ATAGI clinical guidance and obtain written informed consent outlined in Part B, section 1 of the Standards.