Medicines, Poisons and Therapeutic Goods (Vaccinations by Pharmacists) Direction 2022 (No 1)

Disallowable instrument DI2022-77

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.

The 2022 amendment to the Vaccination Standards amends Part B, Section 1 Subclause (b) of the Pharmacist Vaccination Standards, which enables a pharmacists or intern pharmacists to administer an influenza vaccine in line with the Australian Immunisation Handbook (current online version) and not less than five years of age. This lowers the age for influenza vaccine from the previous Vaccination Standards from ten years of age. A minimum age of five years is consistent with the minimum age for a COVID-19 vaccine administered in community pharmacy and is therefore considered an appropriate primary health care setting for the administration of influenza vaccine for this age group.

The 2022 amendment to the Vaccination Standards also removes the requirement that pharmacists obtain written consent prior to administering a vaccine. Obtaining written consent is an unnecessary burden that is inconsistent with the evidence of consent outlined in the Australian Immunisation Handbook. Current practices in ACT Government vaccination clinics, within the primary care setting and the Medicines, Poisons and Therapeutic Goods (Nurse and Midwife Immunisers) Direction 2020 (No 1) (DI2020-290) allow for written or verbal consent.

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).