

Australian Capital Territory

Medicines, Poisons and Therapeutic Goods (Vaccinations by Pharmacists) Direction 2021 (No 1)

Disallowable instrument DI2021-111

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 MPTGR) establishes that a pharmacist is authorised to administer a vaccine to person without a prescription if the pharmacist administers the vaccine in accordance with a direction by the Chief Health Officer.

Section 352 also provides that same section also provides that the Chief Health Officer may, by disallowable instrument, give directions for the administration of a vaccine to a person without prescription by a pharmacist (or intern pharmacists).

This instrument is a direction of the Chief Health Officer issued under section 352 of the MPTGR. 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 Chief Health Officer 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*..

On 5 May 2020, as a result of the COVID-19 public health emergency and in recognition of the additional demand on constrained resources, Part A – pharmacist training was temporarily amended in DI2020-88. The amendments allowed a pharmacist whose cardiopulmonary resuscitation (CPR) certificate or First Aid Training expires during the COVID-19 declared public health emergency to be taken to be compliant against the pharmacist training requirements in Schedule 1 Part A, Items (4) and (5).

The amendments recognised that, due to COVID-19 emergency restrictions, some training providers were unable to deliver first aid or CPR training. This created challenges for pharmacists who are already qualified immunisation providers to meet the requirements for renewing mandatory first aid and CPR refresher training. The amendments recognised the impracticality or inability for pharmacists to attend these face-to-face training courses during acute stages of the COVID-19 pandemic. As face-to-face training is now available in the ACT, and the access issues faced during 2020 are considered unlikely to reoccur in a sustained way, it is appropriate to recommence training requirements. A transition period to 31 August 2021 has been provided in the instrument (at Clause 5) to enable pharmacists to be advised of the recommencement of the training requirements and to ensure they have adequate time to undertake any required training. The date ‘16 March 2020’ is the start date of the permitted period for expired training requirements because this is the date when the COVID-19 public health emergency declaration commenced under NI2020-153.

From 1 September 2021, pharmacists must have completed the required First Aid and CPR training in order to be authorised to administer vaccinations.

Clause 6 provides that the transitional provision at clause 5 expires on 1 September 2021.

Part A of the Vaccination Standards which specifies the supervision requirements for provisionally registered pharmacists (intern pharmacists) has been amended in this version to replace the words ‘direct-supervision’ with ‘supervision’. The word ‘direct’ has been removed to avoid a potential misperception that a supervising pharmacist must be in the same room as an intern pharmacist when they are administering a vaccine. The policy intent of this clause is that a supervising pharmacist must be at the same premises as the intern pharmacist while the intern pharmacist administers a vaccine, whilst not necessarily having to be in the same room.

Part B of the Vaccination Standards provides an outline of general administration; premises, staffing and equipment; and administration area requirements.

The patient age cut-off for administration of a non-influenza vaccine listed in Appendix 1 has been amended to refer to the age that a vaccine is approved for use under the *Therapeutic Goods Act 1989* and not less than 16 years of age, to remove

doubt about a pharmacist's authorisation to administer the COVID-19 (chadox1-s) (AstraZeneca) vaccine, which at the time of notification is only indicated for use in persons greater than or equal to 18 years of age.

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). An amendment has been made in this version of the Vaccination Standards to mandate the reporting of all vaccination events to the AIR, consistent with the requirements of the *Australian Immunisation Register Amendment (Reporting) Bill 2020*, which mandated reporting to the AIR from 1 March 2021.

Appendix 1 describes the vaccines approved to be administered by pharmacists and associated conditions. This section has been amended include a vaccine for COVID-19 included on the Australian Register of Therapeutic Goods. This amendment is intended to enable authorised pharmacists to administer all vaccines for COVID-19 included on the Australian Register of Therapeutic Goods, subject to the associated conditions.

The intent of the first associated condition is to ensure that pharmacists are able to demonstrate that they have successfully completed the Australian Government's COVID-19 vaccination training program to ensure they have the necessary knowledge and skills to be able to safely handle and administer a COVID-19 vaccine, and recognising that specific training in the handling and administration of COVID-19 vaccines is not available through pharmacist immunisation training courses that are recognised under Part A of the Vaccination Standards at the time of notification of this instrument.

The intent of the second associated condition is to ensure pharmacists comply with requirements of the Australian Government COVID-19 Vaccination Program.

The third associated condition is intended to restrict pharmacists and intern pharmacists from administering the COVID-19 (chadox1-s) (AstraZeneca) vaccine to people who are under 50 year of age. This restriction is based on the *Australian Technical Advisory Group on Immunisation (ATAGI) Clinical guidance on use of COVID-19 vaccine in Australia* document which recommends that the *Pfizer (Comirnaty) COVID-19 vaccine* is preferred over the COVID-19 (chadox1-s) (AstraZeneca) vaccine for people aged 50 years due to the very rare risk of thrombosis with thrombocytopenia syndrome (TTS) after administration of COVID-19 (chadox1-s) (AstraZeneca) vaccine.

This age restriction has been included in this instrument to mitigate the risk that a pharmacist may administer the COVID-19 Astra Zeneca vaccine to a person who is under 50 years of age contrary to ATAGI guidance and with regard to the potential for serious harm including death where a person may experience TTS. More information about TTS and its links to vaccination, is available in the ATAGI guidance document.

Appendix 1 has also been amended to authorise pharmacists to administer the measles-mumps-rubella combination vaccine (MMR) by subcutaneous injection, as

the Australian Immunisation Handbook specifies that the vaccine may be administered by subcutaneous or intramuscular injection. Appendix 1 already authorises the administration of the MMR vaccine by intramuscular injection.