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Drugs, Poisons and Controlled Substances Act 1981

PUBLIC HEALTH EMERGENCY ORDER UNDER SECTION 22D

Authorisation for Preparation and Administration – COVID-19 VACCINE

I, Euan Wallace, Secretary to the Department of Health, pursuant to section 22G of the **Act**, extend and amend the **Public Health Emergency Order (PHEO #8) (Order)** published in the Government Gazette on 7 July 2022 in the belief that it is necessary to do so to respond to, or prevent, a public health emergency or 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 and possess and use (including to prepare and administer), any **SARS-CoV-2 (COVID-19)** vaccine approved by the **TGA (COVID-19 VACCINE)** which are Schedule 4 poisons, 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 prior to obtaining, possessing or using any **COVID-19 VACCINE**.

1. Authorisation

By this Order, and subject to the conditions, requirements and restrictions set out in 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.

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**.

SPECIAL

Conditions

- (b) Where a class of person is authorised to obtain and possess and use (including to prepare and administer) the **COVID-19 VACCINE**, each person within that class of **authorised persons** must ensure that they comply with the following on each occasion 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) A **COVID-19 VACCINE** must only be administered 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 clause 2(d).
- (d) An **authorised person** may administer a **COVID-19 VACCINE** to a person that is not included in the patient group for which that **COVID-19 VACCINE** is approved by the TGA if:
- i. **ATAGI** 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 **authorised person** (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 **authorised person** 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**.

3. Training and supervision requirements

- (a) The authorisation to undertake **authorised vaccination activities** is contingent upon:
- i. successful completion of the specified training including all competency assessments; and
 - ii. satisfaction of the supervision requirements
- contained in the Victorian COVID-19 Vaccination Guidelines, as replaced or amended 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, and understand, the most up-to-date training and supervision requirements 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 requirements are met.

4. Supply and premises restrictions

The **authorised vaccination activities** of the **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 and possess, sell or supply any **COVID-19 VACCINE** pursuant to the **Act** or **Regulations** or a **Public Health Emergency Order**.

5. Definitions and interpretation

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

Ahpra means the Australian Health Practitioner Regulation Agency;

ATAGI means the Australian Technical Advisory Group on Immunisation;

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 Act 2009** (Vic);

Nurse practitioner has the same meaning as in the **Act**;

Public Health Emergency Order means an order made under section 22D of the **Act** (including an order extended, amended or varied under section 22G of the **Act**);

Registered medical practitioner has the same meaning as in the **Act**;

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

TGA means the Therapeutic Goods Administration, Australia.

The word ‘including’ in this Order is not a word of limitation.

This Order comes into force on 21 February 2023 and continues in force until 20 August 2023 (dates inclusive), unless revoked earlier.

Dated: 14 February 2023

EUAN WALLACE
Secretary to the Department of Health

SCHEDULE A – AUTHORISED VACCINATION ACTIVITIES

Authorised persons	Authorised vaccination activities
Registered nurses and midwives	(a) obtain and possess the COVID-19 VACCINE from an organisation authorised to obtain and possess, sell or supply the vaccine pursuant to the Act or Regulations or a Public Health Emergency Order ; and (b) reconstitute the 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.
Enrolled nurses	(a) obtain and possess the COVID-19 VACCINE from an organisation authorised to obtain and possess, sell or supply the vaccine pursuant to the Act or Regulations or a Public Health Emergency Order ; and (b) reconstitute the 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.
Registered paramedics	(a) obtain and possess the COVID-19 VACCINE from an organisation authorised to obtain and possess, sell or supply the vaccine pursuant to the Act or Regulations or a Public Health Emergency Order ; and (b) reconstitute the 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; 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> <p>(a) obtain and possess the COVID-19 VACCINE from an organisation authorised to obtain and possess, sell or supply the vaccine pursuant to the Act or Regulations or a Public Health Emergency Order; and</p> <p>(b) reconstitute the COVID-19 VACCINE in accordance with the manufacturer's instructions and transfer to a single-use syringe; and</p> <p>(c) label the syringe for administration (where the product is not labelled when delivered); and</p> <p>(d) administer the COVID-19 VACCINE, that has been reconstituted in accordance with the manufacturer's instructions and transferred to a single-use syringe.</p>
Registered pharmacists	<p>(a) obtain and possess the COVID-19 VACCINE from an organisation authorised to obtain and possess, sell or supply the vaccine pursuant to the Act or Regulations or a Public Health Emergency Order; and</p> <p>(b) reconstitute the COVID-19 VACCINE in accordance with the manufacturer's instructions and transfer to a single-use syringe; and</p> <p>(c) label the syringe for administration (where the product is not labelled when delivered).</p> <p>(d) administer the COVID-19 VACCINE, that has been reconstituted in accordance with the manufacturer's instructions and transferred to a single-use syringe.</p>
Pharmacy technicians	<p>(a) obtain and possess the COVID-19 VACCINE from an organisation authorised to obtain and possess, sell or supply the vaccine pursuant to the Act or Regulations or a Public Health Emergency Order; and</p> <p>(b) reconstitute the COVID-19 VACCINE in accordance with the manufacturer's instructions and transfer to a single-use syringe; and</p> <p>(c) label the syringe for administration (where the product is not labelled when delivered).</p>
Registered medical practitioners and Nurse practitioners	<p>(a) authorise an Aboriginal health practitioner in writing to administer the COVID-19 VACCINE, for a patient under the Registered medical practitioner's or Nurse practitioner's care.</p>

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

I, Euan Wallace, Secretary to the Department of Health, pursuant to section 22G of the **Act**, extend and amend the **Public Health Emergency Order (PHEO #10) (Order)** published in the Government Gazette on 7 July 2022 in the belief that it is necessary to do so to respond to, or prevent, a public health emergency or 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 and possess and supply (including to distribute) **SARS-CoV-2 (COVID-19)** vaccines approved by the **TGA (COVID-19 VACCINE)** which are Schedule 4 poisons, 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 prior to distributing any **COVID-19 VACCINE**.

Authorisation

By this Order, I authorise all health services as bodies corporate by operation of the **Health Services Act 1988 (Vic)** to obtain and possess and supply (including to distribute) any **COVID-19 VACCINE**, and any **relevant Schedule 3 poisons**, to persons authorised to possess any **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) (aged care services)**, and disability services, as defined in the **Disability Act 2006 (Vic) (disability services)**, to obtain and possess and supply (including to distribute) any **COVID-19 VACCINE** and any **relevant Schedule 3 poisons** for the purposes of the any guidelines issued by the Commonwealth or the State of Victoria in relation to COVID-19 vaccination in **aged care services** or **disability services**, 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 and interpretation

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

authorised persons means persons authorised under the **Act** or **Regulations** (including as authorised under a **Public Health Emergency Order**), as amended or replaced from time to time;

Public Health Emergency Order means an order made under section 22D of the **Act** (including an order extended, amended or varied under section 22G of the **Act**);

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

TGA means the Therapeutic Goods Administration, Australia.

The word ‘including’ in this Order is not a word of limitation.

This Order comes into force on 21 February 2023 and continues in force until 20 August 2023 (dates inclusive), unless earlier revoked.

Dated 14 February 2023

EUAN WALLACE
Secretary to the Department of Health

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