

Secretary Approval: Pharmacist Immuniser

DRUGS, POISONS AND CONTROLLED SUBSTANCES REGULATIONS 2017 Approval under regulation 163

Pursuant to Regulation 163 of the Drugs, Poisons and Controlled Substances Regulations 2017 (the Regulations), I, Jacqueline Goodall, Director, Medicines and Poisons Regulation and Delegate of the Secretary, Department of Health, hereby approve:

- (1) the Schedule 4 poisons listed in Appendix 1 for administration by a pharmacist on condition that the pharmacist meets the requirements of a pharmacist immuniser as set out below.
- (2) the Schedule 4 poison listed in Appendix 2 for administration by a pharmacist who meets the requirements of a pharmacist immuniser, and in addition on condition that the pharmacist has satisfactorily completed the Japanese encephalitis eLearning module, as approved by the Deputy Chief Health Officer – Communicable Disease, prior to administering the Japanese encephalitis vaccine.

This approval revokes the Secretary Approval Pharmacist Immuniser published in the Government Gazette G10 Thursday 12 March 2020.

1. This approval applies to:

a pharmacist who at the time of the administration of the Schedule 4 poisons¹ 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 (see Note);

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:

¹ Included in Schedule 4 of the Poisons Standard.

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

- (i) medical practitioner;
- (ii) nurse practitioner;
- (iii) 'Nurse Immuniser'³ that is compliant with Regulation 8(1) of the Drugs, Poisons and Controlled Substance Regulations 2017; or
- (iv) Pharmacist that is compliant with Regulation 99(c) of the Drugs, Poisons and Controlled Substances Regulations 2017;

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).

Note – For a list of the immuniser programs of study that have been recognised by the Chief Health Officer and a link to the Japanese encephalitis eLearning module that has been approved by Deputy Chief Health Officer – Communicable Disease see:

<https://www.health.vic.gov.au/immunisation/programs-of-study>

2. The pharmacist may administer the following Schedule 4 poisons:

1. vaccines listed in Appendix 1 to persons set out in the corresponding entry in column 2, subject to the corresponding exclusions in column 3.
2. vaccine listed in Appendix 2 where the pharmacist has completed the Japanese encephalitis eLearning module, to persons listed in column 2, subject to the exclusions in column 3.

3. The following circumstances apply:

(a) 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

- (IV) Be a mobile or outreach service of one of the premises referred to in paragraphs 3(a)(i)(I), (II) or (III) because the pharmacist administering the vaccines owns, is employed or otherwise engaged by the business referred to in paragraphs 3(a)(i)(I), (II) or (III) and sources the vaccines from those premises.

(b) Any premises referred to in paragraphs 3(a)(i)(I), (II) or (III) on which a pharmacist administers a Schedule 4 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.

(c) All pharmacists administering Schedule 4 poisons:

- (i) must do so in accordance with:

³ 'Nurse Immuniser' is a nurse acting in accordance with a Secretary Approval to administer certain vaccines.

- (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
- (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 Schedule 4 poisons are administered and for a minimum period of 15 minutes afterwards, where administering on premises defined in paragraphs 3(a)(i)(I), (II) or (III).

NOTE: Pharmacists who administer Schedule 4 poisons, as listed in Appendix 1 and Appendix 2, 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 all vaccines listed in Appendix 1 and 2 (whether government funded or not) 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 vaccine. Those Schedule 3 Poisons should be kept on hand and utilised should they be required at the time the vaccine is administered.

Appendix 1

Column 1: Generic name	Column 2: Approval for pharmacists to vaccinate with this vaccine applies to	Column 3: Approval for pharmacists to vaccinate with this vaccine excludes
Influenza vaccines	<ul style="list-style-type: none"> • Vaccination of people aged 5 years and over, excluding those circumstances listed in Column 3. 	<ul style="list-style-type: none"> • Vaccination for travel purposes⁵; • Vaccination of people aged 4 years and under; • Vaccination of people with contraindications defined in the current edition of the <i>Australian Immunisation Handbook</i>⁴.
Pertussis-containing vaccines	<ul style="list-style-type: none"> • Vaccination of people aged 15 years and over, excluding those circumstances listed in Column 3. 	<ul style="list-style-type: none"> • Vaccination for travel purposes⁵; • Vaccination of people aged 14 years and under; • Vaccination for the express purpose of achieving immunity against diphtheria, tetanus or poliomyelitis⁶; • Vaccination of people that are contacts in the event of a case of

⁴ Current version available online.

⁵ Travel medicine is a specialist area that is outside the scope of this approval.

⁶ Pertussis vaccine is only available in Australia in combination with diphtheria and tetanus, or diphtheria, tetanus and poliomyelitis.

Column 1: Generic name	Column 2: Approval for pharmacists to vaccinate with this vaccine <i>applies to</i>	Column 3: Approval for pharmacists to vaccinate with this vaccine <i>excludes</i>
		<p>pertussis, unless directed by the Department of Health⁷; or</p> <ul style="list-style-type: none"> • Vaccination of people with contraindications defined in the current edition of the <i>Australian Immunisation Handbook</i>⁴.
Measles-mumps-rubella vaccine (MMR)	<ul style="list-style-type: none"> • Vaccination of people aged 15 years and over, excluding those circumstances listed in Column 3. 	<ul style="list-style-type: none"> • Vaccination for travel purposes⁵; • Vaccination of people aged 14 years and under; • Vaccination of people with contraindications defined in the current edition of the <i>Australian Immunisation Handbook</i>⁴.
Meningococcal ACWY	<ul style="list-style-type: none"> • Vaccination of people aged 15 years and over, excluding those circumstances listed in Column 3 	<ul style="list-style-type: none"> • Vaccination for travel purposes⁵; • Vaccination of people aged 14 years and under; • Vaccination of people with contraindications defined in the current edition of the <i>Australian Immunisation Handbook</i>⁴.

Appendix 2

Japanese encephalitis vaccine	<ul style="list-style-type: none"> • Vaccination of people that are recommended for vaccination as listed on the Victorian Department of Health's Japanese encephalitis in Victoria website⁸ as amended from time to time. 	<ul style="list-style-type: none"> • Vaccination for people not recommended for vaccination • Vaccination for travel purposes⁵ • Vaccination of people aged 4 years and under; • Vaccination of people with contraindications defined in the current edition of the <i>Australian Immunisation Handbook</i>⁴.
-------------------------------	--	---

⁷ A case of this vaccine-preventable disease is notifiable to the Department of Health under the Public Health and Wellbeing Regulations 2019. The Department of Health will advise on management of the case and contacts.

⁸ Victorian Department of Health, Japanese encephalitis in Victoria – Information for Health Professionals available at: <https://www.health.vic.gov.au/infectious-diseases/information-for-health-professionals-japanese-encephalitis-in-victoria>

This approval takes effect on the date of publication in the Government Gazette.

A handwritten signature in dark ink, appearing to read 'Jacqueline Goodall', with a stylized, cursive script.

Approved by JACQUELINE GOODALL

Date: 19 May 2022

Director, Medicines and Poisons Regulation

Delegate of the Secretary, Department of Health