



Victoria Government Gazette

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DRUGS, POISONS AND CONTROLLED SUBSTANCES REGULATIONS 2017

Secretary Approval: Nurse Immunisers

Approval under Regulation 161

Pursuant to Regulation 161 of the Drugs, Poisons and Controlled Substances Regulations 2017 (the Regulations), I, Stefan Tulloch, Acting 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 possession by a nurse for administration to a patient in that nurse's care on condition that the nurse meets the requirements of a nurse immuniser as set out below.
- (2) the Schedule 4 poison listed in Appendix 2 for possession by a nurse who meets the requirements of a nurse immuniser for administration to a patient in that nurse's care; and in addition, on condition that the nurse 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.
- (3) the Schedule 4 poison listed in Appendix 3 for possession by a nurse who meets the requirements of a nurse immuniser for administration to a patient in that nurse's care on condition that prior to administering the monkeypox vaccine, the nurse immuniser has satisfactorily completed:
 - a) the Monkeypox vaccination eLearning module, as approved by the Deputy Chief Health Officer – Communicable Disease; and
 - b) the Intradermal injection – skills and competency assessment,¹ if administering intradermal monkeypox vaccinations.

This approval revokes the Secretary Approval: Nurse Immunisers published in the Government Gazette S 244 on Thursday 19 May 2022.

Nurse Immunisers

1. The Approval applies to:

A nurse who is registered in Division 1 of the Nursing and Midwifery Board of Australia register who provides evidence to the 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, it was of equivalent standard to a program currently recognised by the Chief Health Officer

¹ Included in the Victorian monkeypox vaccination program guidelines, available at: <https://www.health.vic.gov.au/infectious-diseases/monkeypox>

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

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.

Note: For a list of the ‘Immuniser programs of study’ that have been recognised by the Chief Health Officer and links to the Japanese encephalitis eLearning module and Monkeypox vaccination eLearning module that have been approved by Deputy Chief Health Officer – Communicable Disease see: <https://www.health.vic.gov.au/immunisation/nurse-immuniser-study-programs>

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

- a. vaccines listed in Appendix 1;
- b. vaccine listed in Appendix 2 where the nurse has completed the Japanese encephalitis eLearning module;
- c. vaccine listed in Appendix 3 where the nurse has completed the Monkeypox vaccination eLearning module; and
- d. such other Schedule 4 poisons as are necessary for the treatment of anaphylactic reactions to the vaccines.

2.1. On the condition that the following circumstances apply:

- a. the nurse is employed, contracted, or otherwise engaged by:
 - i. a medical practitioner;
 - ii. municipal council which employs, contracts or ensures access to a medical practitioner;

OR

- iii. health services permit holder who employs, contracts or ensures access to a medical practitioner.
- b. The medical practitioner referred in clause 2.1(a) is available to provide advice to the nurse on the use of the specified Scheduled poisons when needed.
 - c. The nurse possesses and administers only the Schedule 4 poisons obtained by the medical practitioner, municipal council or health services permit holder by whom they are employed, contracted or otherwise engaged.
 - d. The nurse administers the Schedule 4 poisons in:
 - i. the performance of their duties with the medical practitioner, municipal council or health services permit holder (as the case requires)
 - ii. accordance with the edition of the Australian Immunisation Handbook³ that is current at the time of the vaccine administration and
 - iii. accordance with any guidelines issued by Department of Health such as the ‘Approved client groups for immunisation by nurse immunisers’.⁴

³ Current version available online.

⁴ Victorian Department of Health, Approved client groups for immunisation by nurse immunisers, available at: <https://www.health.vic.gov.au/immunisation/nurse-immunisers-approved-client-groups>

Appendix 1: Vaccines**Generic name of vaccine**

Diphtheria	Haemophilus influenzae type b
Hepatitis A	Hepatitis B
Human papillomavirus	Influenza
Measles	Meningococcus
Mumps	Pertussis
Polio	Rotavirus
Rubella	Streptococcus pneumoniae
Tetanus	Varicella/Zoster/Herpes zoster

Appendix 2: Vaccine

Column 1: Generic name of vaccine	Column 2: Additional information
Japanese encephalitis	Approval is limited to people recommended for vaccination as listed on the Victorian Department of Health's Japanese encephalitis in Victoria webpage ⁵ as amended from time to time. Approval does not apply to any person seeking vaccination for international travel purposes.

Appendix 3: Vaccine

Column 1: Generic name of vaccine	Column 2: Additional information
Monkeypox (smallpox/vaccinia virus)	Approval is limited to people recommended for vaccination as listed on the Victorian Department of Health's Monkeypox webpage ⁶ as amended from time to time. Approval does not apply to any person seeking vaccination for travel purposes other than those persons recommended for vaccination as listed on the Victorian Department of Health's Monkeypox webpage ^{5,7}

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

Dated 29 September 2022

STEFAN TULLOCH
Acting Director, Medicines and Poisons Regulation
Delegate of the Secretary, Department of Health

⁵ 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>

⁶ Victorian Department of Health, Monkeypox, available at: <https://www.health.vic.gov.au/infectious-diseases/monkeypox>

⁷ Travel medicine is a specialist area that is outside the scope of this approval.

DRUGS, POISONS AND CONTROLLED SUBSTANCES REGULATIONS 2017

Secretary Approval: Pharmacist Immuniser

Approval under Regulation 163

Pursuant to Regulation 163 of the Drugs, Poisons and Controlled Substances Regulations 2017 (the Regulations), I, Stefan Tulloch, Acting 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.
- (3) the Schedule 4 poison listed in Appendix 3 for administration by a pharmacist who meets the requirements of a pharmacist immuniser on condition that prior to administering the monkeypox vaccine, the pharmacist immuniser has satisfactorily completed:
 - a) the Monkeypox vaccination eLearning module, as approved by the Deputy Chief Health Officer – Communicable Disease; and
 - b) the Intradermal injection – skills and competency assessment,¹ if administering intradermal monkeypox vaccinations.

This approval revokes the Secretary Approval: Pharmacist Immuniser published in the Government Gazette S 244 on Thursday 19 May 2022.

1. This approval applies to:

a pharmacist who at the time of the administration of the Schedule 4 poisons² holds general registration with the Pharmacy Board of Australia³ 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:
 - (i) medical practitioner;
 - (ii) nurse practitioner;
 - (iii) ‘Nurse Immuniser’⁴ 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;

¹ Included in the Victorian monkeypox vaccination program guidelines, available at: <https://www.health.vic.gov.au/infectious-diseases/monkeypox>

² Included in Schedule 4 of the Poisons Standard.

³ This does not include limited registration, provisional registration, non-practising registration, or student registration.

⁴ ‘Nurse Immuniser’ is a nurse acting in accordance with a Secretary Approval to administer certain vaccines.

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 links to the Japanese encephalitis eLearning module and the Monkeypox vaccination eLearning module that have 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:

- (a) vaccines listed in Appendix 1 to persons set out in the corresponding entry in column 2, subject to the corresponding exclusions in column 3.
- (b) 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.
- (c) vaccine listed in Appendix 3 where the pharmacist has completed the Monkeypox vaccination eLearning module, to persons listed in column 2, subject to the exclusions in column 3.

3. On the condition that 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:
 - (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 5⁵* 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 Appendices 1, 2 and 3, 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 Appendices 1, 2 and 3 (whether government funded or not) by pharmacists.

⁵ Current version available online.

Note: Pharmacists who administer the Schedule 4 poison, as listed in Appendix 3 are referred to the edition of the *Victorian Monkeypox Vaccination Program guidelines*, current at the time of administration and issued by the Department of Health.

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 of vaccine	Column 2: Approval for pharmacists to vaccinate with this vaccine applies to	Column 3: Approval for pharmacists to vaccinate with this vaccine excludes
Influenza	<ul style="list-style-type: none"> ● Vaccination of people aged 5 years and older, excluding those circumstances listed in Column 3. 	<ul style="list-style-type: none"> ● Vaccination for travel purposes⁶; ● Vaccination of people aged 4 years and younger; ● Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook.⁵
Diphtheria-tetanus-pertussis vaccines	<ul style="list-style-type: none"> ● Vaccination of people aged 12 years and older, excluding those circumstances listed in Column 3. 	<ul style="list-style-type: none"> ● Vaccination for travel purposes⁶; ● Vaccination of people aged 11 years and younger; ● Vaccination for the express purpose of post-exposure prophylaxis in people with a tetanus-prone wound⁷; ● Vaccination of people that are contacts in the event of a case of pertussis, unless directed by the Department of Health⁸; ● Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook.⁵
Human papillomavirus (HPV)	<ul style="list-style-type: none"> ● Vaccination of people aged 12 years and older, excluding those circumstances listed in Column 3. 	<ul style="list-style-type: none"> ● Vaccination for travel purposes⁶; ● Vaccination of people aged 11 years and younger; ● Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook.⁵

⁶ Travel medicine is a specialist area that is outside the scope of this approval.

⁷ Pertussis vaccine is only available in Australia in combination with diphtheria and tetanus, or diphtheria, tetanus and poliomyelitis.

⁸ 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.

Column 1: Generic name of vaccine	Column 2: Approval for pharmacists to vaccinate with this vaccine applies to	Column 3: Approval for pharmacists to vaccinate with this vaccine excludes
Measles- mumps-rubella vaccine (MMR)	<ul style="list-style-type: none"> • Vaccination of people aged 15 years and older, excluding those circumstances listed in Column 3. 	<ul style="list-style-type: none"> • Vaccination for travel purposes⁶; • Vaccination of people aged 14 years and younger; • Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook.⁵
Meningococcal ACWY	<ul style="list-style-type: none"> • Vaccination of people aged 15 years and older, excluding those circumstances listed in Column 3. 	<ul style="list-style-type: none"> • Vaccination for travel purposes⁶; • Vaccination of people aged 14 years and younger; • Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook.⁵
Pneumococcal	<ul style="list-style-type: none"> • Vaccination of people aged 50 years and older, excluding those circumstances listed in Column 3. 	<ul style="list-style-type: none"> • Vaccination for travel purposes⁶; • Vaccination of people aged 49 years and younger; • Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook.⁵
Herpes zoster/ varicella zoster	<ul style="list-style-type: none"> • Vaccination of people aged 50 years and older, excluding those circumstances listed in Column 3. 	<ul style="list-style-type: none"> • Vaccination for travel purposes⁶; • Vaccination of people aged 49 years and younger; • Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook.⁵

Appendix 2

Japanese encephalitis	<ul style="list-style-type: none"> • Vaccination of people aged 5 years and older that are recommended for vaccination as listed on the Victorian Department of Health's Japanese encephalitis in Victoria website⁹ as amended from time to time. 	<ul style="list-style-type: none"> • Vaccination for people not recommended for vaccination; • Vaccination for travel purposes⁶; • Vaccination of people aged 4 years and younger; • Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook.⁵
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⁹ 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>

Appendix 3

<p>Monkeypox/ smallpox/ vaccinia virus</p>	<ul style="list-style-type: none"> ● Vaccination of people aged 5 years and older that are recommended for vaccination as listed on the Victorian Department of Health’s Monkeypox website¹⁰ as amended from time to time. 	<ul style="list-style-type: none"> ● Vaccination for people not recommended for vaccination; ● Vaccination for travel purposes other than those people recommended for vaccination as listed on the Department of Health’s Monkeypox webpage^{6, 9}; ● Vaccination of people aged 4 years and younger; ● Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook (or current recommendations issued by the Australian Technical Advisory Group on Immunisation (ATAGI)).⁵
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This approval takes effect on the date of publication in the Victorian Government Gazette.

Dated 29 September 2022

STEFAN TULLOCH
 Acting Director, Medicines and Poisons Regulation
 Delegate of the Secretary, Department of Health

¹⁰ Victorian Department of Health, Monkeypox, available at: <https://www.health.vic.gov.au/infectious-diseases/monkeypox>

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