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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 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:**

- 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 Victoria² in the approved area of practice – Immunisation;

OR

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

OR

- 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

- 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;

OR

- 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;

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.

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AND

- has successfully completed the Commonwealth COVID-19 Vaccination Training Program;

AND

- 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 <i>applies to</i>	Approval for nurses to possess this vaccine in order to administer <i>excludes</i>
SARS-CoV-2 (COVID-19) VACCINE (COVID-19 VACCINE)	<ul style="list-style-type: none"> • Possession of the COVID-19 VACCINE for the purpose of administering it to 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"> • Possession of the COVID-19 VACCINE for the purpose of administering it to people ineligible to receive the vaccine in accordance with regulatory approval granted by the Therapeutic Goods Administration; • Possession of the COVID-19 VACCINE for the purpose of administering it to people with contraindications defined in the current edition of the <i>Australian Immunisation Handbook</i>.³

3. The following circumstances apply:

- 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.
- The nurse must be employed or contracted by:
 - a medical practitioner; or
 - a municipal council which employs, contracts or ensures access to a medical practitioner or nurse practitioner; or
 - a health services permit holder who employs, contracts or ensures access to a medical practitioner or nurse practitioner; or
 - an agency funded by the Victorian Government or the Government of Australia who employs, contracts or ensures access to a medical practitioner or nurse practitioner.
- 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.
- 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 or contracted.

³ Current version available online.

- (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 Handbook⁴ 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 administering the COVID-19 VACCINE; 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.

This Approval 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.

Dated 20 February 2021

PROFESSOR EUAN WALLACE
Secretary to the Department of Health

⁴ Current version available online.

⁵ Current version available online.

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 possess in order 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.

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. The following circumstances apply:

- (a) The pharmacist may possess or obtain the COVID-19 VACCINE from an organisation, whose premises are listed in paragraph 3(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 3(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 3(c)(i)(I), (II) or (III) and sources the COVID-19 VACCINE from those premises;

OR

- (iii) be premises established by a municipal council or the Victorian Government or Government of Australia for the purpose of administration of the COVID-19 VACCINE where the pharmacist referred in paragraphs 3(c)(i)(I), (II) or (III):
 - (I) is employed or otherwise engaged by the municipal council or the Victorian Government or Government of Australia or an agency funded by the Department of Health; and
 - (II) obtains the COVID-19 VACCINE from the Government of Australia.
- (d) Any premises referred to in paragraphs 3(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 the administration.

- (e) All pharmacists administering the COVID-19 VACCINE:
- (i) 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 5*⁴ 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); and
 - (ii) 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 3(c)(i)(I), (II) or (III).

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, and those Schedule 3 Poisons should be kept on hand and utilised should they be required at the time the vaccine is administered.

This Approval 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.

Dated 20 February 2021

PROFESSOR EUAN WALLACE
Secretary to the Department of Health

⁴ Current version available online.

Drugs, Poisons and Controlled Substances Act 1981**PUBLIC HEALTH EMERGENCY ORDER UNDER SECTION 22D****Authorisation for preparation and administration – COVID-19 VACCINE**

I, Professor Euan Wallace, Secretary to the Department of Health, pursuant to section 22D of the **Drugs, Poisons and Controlled Substances Act 1981**, make this Public Health Emergency Order (**Order**) in the belief that it is necessary to do so to prevent or respond to, a serious risk to public health posed to the State of Victoria by severe acute respiratory syndrome coronavirus 2 (**SARS-CoV-2**).

The purpose of this Order is to address the public health emergency posed by the ongoing global SARS-CoV-2 pandemic, which is currently affecting the State of Victoria.

In furtherance of that purpose, this Order is intended to facilitate the SARS-CoV-2 (COVID-19) VACCINE program, by authorising classes of persons to obtain, possess and use (including to administer), any SARS-CoV-2 (COVID-19) VACCINE approved by the TGA (**COVID-19 VACCINE**) which is a Schedule 4 poison and any Schedule 3 poisons necessary for the treatment of anaphylactic reactions to the COVID-19 vaccine (**relevant Schedule 3 poisons**) under the conditions outlined in this Order.

All authorised persons, irrespective of their status under the Act and the Regulations, are to adhere to the conditions of this Order prior to obtaining and possessing, using COVID-19 VACCINE.

1. Authorisation

By this Order, I authorise the following classes of persons (**authorised persons**) to undertake **authorised vaccination activities** in relation to the COVID-19 VACCINE:

- (a) registered nurses registered under the **Health Practitioner Regulation National Law**, to practice in the nursing profession; and
- (b) midwives registered under the **Health Practitioner Regulation National Law**, to practice in the midwifery profession; and
- (c) enrolled nurses registered under the **Health Practitioner Regulation National Law** to practice in the nursing profession (other than as a student or with a notation on their registration “Does not hold Board-approved qualification in administration of medicines”) and has successfully completed unit(s) of study on intramuscular injectable medications as part of the Board-approved qualification in administration of medicines; and
- (d) paramedics registered under the **Health Practitioner Regulation National Law** to practice in the paramedicine profession; and
- (e) Aboriginal health practitioners registered under the **Health Practitioner Regulation National Law** to practice as an Aboriginal health practitioner; and
- (f) pharmacists registered under the **Health Practitioner Regulation National Law** to practice in the pharmacy profession; and
- (g) pharmacy technicians; and
- (h) fourth year tertiary students registered with **AHPRA**, who are training and/or studying to qualify for registration as a pharmacist under the **Health Practitioner Regulation National Law** to practice in the pharmacy profession; and
- (i) intern pharmacists provisionally registered with **AHPRA**.

2. Activities authorised

- (a) The table at Schedule A details the activities that each class of authorised persons may perform in relation to delivery of COVID-19 VACCINE.

- (b) Where a class of person is authorised to possess and use (including to administer) the COVID-19 VACCINE, each person within that class must ensure that they comply with the following when they do so:
 - i. the Victorian COVID-19 Vaccination Guidelines (current at the time of administering the COVID-19 VACCINE); and
 - ii. the Australian Immunisation Handbook (current at the time of administering the COVID-19 VACCINE); and
 - iii. the National Vaccine Storage Guidelines: Strive for 5 (current at the time of administering the COVID-19 VACCINE); and
 - iv. any guidelines issued by the Department of Health or the Government of Australia in relation to any COVID-19 VACCINE (current at the time of administering the COVID-19 VACCINE).
- (c) An approved COVID-19 VACCINE must only be used for persons indicated by the TGA to receive the vaccine.
- (d) The authorisations granted in clauses 1 and 2 are subject to the conditions detailed in clauses 3 and 4.

3. Training and supervision requirements

- (a) The authorisation to undertake authorised vaccination activities is contingent upon:
 - (i) completion of the **training requirements**; and
 - (ii) satisfaction of the supervision requirements contained in the Victorian COVID-19 Vaccination Guidelines as updated from time to time.
- (b) It is the responsibility of persons authorised under clause 1 to undertake authorised vaccination activities to:
 - (i) be aware of the most up-to-date training and supervision arrangements that apply to them by regularly checking the Victorian COVID-19 Vaccination Guidelines; and
 - (ii) undertake the authorised vaccination activities only if their training and supervision arrangements are met.

4. Supply and premises restrictions

The authorised vaccination activities of COVID-19 VACCINE as detailed in Schedule A must take place at premises designated for vaccination service provision by organisations or individuals authorised to obtain, possess, sell or supply the vaccine pursuant to the **Act** or **Regulations** or a **Public Health Emergency Order** or any other premises as authorised by the Department of Health from time to time.

5. Definitions

Act means the *Drugs, Poisons and Controlled Substances Act 1981 (Vic)*;

AHPRA means the Australian Health Practitioner Regulation Agency;

Authorised persons has the meaning in clause 1;

Authorised vaccination activities means the activities detailed in Schedule A;

Health Practitioner Regulation National Law means the *Health Practitioner Regulation National Law (Vic) Act 2009*;

Nurse practitioner has the same meaning as in the *Drugs, Poisons and Controlled Substances Act 1981*;

Public Health Emergency Order means Authorisation for distribution – SARS-CoV-2 (COVID-19) VACCINE or Authorisation – SARS-CoV-2 (COVID-19) VACCINE (Aspen Medical);

Registered medical practitioner has the same meaning as in the *Drugs, Poisons and Controlled Substances Act 1981*;

Regulations means the *Drugs, Poisons and Controlled Substances Regulations 2017*;

TGA means the Therapeutic Goods Administration, Australia;

Training requirements means completion of the following programs:

- (a) Victorian COVID-19 eLearning Competency Training package; and
- (b) Commonwealth COVID-19 Vaccination Training program; and
- (c) Any additional training and competency requirements contained in the Victorian COVID-19 Vaccination Guidelines.

This order comes into force on the date of publication in the Government Gazette and continues in force for a period of six months, unless revoked earlier.

Dated 20 February 2021

PROFESSOR EUAN WALLACE
Secretary to the Department of Health

SCHEDULE A – AUTHORISED SARS-CoV-2 VACCINATION ACTIVITIES

Authorised persons	Authorised vaccination activities
Registered nurses and midwives	<ul style="list-style-type: none"> (a) possess or obtain COVID-19 VACCINE from an organisation authorised to obtain, possess, sell or supply the vaccine pursuant to the Act or Regulations or a Public Health Emergency Order; and (b) reconstitute COVID-19 VACCINE in accordance with the manufacturer’s instructions and transfer to a single-use syringe; and (c) label the syringe for administration (where the product is not labelled when delivered); and. (d) administer COVID-19 VACCINE, that has been reconstituted in accordance with the manufacturer’s instructions and transferred to a single-use syringe, to persons approved by the TGA as eligible to receive the vaccine.
Enrolled nurses	<ul style="list-style-type: none"> (a) possess or obtain COVID-19 VACCINE from an organisation authorised to obtain, possess, sell or supply the vaccine pursuant to the Act or Regulations or a Public Health Emergency Order; and (b) reconstitute COVID-19 VACCINE in accordance with the manufacturer’s instructions and transfer to a single-use syringe; and (c) label the syringe for administration (where the product is not labelled when delivered); and. (d) administer the COVID-19 VACCINE, that has been reconstituted in accordance with the manufacturer’s instructions and transferred to a single-use syringe, to persons approved by the TGA as eligible to receive the vaccine.
Registered paramedics	<ul style="list-style-type: none"> (a) possess or obtain COVID-19 VACCINE from an organisation authorised to obtain, possess, sell or supply the vaccine pursuant to the Act or Regulations or a Public Health Emergency Order; and (b) reconstitute COVID-19 VACCINE in accordance with the manufacturer’s instructions and transfer to a single-use syringe; and (c) label the syringe for administration (where the product is not labelled when delivered); and (d) administer the COVID-19 VACCINE, that has been reconstituted in accordance with the manufacturer’s instructions and transferred to a single-use syringe, to persons approved by the TGA as eligible to receive the vaccine; and (e) possess and use Schedule 3 medicines obtained by the paramedic’s employer or another organisation authorised to obtain Schedule 3 medicines pursuant to the Act or Regulations or a Public Health Emergency Order to administer to persons should a therapeutic need arise following COVID-19 VACCINE administration.

Registered Aboriginal health practitioners	<p>Under an administration order from a Registered medical practitioner or a nurse practitioner:</p> <ul style="list-style-type: none"> (a) possess or obtain COVID-19 VACCINE from an organisation authorised to obtain, possess, sell or supply the vaccine pursuant to the Act or Regulations or a Public Health Emergency Order; and (b) reconstitute COVID-19 VACCINE in accordance with the manufacturer's instructions and transfer to a single-use syringe; and (c) label the syringe for administration (where the product is not labelled when delivered).; and (d) administer the COVID-19 VACCINE, that has been reconstituted in accordance with the manufacturer's instructions and transferred to a single-use syringe, to persons approved by the TGA as eligible to receive the vaccine.
Registered pharmacists	<ul style="list-style-type: none"> (a) possess or obtain COVID-19 VACCINE from an organisation authorised to obtain, possess, sell or supply the vaccine pursuant to the Act or Regulations or a Public Health Emergency Order; and (b) reconstitute COVID-19 VACCINE in accordance with the manufacturer's instructions and transfer to a single-use syringe; and (c) label the syringe for administration (where the product is not labelled when delivered).
Pharmacy technicians	<ul style="list-style-type: none"> (a) possess or obtain COVID-19 VACCINE from an organisation authorised to obtain, possess, sell or supply the vaccine pursuant to the Act or Regulations or a Public Health Emergency Order; and (b) reconstitute COVID-19 VACCINE in accordance with the manufacturer's instructions and transfer to a single-use syringe; and (c) label the syringe for administration (where the product is not labelled when delivered).
Pharmacy students registered with AHPRA (student registration) and Intern pharmacists provisionally registered with AHPRA	<ul style="list-style-type: none"> (a) possess or obtain COVID-19 VACCINE from an organisation authorised to obtain, possess, sell or supply the vaccine pursuant to the Act or Regulations or a Public Health Emergency Order; and (b) reconstitute COVID-19 VACCINE in accordance with the manufacturer's instructions and transfer to a single-use syringe; and (c) label the syringe for administration (where the product is not labelled when delivered).
Registered medical practitioners and Nurse practitioners	<ul style="list-style-type: none"> (a) authorise an Aboriginal health practitioner in writing to administer COVID-19 VACCINE in relation to persons approved by the TGA as eligible to receive the vaccine, for a patient under the Registered medical practitioner's or Nurse practitioner's care.

Drugs, Poisons and Controlled Substances Act 1981

PUBLIC HEALTH EMERGENCY ORDER UNDER SECTION 22D

Authorisation for administration - COVID-19 VACCINE (students)

I, Professor Euan Wallace, Secretary to the Department of Health, pursuant to section 22D of the **Drugs, Poisons and Controlled Substances Act 1981**, make this Public Health Emergency Order (**Order**) in the belief that it is necessary to do so to respond to or prevent a serious risk to public health posed to the State of Victoria by severe acute respiratory syndrome coronavirus 2 (**SARS-CoV-2**).

The purpose of this Order is to address the public health emergency posed by the ongoing global SARS-CoV-2 (COVID-19) pandemic, which is currently affecting the State of Victoria.

In furtherance of that purpose, this Order is intended to facilitate the SARS-CoV-2 (COVID-19) VACCINE program, by authorising classes of persons to obtain, possess and use (including to administer) any SARS-CoV-2 (COVID-19) VACCINE approved by the Therapeutic Goods Administration (**COVID-19 VACCINE**) under the conditions outlined in this Order.

All authorised persons, irrespective of their status under the **Act** and the **Regulations**, are to adhere to the conditions of this Order prior to obtaining, possessing and using COVID-19 VACCINE.

1. Authorisation

By this Order, I authorise the following classes of persons (**authorised persons**) to undertake **authorised vaccination activities** in relation to the COVID-19 VACCINE:

- (a) tertiary students registered with **AHPRA**, who are training and/or studying to qualify for registration in the fields of:
 - (i) medicine, having successfully completed all units of study from the third year of a Bachelor's program or the first year of study of a post-graduate program or Master's program leading to provisional registration with **AHPRA** as a medical intern; or
 - (ii) nursing, having successfully completed all units of study from the second year of a Bachelor's program or the first year of study of a two-year Master's program leading to initial registration with **AHPRA** as a registered nurse; or
 - (iii) midwifery, having successfully completed all units of study from the second year of a Bachelor's program or the first year of study of a two-year Master's program leading to initial registration with **AHPRA** as a midwife; or
 - (iv) paramedicine, having successfully completed all units of study from the second year of a Bachelor's program leading to initial registration with **AHPRA** as a paramedic.

2. Activities authorised

- (a) The authorised persons may undertake the following authorised vaccination activities:
 - (i) possess or obtain a vaccine from an organisation authorised to obtain, possess or supply the vaccine pursuant to the **Act** or **Regulations** or a **Public Health Emergency Order**; and
 - (ii) reconstitute COVID-19 VACCINE in accordance with the manufacturer's instructions and transfer to a single-use syringe; and
 - (iii) label the syringe for administration (where the product is not labelled when delivered); and
 - (iv) administer COVID-19 VACCINE, that has been reconstituted in accordance with the manufacturer's instructions and transferred to a single-use syringe, to persons approved by the **TGA** as eligible to receive the vaccine.

- (b) Where a class of person is authorised to use (including use to administer) COVID-19 VACCINE, each person within the class must ensure that they comply with the following when they do so:
 - (i) Victorian COVID-19 Vaccination Guidelines (current at the time of administering the COVID-19 VACCINE); and
 - (ii) Australian Immunisation Handbook (current at the time of administering the COVID-19 VACCINE); and
 - (iii) National Vaccine Storage Guidelines: Strive for 5 (current at the time of administering the COVID-19 VACCINE); and
 - (iv) any guidelines issued by the Department of Health or the Government of Australia in relation to any COVID-19 VACCINE approved by the TGA (current at the time of administering the COVID-19 VACCINE).
- (c) An approved COVID-19 VACCINE must only be used for persons indicated by the TGA to receive the vaccine.
- (d) The authorisations granted in clauses 1 and 2 are subject to the conditions detailed in clauses 3 and 4.

3. Training and supervision requirements

- (a) The authorisation to undertake authorised vaccination activities is contingent upon:
 - (i) completion of the **training requirements**; and
 - (ii) satisfaction of the supervision requirements contained in the Victorian COVID-19 Vaccination Guidelines as updated from time to time.
- (b) It is the responsibility of persons authorised under clause 1 to undertake authorised vaccination activities to:
 - (i) be aware of the most up-to-date training and supervision arrangements that apply to them by regularly checking the Victorian COVID-19 Vaccination Guidelines; and
 - (ii) undertake the authorised vaccination activities only if their training and supervision arrangements are met.

4. Supply and premises restrictions

The authorised vaccination activities of COVID-19 VACCINE as detailed in subclauses 2(a)(i) – (iv) of this Order must take place at premises designated for vaccination service provision by organisations or individuals authorised to obtain, possess and supply COVID-19 VACCINE pursuant to the **Act** or **Regulations** or a **Public Health Emergency Order** or at any other premises as authorised by the Department of Health from time to time.

5. Definitions

Act means the *Drugs, Poisons and Controlled Substances Act 1981* (Vic);

AHPRA means the Australian Health Practitioner Regulation Agency;

Authorised persons has the meaning in clause 1;

Public Health Emergency Order means Authorisation for distribution – SARS-CoV-2 (COVID-19) VACCINE or Authorisation – SARS-CoV-2 (COVID-19) VACCINE (Aspen Medical);

Regulations means the *Drugs, Poisons and Controlled Substances Regulations 2017*;

TGA means the Therapeutic Goods Administration, Australia;

Training requirements means completion of the following programs:

- (a) Victorian COVID-19 eLearning Competency Training package; and
- (b) Commonwealth COVID-19 Vaccination Training program; and
- (c) Any additional training and competency requirements contained in the Victorian COVID-19 Vaccination Guidelines.

This order comes into force on the date of publication in the Government Gazette and continues in force for a period of six months, unless revoked earlier.

Dated 20 February 2021

PROFESSOR EUAN WALLACE
Secretary to the Department of Health

Drugs, Poisons and Controlled Substances Act 1981
PUBLIC HEALTH EMERGENCY ORDER UNDER SECTION 22D
Authorisation for distribution - COVID-19 VACCINE

I, Professor Euan Wallace, Secretary to the Department of Health, pursuant to section 22D of the **Drugs, Poisons and Controlled Substances Act 1981**, make this Public Health Emergency Order (**Order**) in the belief that it is necessary to do so to prevent or respond to, a serious risk to public health posed to the State of Victoria by severe acute respiratory syndrome coronavirus 2 (**SARS-CoV-2**).

The purpose of this Order is to address the public health emergency posed by the ongoing global SARS-CoV-2 pandemic, which is currently affecting the State of Victoria.

In furtherance of that purpose, this Order is intended to facilitate the SARS-CoV-2 (COVID-19) VACCINE program, by authorising classes of persons to obtain and distribute SARS-CoV-2 (COVID-19) VACCINE approved by the TGA (**COVID-19 VACCINE**) which are a Schedule 4 poison and any Schedule 3 poisons necessary for the treatment of anaphylactic reactions to the COVID-19 VACCINE (**relevant Schedule 3 poisons**) under the conditions outlined in this Order.

All authorised persons, irrespective of their status under the Act and the Regulations, are to adhere to the conditions of this Order prior to distributing COVID-19 VACCINE.

Authorisation

By this Order, I authorise all health services as bodies corporate by operation of the **Health Services Act 1988** to obtain and possess or supply any COVID-19 VACCINE, and any relevant Schedule 3 poisons, to persons authorised to possess COVID-19 VACCINE and relevant Schedule 3 poisons in accordance with the Act, the Regulations and any other applicable Victorian legislation, where the health service complies with manufacturer's directions and Victorian and Commonwealth requirements for the:

- (i) safe and secure storage and distribution of medicines;
- (ii) retention of records;
- (iii) storage of temperature-sensitive medicines and cold chain management; and
- (iv) disposal of unused, unwanted, or expired medicines.

By this Order, I authorise all aged care services, as defined in the **Aged Care Act 1997** (Cth), and disability services, as defined in the **Disability Act 2006**, to obtain and possess or supply any COVID-19 VACCINE and any relevant Schedule 3 poisons for the purposes of the *COVID-19 Vaccination Program Commonwealth Aged Care Implementation Plan* and the *COVID-19 Vaccination Program Disability Sector Implementation Plan*, where the service complies with manufacturer's directions and Victorian and Commonwealth requirements for the:

- (i) safe and secure storage and distribution of medicines;
- (ii) retention of records;
- (iii) storage of temperature-sensitive medicines and cold chain management; and
- (iv) disposal of unused, unwanted, or expired medicines.

Definitions

Act means the *Drugs, Poisons and Controlled Substances Act 1981* (Vic);

Regulations means the *Drugs, Poisons and Controlled Substances Regulations 2017*;

TGA means the Therapeutic Goods Administration, Australia.

This order comes into force on the date of publication in the Government Gazette and continues in force for a period of six months, unless earlier revoked.

Dated 20 February 2021

PROFESSOR EUAN WALLACE
Secretary to the Department of Health

Drugs, Poisons and Controlled Substances Act 1981

PUBLIC HEALTH EMERGENCY ORDER UNDER SECTION 22D

Authorisation - COVID-19 VACCINE (Aspen Medical)

I, Professor Euan Wallace, Secretary to the Department of Health, pursuant to section 22D of the **Drugs, Poisons and Controlled Substances Act 1981**, make this Public Health Emergency Order (**Order**) in the belief that it is necessary to do so to prevent or respond to, a serious risk to public health posed to the State of Victoria by severe acute respiratory syndrome coronavirus 2 (**SARS-CoV-2**).

The purpose of this Order is to address the public health emergency posed by the ongoing global SARS-CoV-2 pandemic, which is currently affecting the State of Victoria.

In furtherance of that purpose, this Order is intended to facilitate the SARS-CoV-2 (COVID-19) VACCINE program, by authorising Aspen Medical Pty Ltd ACN 105 250 413 (**Aspen Medical**) to obtain and possess SARS-CoV-2 (COVID-19) VACCINE approved by the **TGA (COVID-19 VACCINE)** which is a Schedule 4 poison and any Schedule 3 poisons necessary for the treatment of anaphylactic reactions to the COVID-19 VACCINE (**relevant Schedule 3 poisons**) in accordance with the conditions outlined in this Order.

All authorised persons, irrespective of their status under the Act and the Regulations, are to adhere to the conditions of this Order.

Authorisation

By this Order, I authorise Aspen Medical, to obtain and possess any COVID-19 VACCINE and any relevant Schedule 3 poisons in accordance with the **Act**, the **Regulations** and any other applicable Victorian legislation, subject to Aspen Medical complying with the requirements of the *COVID-19 Vaccination Program Commonwealth Aged Care Implementation Plan* and the *COVID-19 Vaccination Program Disability Sector Implementation Plan*, and manufacturers' directions and Victorian and Commonwealth requirements for the:

- i. safe and secure storage, transport and custody of the medicines;
- ii. retention of records;
- iii. storage of temperature-sensitive medicines and cold chain management
- iv. disposal of unused, unwanted, or expired medicines; and
- v. appropriate preparation and administration of the COVID-19 VACCINE by **authorised persons**;

The authorisation of Aspen Medical, to obtain and possess any COVID-19 VACCINE and any relevant Schedule 3 poisons by this Order, is also subject to Aspen Medical complying with the requirement to:

- i. implement a quality and safety framework in accordance with the Australian Commission on Safety and Quality in Health Care's National Safety and Quality Health Service Standards;
- ii. implement an operational clinical governance framework in accordance with the Australian Commission on Safety and Quality in Health Care's National Model Clinical Governance Framework;
- iii. ensure reporting of medically attended adverse events as per recommendations issued by the TGA and in line with the Victorian Surveillance of Adverse Events Following Vaccination in the Community reporting requirements.

As part of this Order, Aspen Medical must comply with any reasonable direction given by the Department of Health for the purposes of compliance with the conditions of this Order.

Definitions

Act means the *Drugs, Poisons and Controlled Substances Act 1981* (Vic);

Aspen Medical means Aspen Medical Pty Ltd ACN 105 250 413;

Authorised persons means persons authorised under the **Act, Regulations**, Secretary Approval: Nurse Immuniser – COVID-19 VACCINE, Secretary Approval: Pharmacist Immuniser – COVID-19 VACCINE or Public Health Emergency Order – Authorisation for preparation and administration -COVID-19 VACCINE, Public Health Emergency Order – Authorisation for administration -COVID-19 VACCINE (students);

Regulations means the *Drugs, Poisons and Controlled Substances Regulations 2017*;

TGA means the Therapeutic Goods Administration, Australia.

This order comes into force on the date of publication in the Government Gazette and continues in force for a period of six months, unless revoked earlier.

Dated 20 February 2021

PROFESSOR EUAN WALLACE
Secretary to the Department of Health

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