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DRUGS, POISONS AND CONTROLLED SUBSTANCES REGULATIONS 2017, REGULATION 161

Secretary Approval: Nurse Immunisers

SARS-COV-2 (COVID-19) VACCINE

Regulation 8 of the Drugs, Poisons and Controlled Substances Regulations 2017 (the **Regulations**) authorises nurses and registered midwives to be in possession of Schedule 4, Schedule 8 and Schedule 9 poisons that are necessary for administration to a patient.[1] Where that authorisation is not otherwise granted by the Regulations or the **Drugs, Poisons and Controlled Substances Act 1981** (the **Act**), authorisation can be granted by the approval of the Secretary under regulation 161.

In making this approval under regulation 161, the Secretary considers that the possession is (a) necessary for the provision of health services and (b) within the competence of a nurse without the supervision or instruction of a medical practitioner, dentist, nurse practitioner, authorised midwife, authorised optometrist or authorised podiatrist (as the case requires). Authorisation has not otherwise been granted by the Regulations or the Act.

Secretary Approval: Nurse Immunisers – SARS-CoV-2 (COVID-19) VACCINE

Approval under Regulation 161(1) of the
Drugs, Poisons and Controlled Substances Regulations 2017
to possess in order to administer without supervision or instruction

1. The approval applies to a nurse who at the time of the administration of the Schedule 4 poison, namely any SARS-CoV-2 (COVID-19) VACCINE approved by the Therapeutic Goods Administration (COVID-19 VACCINE) is registered in Division 1 of the Nursing and Midwifery Board of Australia register and is not already endorsed to possess Schedule 4 Poisons under section 94 of the Health Practitioner Regulation National Law and who provides evidence to their employer of currency of competence and ongoing professional development in immunisation and who:

(a) on 30 June 2010 was registered in division 1 of the register of nurses endorsed under section 27A of the **Health Professions Registration Act 2005** by the Nurses Board of Victoria[2] in the approved area of practice – Immunisation;

OR

(b) has satisfactorily completed the assessment of a nurse immuniser program recognised by the Chief Health Officer (see Note);

OR

(c) has satisfactorily completed the assessment of an 'Immuniser program of study' recognised by the Chief Health Officer, providing the education provider offers the program to nurses;

OR

(d) has satisfactorily completed a nurse immuniser program not recognised by the Chief Health Officer and has written confirmation from the program provider that, at the time the program was completed, the program was of equivalent standard to a program currently recognised by the Chief Health Officer;

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[1] Included in Schedules 4, 8 and 9 respectively of the Poisons Standard.

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

OR

(e) 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

(f) has successfully completed the Commonwealth COVID-19 Vaccination Training Program; and

(g) has satisfactorily completed any additional training and competency requirements required by the Victorian COVID-19 Vaccination Guidelines.

Note: For the nurse immuniser programs recognised by the Chief Health Officer see https://www2.health.vic.gov.au/public-health/immunisation/immunisers-in-victoria/nurse-immunisers

2. The nurse may possess the following Schedule 4 poison in order to administer without supervision or instruction:

Generic name	**Approval for nurses to possess this vaccine in order to administer *applies to***	**Approval for nurses to possess this vaccine in order to administer *excludes***
SARS-CoV-2 (COVID-19) VACCINE	• Possession of the COVID-19 VACCINE for the purpose of administering it to persons included in the patient group for which that COVID-19 VACCINE has been approved by the Therapeutic Goods Administration (TGA), excluding those circumstances listed in Column 3.	• Possession of the COVID-19 VACCINE for the purpose of administering it to persons not included in the patient group for which that COVID-19 VACCINE has been approved by the TGA, except if the COVID-19 VACCINE is administered in accordance with paragraph 3(f); • Possession of the COVID-19 VACCINE for the purpose of administering it to people with contraindications defined in the current edition of the *Australian Immunisation Handbook*.[3]

3. The following circumstances apply:

(a) The nurse may administer the 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.

(b) The nurse must be employed, contracted or otherwise engaged 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. 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 medical practitioner or nurse practitioner referred in paragraph (b) is available to provide advice to the nurse on the use of the COVID-19 VACCINE when needed.

[3] Current version available online.

(d) The nurse possesses and administers only the Schedule 4 poisons obtained by the medical practitioner, municipal council, health services permit holder or Victorian Government or Government of Australia-funded agency, by whom the nurse is employed, contracted or otherwise engaged.

(e) The nurse administers the COVID-19 VACCINE in:

i. the performance of their duties with the medical practitioner, municipal council, health services permit holder or Victorian Government or Government of Australia-funded agency (as the case requires); and

ii. accordance with the edition of the Australia Immunisation Handbook[4] that is current at the time of the administration; and

iii. accordance with the edition of the National Vaccine Storage Guidelines: Strive for 5[5] that is current at the time of the administration; and

iv. accordance with the Victorian COVID-19 Vaccination Guidelines current at the time of the administration; and

v. accordance with any guidelines issued by the Victorian Government or Government of Australia in relation to any COVID-19 VACCINE that are the current edition at the time of the administration.

(f) The nurse must only administer a COVID-19 VACCINE to persons included in the patient group for which that COVID-19 VACCINE is approved by the TGA, except if the COVID-19 VACCINE is administered in accordance with the below:

i. the Australian Technical Advisory Group on Immunisation has recommended that the patient group to which the person belongs receive that COVID-19 VACCINE; and

ii. it is within the competency of the nurse (based on the successful completion of relevant training and competency assessments) to make an assessment as to whether that COVID-19 VACCINE is clinically appropriate for the particular person; and

iii. the administration of that COVID-19 VACCINE to the person is consistent with the best practice clinical guidelines issued by the State and Commonwealth Governments; and

iv. prior to administration of the COVID-19 VACCINE, the nurse informs the person that the administration of that COVID-19 VACCINE has not been approved by the TGA for the patient group to which that person belongs and obtains and records the person's consent to the administration of that COVID-19 VACCINE.

Dated 19 October 2022

PROFESSOR EUAN M WALLACE AM
Secretary, Department of Health

This Approval takes effect on 20 October 2022 and continues in force for a period of not more than twelve months, unless revoked earlier.

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[4] Current version available online.
[5] Current version available online.

DRUGS, POISONS AND CONTROLLED SUBSTANCES REGULATIONS 2017, REGULATION 163

Secretary Approval: Pharmacist Immunisers

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 section 14A of the **Drugs, Poisons and Controlled Substances Act 1981** does not apply.

Secretary Approval Pharmacist Immunisers – 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 Australia[2] 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.

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[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.

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

Generic name	Approval for pharmacists to vaccinate with this vaccine *applies to*	Approval for pharmacists to vaccinate with this vaccine *excludes*
SARS-CoV-2 (COVID-19) VACCINE	• Vaccination of persons included in the patient group for which that COVID-19 VACCINE has been approved by the Therapeutic Goods Administration (**TGA**), excluding those circumstances listed in Column 3.	• Vaccination of persons not included in the patient group for which that COVID-19 VACCINE has been approved by the TGA, except if the COVID-19 VACCINE is administered in accordance with paragraph 7; • Vaccination of people with contraindications defined in the current edition of the *Australian Immunisation Handbook*. [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 and 7.

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).

[4] Current version available online.

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 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 or otherwise engaged 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 when needed.

(d) The pharmacist administers the 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[5] that is current at the time of the administration; and

(ii) the edition of the National Vaccine Storage Guidelines: Strive for 5[6] that is current at the time of the administration; and

(iii) the Victorian COVID-19 Vaccination Guidelines (current at the time of the administration); 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 the administration).

7. The pharmacist must only administer a COVID-19 VACCINE to persons included in the patient group for which the COVID-19 VACCINE is approved by the TGA, except if the COVID-19 VACCINE is administered in accordance with the below:

a. the Australian Technical Advisory Group on Immunisation has recommended that the patient group to which the person belongs receive that COVID-19 VACCINE; and

b. it is within the competency of the pharmacist (based on the successful completion of relevant training and competency assessments) to make an assessment as to whether that COVID-19 VACCINE is clinically appropriate for the particular person; and

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[5] Current version available online.

[6] Current version available online.

c. the administration of that COVID-19 VACCINE to the person is consistent with the best practice clinical guidelines issued by the State and Commonwealth Governments; and

d. prior to administration of the COVID-19 VACCINE, the pharmacist informs the person that the administration of that COVID-19 VACCINE has not been approved by the TGA for the patient group to which that person belongs and obtains and records the person's consent to the administration of that 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 19 October 2022

PROFESSOR EUAN M. WALLACE AM
Secretary to the Department of Health

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