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DRUGS, POISONS AND CONTROLLED SUBSTANCES REGULATIONS 2017, REGULATION 163

Secretary Approval: Pharmacist Immuniser –
SARS-CoV-2 (COVID-19) VACCINE

Regulation 99(c) of the *Drugs, Poisons and Controlled Substances Regulations 2017* (the Regulations) authorises pharmacists to administer a Schedule 4 poison without an instruction from a registered medical practitioner, dentist, nurse practitioner or authorised midwife provided that the Secretary has approved the poison under regulation 163 of the Regulations, the pharmacist has taken all reasonable steps to ensure a therapeutic need exists for the poison and any conditions in the approval are complied with. In making this approval under regulation 163, the Secretary considers that the making of this approval is necessary for the provision of health services and s 14A of the **Drugs, Poisons and Controlled Substances Act 1981** does not apply.

Secretary Approval Pharmacist Immuniser – SARS-COV-2 (COVID-19) VACCINE

Approval under Regulation 163(1) of the Drugs, Poisons and Controlled Substances Regulations 2017 to administer without instruction

1. **This approval applies to a pharmacist who, at the time of the administration of the Schedule 4 poison,¹ namely any SARS-CoV-2 (COVID-19) VACCINE approved by the Therapeutic Goods Administration (COVID-19 VACCINE), holds general registration with the Pharmacy Board of Australia² and:**

- (a) has satisfactorily completed the assessment of an ‘Immuniser program of study’ recognised by the Chief Health Officer;

OR

- (b) has satisfactorily completed the assessment of an ‘Immuniser program of study’ that meets the curriculum content requirements of the National Immunisation Education Framework for Health Professionals; and
- (c) has recency of practice and continuing professional development in immunisation (as defined from time to time by the Pharmacy Board of Australia);

OR

- (d) is currently completing clinical practice in a hospital, pharmacy, pharmacy depot, general practice or immunisation clinic as part of an ‘Immuniser program of study’ recognised by the Chief Health Officer under the direct supervision of a:
 - (i) medical practitioner;
 - (ii) nurse practitioner;
 - (iii) ‘Nurse Immuniser’³ that is compliant with Regulation 8(1) of the Regulations; or
 - (iv) Pharmacist that is compliant with Regulation 99(c) of the Regulations;

AND

- (e) holds a current first aid certificate (to be updated every three years); and
- (f) holds a current cardiopulmonary resuscitation certificate (to be updated annually); and
- (g) has successfully completed the Commonwealth COVID-19 Vaccination Training Program; and
- (h) has satisfactorily completed any additional training and competency requirements required by the Victorian COVID-19 Vaccination Guidelines.

¹ Included in Schedule 4 of the Poisons Standard.

² This does not include limited registration, provisional registration, non-practising registration, or student registration.

³ ‘Nurse Immuniser’ is a nurse acting in accordance with a Secretary Approval to possess and use certain vaccines.

SPECIAL

2. The pharmacist may administer the following Schedule 4 poison without instruction:

Generic name	Approval for pharmacists to vaccinate with this vaccine <i>applies to</i>	Approval for pharmacists to vaccinate with this vaccine <i>excludes</i>
SARS-CoV-2 (COVID-19) VACCINE	<ul style="list-style-type: none"> ● Vaccination of people approved by the Therapeutic Goods Administration as eligible to receive the vaccine, excluding those circumstances listed in Column 3. 	<ul style="list-style-type: none"> ● Vaccination of people ineligible to receive the vaccine in accordance with regulatory approval granted by the Therapeutic Goods Administration; ● Vaccination of people with contraindications defined in the current edition of the <i>Australian Immunisation Handbook</i>.⁴

3. A pharmacist authorised by this approval in accordance with the circumstances in paragraph 4 or 5 must follow the requirements of paragraph 6.

4. The following circumstances apply to pharmacists administering the COVID-19 VACCINE when they own, are employed or otherwise engaged by an organisation listed in paragraph 4(c):

- (a) The pharmacist may possess or obtain the COVID-19 VACCINE from an organisation, whose premises are listed in paragraph 4(c), and who is authorised to obtain, possess and/or supply the COVID-19 VACCINE.
- (b) The pharmacist may administer COVID-19 VACCINE that has been reconstituted in accordance with the manufacturer's instructions and transferred to a single-use syringe ready for administration by a person authorised by the Secretary to do so.
- (c) The premises on which a pharmacist administers the Schedule 4 poisons must:
 - (i) be one of the following premises:
 - (I) a hospital; or
 - (II) a pharmacy as defined in the **Pharmacy Regulation Act 2010**; or
 - (III) a pharmacy depot, as defined in the **Pharmacy Regulation Act 2010**, that is a stand-alone business in premises owned or leased by the licensee of the related pharmacy;

OR

- (ii) be a mobile or outreach service of one of the premises referred to in paragraphs 4(c)(i)(I), (II) or (III) because the pharmacist administering the COVID-19 VACCINE owns, is employed or otherwise engaged by the business referred in paragraphs 4(c)(i)(I), (II) or (III) and sources the COVID-19 VACCINE from those premises;
- (d) Any premises referred to in paragraphs 4(c)(i)(I), (II) or (III) on which a pharmacist administers the COVID-19 VACCINE must meet the guidelines for facilities for immunisation services described in the *Victorian Pharmacy Authority Guidelines* that are current at the time of administration.
- (e) The pharmacist must ensure that at least one other staff member that holds a current first aid and cardiopulmonary resuscitation certificate is on duty in the pharmacy when the COVID-19 VACCINE is administered and for a minimum period of 15 minutes afterwards, where administering on premises defined in paragraphs 4(c)(i)(I), (II) or (III).

5. The following circumstances apply to pharmacists administering the COVID-19 VACCINE when they are not employed or otherwise engaged by an organisation listed in paragraph 4(c):

- (a) The pharmacist may administer the COVID-19 VACCINE that has been reconstituted in accordance with the manufacturer's instructions and transferred

⁴ Current version available online.

to a single-use syringe ready for administration by a person authorised by the Secretary to do so.

- (b) The pharmacist must be employed or contracted by:
 - (i) a medical practitioner; or
 - (ii) a municipal council that employs, contracts or ensures access to a medical practitioner or nurse practitioner; or
 - (iii) a health services permit holder who employs, contracts or ensures access to a medical practitioner or nurse practitioner; or
 - (iv) a health service authorised by the Victorian Government under a Public Health Emergency Order to obtain, possess, use and/or supply the COVID-19 VACCINE that employs, contracts or ensures access to a medical practitioner or nurse practitioner; or
 - (v) an agency funded by the Victorian Government or the Government of Australia that employs, contracts or ensures access to a medical practitioner or nurse practitioner.
- (c) The pharmacist administers the COVID-19 VACCINE only when a medical practitioner or nurse practitioner referred in paragraph 5(b)(i), (ii), (iii), (iv) or (v) is available to provide advice to the pharmacist on the use of the COVID-19 VACCINE if needed.
- (d) The pharmacist administers COVID-19 VACCINE that has been allocated to the individuals/organisations referred in paragraph 5(b)(i), (ii), (iii), (iv) or (v) by the Government of Australia.

6. The following circumstances apply to ALL pharmacists authorised by this approval:

- (a) All pharmacists administering the COVID-19 VACCINE must do so in accordance with:
 - (i) the edition of the *Australian Immunisation Handbook*⁴ that is current at the time of the administration; and
 - (ii) the edition of the National Vaccine Storage Guidelines: Strive for 54 that is current at the time of the administration; and
 - (iii) the Victorian COVID-19 Vaccination Guidelines (as amended from time to time and current at the time of administering the COVID-19 VACCINE); and
 - (iv) any guidelines issued by the Victorian Government and Government of Australia in relation to any COVID-19 VACCINE (current at the time of administering the COVID-19 VACCINE).

NOTE: Pharmacists who administer COVID-19 VACCINE are referred to the edition of the *Victorian Pharmacist-Administered Vaccination Program Guidelines* current at the time of administration and issued by the Department of Health, which apply to the administration of all government-funded vaccines by pharmacists. These guidelines contain best practice guidance for the administration of vaccines by pharmacists.

NOTE: Pharmacists are permitted to possess and administer Schedule 3 poisons pursuant to Regulation 141 of the Regulations. Accordingly, pharmacists are permitted to possess and administer Schedule 3 Poisons that are necessary for the treatment of anaphylactic reactions to the COVID-19 VACCINE. Those Schedule 3 Poisons should be kept on hand and utilised should they be required at the time the vaccine is administered.

Dated 6 May 2021

Approved PROFESSOR EUAN WALLACE
Secretary to the Department of Health

This Approval supersedes the Secretary Approval: Pharmacist Immuniser – SARS-CoV-2 (COVID-19) VACCINE published in the Government Gazette S 80 21 February 2021 pp. 4–7 and takes effect on the date of publication in the Government Gazette and continues in force for a period of not more than twelve months, unless revoked earlier.

⁴ Current version available online.

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