



Victoria Government Gazette

No. S 535 Thursday 3 October 2024
By Authority of Victorian Government Printer

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, Nitsa Karahalios, Director, Regulatory Compliance and Operations – Health and Delegate of the Secretary, Department of Health, hereby approve:

- (1) the Schedule 4 poisons listed in Appendices 1–3 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 poisons listed in Appendix 4 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 a respiratory syncytial virus (RSV) vaccine or RSV therapeutic product, the nurse immuniser has satisfactorily completed any additional training and competency requirements in relation to that Schedule 4 poison as listed on the Victorian Department of Health’s Respiratory syncytial virus (RSV) immunisation webpage¹ at the time of administration.
- (3) the Schedule 4 poison listed in Appendix 5 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 a SARS-CoV-2 (COVID-19) vaccine, the nurse immuniser has satisfactorily completed any additional training and competency requirements in relation to that Schedule 4 poison as listed on the Victorian Department of Health’s COVID-19 vaccine webpage² at the time of administration.

This approval revokes the Secretary Approval: Nurse Immunisers published in the Government Gazette S 148 pages 1–4 on Wednesday 27 March 2024, and the Secretary Approval: Nurse Immunisers SARS-COV-2 (COVID-19) VACCINE published in the Government Gazette S 530 pages 1–3 on Thursday 5 October 2023.

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 Victoria³ 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

¹ Victorian Department of Health, Respiratory syncytial virus (RSV) immunisation, available at: www.health.vic.gov.au/immunisation/respiratory-syncytial-virus-immunisation

² Victorian Department of Health, COVID-19 vaccine, available at: www.health.vic.gov.au/immunisation/covid-19-vaccine

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

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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

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 see: www.health.vic.gov.au/immunisation/nurse-immuniser-study-programs

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

- a. vaccines listed in Appendices 1–3;
- b. vaccine or therapeutic product listed in Appendix 4 where the nurse has completed any additional training and competency requirements in relation to that Schedule 4 poison as listed on the Victorian Department of Health’s Respiratory syncytial virus (RSV) immunisation webpage¹, at the time of administration;
- c. vaccine listed in Appendix 5 where the nurse has completed any additional training and competency requirements in relation to that Schedule 4 poison as listed on the Victorian Department of Health’s COVID-19 vaccine webpage², at the time of administration; 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 Handbook⁴ that is current at the time of the Schedule 4 poison administration; and
 - iii. accordance with any guidelines issued by Department of Health such as the ‘Approved client groups for immunisation by nurse immunisers’⁵.

⁴ Current version available online.

⁵ Victorian Department of Health, Approved client groups for immunisation by nurse immunisers, available at: 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
Herpes zoster (shingles)	Human papillomavirus
Influenza	Measles
Meningococcal	Mumps
Pertussis	Pneumococcal
Polio	Rotavirus
Rubella	Tetanus
Varicella (chickenpox)	

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 webpage ⁶ at the time of administration. Approval does not apply to any person seeking vaccination for travel purposes other than those people recommended for vaccination as listed on the Department of Health's Japanese encephalitis webpage ^{6,7} .

Appendix 3: Vaccine

Column 1: Generic name of vaccine	Column 2: Additional information
Mpox (monkeypox/vaccinia virus)	Approval is limited to people recommended for vaccination as listed on the Victorian Department of Health's Mpox (monkeypox) webpage ⁸ at the time of administration. 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 Mpox (monkeypox) webpage ^{7,8} .

⁶ Victorian Department of Health, Japanese encephalitis, available at: www.health.vic.gov.au/infectious-diseases/japanese-encephalitis

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

⁸ Victorian Department of Health, Mpox (monkeypox), available at: www.health.vic.gov.au/infectious-diseases/mpox-monkeypox

Appendix 4: Vaccine or therapeutic product

Column 1: Generic name of vaccine or therapeutic product	Column 2: Additional information
Respiratory syncytial virus (RSV) vaccine or RSV therapeutic product as listed on the Victorian Department of Health's Respiratory syncytial virus (RSV) immunisation webpage ¹	<p>Approval is limited to people recommended for immunisation as listed on the Victorian Department of Health's Respiratory syncytial virus (RSV) immunisation webpage¹ at the time of administration.</p> <p>Approval does not apply to any person seeking immunisation for travel purposes other than those people recommended for immunisation as listed on the Department of Health's Respiratory syncytial virus (RSV) immunisation webpage^{1,7}.</p>

Appendix 5: Vaccine

Column 1: Generic name of vaccine	Column 2: Additional information
SARS-CoV-2 (COVID-19)	<p>Approval is limited to persons included in the patient group for which that COVID-19 vaccine has been approved for by the Therapeutic Goods Administration, or the patient group as recommended by the Australian Technical Advisory Group on Immunisation².</p> <p>Approval does not apply to any person seeking immunisation for travel purposes⁷.</p>

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

Dated 26 September 2024

Approved by NITSA KARAHALIOS
 Director, Regulatory Compliance and Operations – Health
 Delegate of the Secretary, Department of Health

DRUGS, POISONS AND CONTROLLED SUBSTANCES REGULATIONS 2017

Secretary Approval: Registered Aboriginal and Torres Strait Islander Health Practitioner Immuniser
Approval under Regulation 160

Pursuant to Regulation 160 of the Drugs, Poisons and Controlled Substances Regulations 2017 (the Regulations), I, Nitsa Karahalios, Director, Regulatory Compliance and Operations – Health, and Delegate of the Secretary, Department of Health, hereby approve:

- (1) the Schedule 4 poisons listed in Appendices 1–3 for possession by a registered Aboriginal and Torres Strait Islander health practitioner for administration to a person under that registered Aboriginal and Torres Strait Islander health practitioner’s care on condition that the Aboriginal and Torres Strait Islander health practitioner meets the requirements of a registered Aboriginal and Torres Strait Islander health practitioner immuniser as set out below.
- (2) the Schedule 4 poison listed in Appendix 4 for possession by a registered Aboriginal and Torres Strait Islander health practitioner who meets the requirements of a registered Aboriginal and Torres Strait Islander health practitioner immuniser for administration to a person under that registered Aboriginal and Torres Strait Islander health practitioner’s care; and on condition that prior to the administration of a SARS-CoV-2 (COVID-19) vaccine, the registered Aboriginal and Torres Strait Islander health practitioner has satisfactorily completed any additional training and competency requirements in relation to that Schedule 4 poison as listed on the Victorian Department of Health’s COVID-19 vaccine webpage¹ at the time of administration.
- (3) the Schedule 4 poisons listed in Appendix 5 for possession by a registered Aboriginal and Torres Strait Islander health practitioner who meets the requirements of a registered Aboriginal and Torres Strait Islander health practitioner immuniser for administration to a person under that registered Aboriginal and Torres Strait Islander health practitioner’s care; and on condition that the registered Aboriginal and Torres Strait Islander health practitioner has satisfactorily completed any additional training and competency requirements in relation to that Schedule 4 poison as listed on the Victorian Department of Health’s Respiratory syncytial virus (RSV) immunisation webpage² at the time of administration.

This approval revokes the Secretary Approval: Registered Aboriginal and Torres Strait Islander Health Practitioner Immuniser published in the Government Gazette S 148 pages 11–14 on Wednesday 27 March 2024.

1. **The approval applies to a registered health practitioner who at the time of possession and administration of the Schedule 4 poisons holds general registration with the Aboriginal and Torres Strait Islander Health Practice Board of Australia³ and:**
 - a. has satisfactorily completed the assessment of an ‘Immuniser program of study’ recognised by the Chief Health Officer (see note); and
 - b. holds a current first aid certificate (to be updated every three years); and
 - c. 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 see: www.health.vic.gov.au/immunisation/atshp-immuniser-study-programs
2. **The registered Aboriginal and Torres Strait Islander health practitioner may possess and administer the following Schedule 4 poisons:**
 - a. vaccines listed in Appendices 1–3; and
 - b. vaccine listed in Appendix 4 where the registered Aboriginal and Torres Strait Islander health practitioner has satisfactorily completed any additional training and competency requirements in relation to that Schedule 4 poison as listed on the Victorian Department of Health’s COVID-19 vaccine webpage¹ at the time of administration; and

¹ Victorian Department of Health, COVID-19 vaccine, available at: www.health.vic.gov.au/immunisation/covid-19-vaccine

² Victorian Department of Health, Respiratory syncytial virus (RSV) immunisation, available at: www.health.vic.gov.au/immunisation/respiratory-syncytial-virus-immunisation

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

- c. vaccine or therapeutic product listed in Appendix 5 where the registered Aboriginal and Torres Strait Islander health practitioner has satisfactorily completed any additional training and competency requirements in relation to that Schedule 4 poison as listed on the Department of Health's Respiratory syncytial virus (RSV) immunisation webpage² at the time of administration.

3. On the condition that the following circumstances apply:

- a. the registered Aboriginal and Torres Strait Islander health practitioner is employed, contracted, or otherwise engaged by a service provider in Victoria who employs or contracts a registered medical practitioner, nurse practitioner or authorised midwife.
- b. a registered medical practitioner, nurse practitioner or authorised midwife referred to in clause 3(a) provides a written instruction to the registered Aboriginal and Torres Strait Islander health practitioner to administer a Schedule 4 poison to a person under the registered Aboriginal and Torres Strait Islander health practitioner's care.
- c. the registered Aboriginal and Torres Strait Islander health practitioner must comply with the edition of the Victorian Guidelines for the administration of vaccines by registered Aboriginal and Torres Strait Islander health practitioners⁴ current at the time of administration.
- d. the registered Aboriginal and Torres Strait Islander health practitioner, when undertaking any authorised immunisation activities, must be under the indirect supervision of either:
 - i. the registered medical practitioner, nurse practitioner or authorised midwife referred to in clause 3(a); or
 - ii. a registered medical practitioner, nurse practitioner or authorised midwife with immunisation within their professional practice scope; or
 - iii. a nurse who is employed, contracted or otherwise engaged by a service provider in Victoria referred to in clause 3(a), and provides evidence to that service provider of currency of competence and ongoing professional development in immunisation and who:
 - I. 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 Victoria⁵ in the approved area of practice – Immunisation; or
 - II. has satisfactorily completed the assessment of a nurse immuniser program recognised by the Chief Health Officer; or
 - III. 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
 - IV. 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; or
 - V. 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.

⁴ Victorian Department of Health, Victorian Guidelines for the administration of vaccines by Aboriginal and Torres Strait Islander health practitioners, available at: www.health.vic.gov.au/immunisation/victorian-guidelines-for-atsihp-immunisers

⁵ This does not include limited registration, provisional registration, non-practising registration, or student registration.

- e. the registered Aboriginal and Torres Strait Islander health practitioner administers the Schedule 4 poisons in:
- i. the performance of their duties with the service provider in Victoria by whom they are employed or contracted; and
 - ii. accordance with the edition of the *Australian Immunisation Handbook*⁶ that is current at the time of the administration; and
 - iii. accordance with the edition of the National Vaccine Storage Guidelines: Strive for 5⁶ that is current at the time of the administration; and
 - iv. accordance with the edition of the Victorian Guidelines for the administration of vaccines by registered Aboriginal and Torres Strait Islander health practitioners⁴, as issued by the Department of Health, that is current at the time of administration.

Definitions and interpretation

Indirect supervision means that the registered Aboriginal and Torres Strait Islander health practitioner must consult with the nominated supervisor as referred to in clause 3(d), with the nominated supervisor required to always be physically present in the workplace during opening hours and available during those times to observe and discuss the management of people under the care of the registered Aboriginal and Torres Strait Islander health practitioner and/or the performance of the registered Aboriginal and Torres Strait Islander health practitioner when necessary.

Authorised midwife has the same meaning as in the *Drugs, Poisons and Controlled Substances Regulations 2017*

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

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

Appendix 1: Vaccines

Diphtheria

Haemophilus influenzae type b

Hepatitis A

Hepatitis B

Herpes zoster (shingles)

Human papillomavirus

Influenza

Measles

Meningococcal ACWY

Meningococcal B

Mumps

Pertussis

Pneumococcal

Polio

Rotavirus

Rubella

Tetanus

Varicella (chickenpox)

⁶ Current version available online.

Appendix 2: Vaccine

Japanese encephalitis

Approval is limited to people recommended for vaccination as listed on the Victorian Department of Health's Japanese encephalitis webpage⁷ at the time of administration.

Appendix 3: Vaccine

Mpox (monkeypox/vaccinia virus)

Approval is limited to people recommended for vaccination as listed on the Victorian Department of Health's Mpox webpage⁸ at the time of administration.

Appendix 4: Vaccine

SARS-CoV-2 (COVID-19)

Appendix 5: Vaccine or therapeutic product

Respiratory syncytial virus (RSV) vaccine or RSV therapeutic product as listed on the Victorian Department of Health's Respiratory syncytial virus (RSV) immunisation webpage².

Approval is limited to people recommended for immunisation as listed on the Victorian Department of Health's Respiratory syncytial virus (RSV) immunisation webpage² at the time of administration.

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

Dated 26 September 2024

NITSA KARAHALIOS
Director, Regulatory Compliance and Operations – Health
Delegate of the Secretary, Department of Health

⁷ Victorian Department of Health, Japanese encephalitis, available at: www.health.vic.gov.au/infectious-diseases/japanese-encephalitis

⁸ Victorian Department of Health, Mpox (monkeypox), available at: www.health.vic.gov.au/infectious-diseases/mpox-monkeypox

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, Nitsa Karahalios, Director, Regulatory Compliance and Operations – Health, and Delegate of the Secretary, Department of Health, hereby approve:

- (1) the Schedule 4 poisons listed in Appendices 1–3 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 poisons listed in Appendix 4 for administration by a pharmacist who meets the requirements of a pharmacist immuniser, and on condition that prior to administering a respiratory syncytial virus (RSV) vaccine or RSV therapeutic product, the pharmacist has satisfactorily completed any additional training and competency requirements in relation to that Schedule 4 poison as listed on the Victorian Department of Health’s Respiratory syncytial virus (RSV) immunisation webpage¹ at the time of administration.
- (3) the Schedule 4 poison listed in Appendix 5 for administration by a pharmacist who meets the requirements of a pharmacist immuniser, and on condition that prior to the administration of a SARS-CoV-2 (COVID-19) vaccine, the pharmacist has satisfactorily completed any additional training and competency requirements in relation to that Schedule 4 poison as listed on the Victorian Department of Health’s COVID-19 vaccine webpage² at the time of administration.

This approval revokes the Secretary Approval: Pharmacist Immuniser published in the Government Gazette S 148 pages 5–10 on Wednesday 27 March 2024 and Secretary Approval: Pharmacist Immunisers SARS-CoV-2 (COVID-19) VACCINE S 530 pages 4–7 on 5 October 2023.

1. This approval applies to:

a pharmacist who at the time of the administration of the Schedule 4 poisons 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 Victorian Department of Health, Respiratory syncytial virus (RSV) immunisation, available at: www.health.vic.gov.au/immunisation/respiratory-syncytial-virus-immunisation

² Victorian Department of Health, COVID-19 vaccine, available at: www.health.vic.gov.au/immunisation/covid-19-vaccine

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 see: www.health.vic.gov.au/immunisation/programs-of-study

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

- (a) vaccines listed in Appendices 1–3 to persons set out in the corresponding entry in column 2, subject to the corresponding exclusions in column 3;
- (b) vaccine or therapeutic product listed in Appendix 4 where the pharmacist has completed any additional training or competency requirements in relation to that Schedule 4 poison as listed on the Victorian Department of Health’s Respiratory syncytial virus (RSV) immunisation webpage¹ at the time of administration, to persons listed in column 2, subject to the exclusions in column 3; and
- (c) vaccine listed in Appendix 5 where the pharmacist has completed any additional training and competency requirements in relation to that Schedule 4 poison as listed on the Victorian Department of Health’s COVID-19 vaccine webpage² at the time of administration, to persons listed in column 2, subject to the exclusions in column 3. The pharmacist may administer the vaccine listed in Appendix 5 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.

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 Schedule 4 poisons owns, is employed or otherwise engaged by the business referred to in paragraphs 3(a)(i)(I), (II) or (III) and sources the Schedule 4 poisons 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 poison 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) ***Where a pharmacist is not employed, contracted or otherwise engaged by an organisation listed in paragraph 3(a), the following circumstances apply:***
 - (i) The pharmacist administering the vaccine listed in Appendix 5 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 service 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 Government of Australia that employs, contracts or ensures access to a medical practitioner or nurse practitioner.
- (ii) The pharmacist administers the vaccine listed in Appendix 5 when a medical practitioner or nurse practitioner referred to in paragraph 3(c)(i)(I), (II), (III) or (IV) is available to provide advice to the pharmacist on the use of the Schedule 4 poisons when needed.
- (iii) The pharmacist administers Schedule 4 poisons as part of their responsibilities when engaged by a Residential Aged Care Home under the Tier 2 of the Aged Care On-site Pharmacist Measure⁵, when the:
 - (I) Residential Aged Care Home ensures access to a medical practitioner or nurse practitioner; and
 - (II) medical practitioner or nurse practitioner referred to in paragraph 3(c)(iii)(I) is available to provide advice to the pharmacist on the use of the Schedule 4 poisons when needed.
- (d) **All pharmacists administering Schedule 4 poisons:**
 - (i) must do so in accordance with:
 - (I) the edition of the *Australian Immunisation Handbook*⁶ that is current at the time of the administration; and
 - (II) the edition of the National Vaccine Storage Guidelines: Strive for 5⁶ that is current at the time of the administration; and
 - (III) any additional requirements specified on the Victorian Department of Health's COVID-19 webpage² or otherwise specified by the Victorian Government (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, 3, 4 and 5, 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 Schedule 4 poisons listed in Appendices 1, 2, 3, 4 and 5 (whether government-funded or not) by pharmacists.

Note: Pharmacists who administer the Schedule 4 poison, as listed in Appendix 3 are referred to the edition of the *Victorian mpox (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 Schedule 4 poison. Those Schedule 3 Poisons should be kept on hand and utilised should they be required at the time the Schedule 4 poison is administered.

⁵ Australian Government, Department of Health and Aged Care. 2022. Pharmacy Programs Administrator. Aged Care On-Site Pharmacist (ACOP) Measure Tier 2 – RACH claims and receives payments, available at: www.ppaonline.com.au/programs/aged-care-on-site-pharmacist-measure/tier-2

⁶ Current version available online.

Appendix 1

Column 1: Generic name of vaccine	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>
Herpes zoster (shingles) Human papillomavirus (HPV) Influenza Measles-mumps-rubella (MMR) Meningococcal ACWY Pneumococcal	<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 purposes⁷; • Vaccination of people aged 4 years and younger; • Vaccination of people with contraindications defined in the current edition of the <i>Australian Immunisation Handbook</i>⁶.
Diphtheria-tetanus-pertussis vaccines	<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 purposes⁷; • Vaccination of people aged 4 years and younger; • Vaccination of people that are contacts in the event of a case of pertussis, unless directed by the Department of Health⁸; • Vaccination for the express purpose of post-exposure prophylaxis in people with a tetanus-prone wound⁹; • Vaccination of people with contraindications defined in the current edition of the <i>Australian Immunisation Handbook</i>⁶.

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 webpage¹⁰ at the time of administration. 	<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 Victorian Department of Health's Japanese encephalitis webpage^{7,10}; • Vaccination of people aged 4 years and younger; • Vaccination of people with contraindications defined in the current edition of the <i>Australian Immunisation Handbook</i>⁶.
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⁷ Travel medicine is a specialist area that is outside the scope of this approval.

⁸ Pertussis vaccine is only available in Australia in combination with diphtheria and tetanus, or diphtheria, tetanus and poliomyelitis.

⁹ A case of this vaccine-preventable disease is notifiable to the Victorian Department of Health under the Public Health and Wellbeing Regulations 2019. The Department of Health will advise on management of the case and contacts.

¹⁰ Victorian Department of Health, Japanese encephalitis, available at: www.health.vic.gov.au/infectious-diseases/japanese-encephalitis

Appendix 3

Mpox (monkeypox/ vaccinia virus)	<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 Mpox (monkeypox) webpage¹¹ at the time of administration. 	<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 Victorian Department of Health's Mpox (monkeypox) webpage^{7,11}; • Vaccination of people aged 4 years and younger; • Vaccination of people with contraindications defined in the current edition of the <i>Australian Immunisation Handbook</i> (or current recommendations issued by the Australian Technical Advisory Group on Immunisation (ATAGI))⁶.
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Appendix 4

Column 1: Generic name of vaccine or therapeutic product	Column 2: <ul style="list-style-type: none"> • Approval for pharmacists to immunise with this vaccine or therapeutic product applies to 	Column 3: <ul style="list-style-type: none"> • Approval for pharmacists to immunise with this vaccine or therapeutic product excludes
Respiratory syncytial virus (RSV) vaccine or RSV therapeutic product as listed on the Victorian Department of Health's Respiratory syncytial virus (RSV) immunisation webpage ¹	<ul style="list-style-type: none"> • Immunisation of people aged 5 years and older that are recommended for immunisation as listed on the Victorian Department of Health's Respiratory syncytial virus (RSV) immunisation webpage¹ at the time of administration. 	<ul style="list-style-type: none"> • Immunisation of people not recommended for immunisation; • Immunisation for travel purposes other than those people recommended for immunisation as listed on the Victorian Department of Health's Respiratory syncytial virus (RSV) immunisation webpage^{1,7}; • Immunisation of people aged 4 years and younger; • Immunisation of people with contraindications defined in the current edition of the <i>Australian Immunisation Handbook</i> (or current recommendations issued by the Australian Technical Advisory Group on Immunisation (ATAGI))⁶.

¹¹ Victorian Department of Health, Mpox (monkeypox), available at: www.health.vic.gov.au/infectious-diseases/mpox-monkeypox

Appendix 5

Column 1: Generic name of vaccine	Column 2: Approval for pharmacists to immunise with this vaccine or therapeutic product <i>applies to</i>	Column 3: Approval for pharmacists to immunise with this vaccine or therapeutic product <i>excludes</i>
SARS-CoV-2 (COVID-10)	<ul style="list-style-type: none"> ● Vaccination of people aged 5 years and older, and included in the patient group for which that COVID-19 vaccine has been approved for by the Therapeutic Goods Administration, or the patient group as recommended by the Australian Technical Advisory Group on Immunisation (ATAGI)², excluding those circumstances listed in Column 3. 	<ul style="list-style-type: none"> ● Vaccination for travel purposes⁷; ● Vaccination of people aged 4 years and younger; ● Vaccination of people with contraindications defined in the current edition of the <i>Australian Immunisation Handbook</i> (or current recommendations issued by the Australian Technical Advisory Group on Immunisation (ATAGI))⁶.

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

Dated 26 September 2024

Approved by NITSA KARAHALIOS
 Director, Regulatory Compliance and Operations – Health
 Delegate of the Secretary, Department of Health

DRUGS, POISONS AND CONTROLLED SUBSTANCES REGULATIONS 2017

Secretary Approval: Intern Pharmacist Immuniser

Approval under Regulation 163

Pursuant to Regulation 163 of the Drugs, Poisons and Controlled Substances Regulations 2017 (the Regulations), I, Nitsa Karahalios, Director, Regulatory Compliance and Operations – Health, and Delegate of the Secretary, Department of Health, hereby approve:

- (1) the Schedule 4 poisons listed in Appendices 1–3 for administration by an intern pharmacist on condition that the intern pharmacist meets the requirements of an intern pharmacist immuniser as set out below.
- (2) the Schedule 4 poisons listed in Appendix 4 for administration by an intern pharmacist who meets the requirements of an intern pharmacist immuniser, and on condition that prior to administering a respiratory syncytial virus (RSV) vaccine or RSV therapeutic product, the intern pharmacist has satisfactorily completed any additional training and competency requirements in relation to that Schedule 4 poison as listed on the Victorian Department of Health’s Respiratory syncytial virus (RSV) immunisation webpage¹ at the time of administration.
- (3) The Schedule 4 poison listed in Appendix 5 for administration by an intern pharmacist who meets the requirements of an intern pharmacist immuniser, and on condition that prior to administering a SARS-CoV-2 (COVID-19) vaccine, the intern pharmacist has satisfactorily completed any additional training and competency requirements in relation to that Schedule 4 poison as listed on the Victorian Department of Health’s COVID-19 webpage² at the time of administration.

This approval revokes the Secretary Approval: Intern Pharmacist Immuniser published in the Government Gazette S 194 on Wednesday 24 April 2024.

1. This approval applies to:

an intern pharmacist, who at the time of the administration of the Schedule 4 poisons holds provisional 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 Victorian Department of Health, Respiratory syncytial virus (RSV) immunisation, available at: www.health.vic.gov.au/immunisation/respiratory-syncytial-virus-immunisation

² Victorian Department of Health, COVID-19 vaccine, available at: www.health.vic.gov.au/immunisation/covid-19-vaccine

³ This does not include general registration, limited 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 see: www.health.vic.gov.au/immunisation/programs-of-study

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

- (a) vaccines listed in Appendices 1–3 to persons set out in the corresponding entry in column 2, subject to the corresponding exclusions in column 3.
- (b) vaccine or therapeutic product listed in Appendix 4 where the intern pharmacist has completed any additional training and competency requirements in relation to that Schedule 4 poison listed on the Victorian Department of Health’s Respiratory syncytial virus (RSV) immunisation webpage¹ at the time of administration, to persons listed in column 2, subject to the corresponding exclusions in column 3.
- (c) vaccine listed in Appendix 5 where the intern pharmacist has completed any additional training and competency requirements in relation to that Schedule 4 poison as listed on the Victorian Department of Health’s COVID-19 vaccine webpage² at the time of administration, 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 an intern 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 intern pharmacist administering the Schedule 4 poisons is employed or otherwise engaged by the business referred to in paragraphs 3(a)(i)(I), (II) or (III) and sources the Schedule 4 poisons from those premises.
- (b) *Any premises referred to in paragraphs 3(a)(i)(I), (II) or (III) on which an intern pharmacist administers a Schedule 4 poison 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 intern 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 5*⁵ that is current at the time of the administration; and
 - (III) any additional requirements specified on the Victorian Department of Health’s COVID-19 vaccine website² or otherwise specified by the Victorian Government (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).

⁵ Current version available online.

(d) All intern pharmacists administering Schedule 4 poisons:

- (i) must only do so when employed, contracted, or otherwise engaged by a business referred to in paragraphs 3(a)(i)(I), (II) or (III) who employs or contracts a pharmacist who meets the requirements of a pharmacist immuniser.
- (ii) must only do so under the direct supervision of a pharmacist referred to in clause 3(d)(i) (see Note).

Note: Intern pharmacists who administer Schedule 4 poisons, as listed in Appendices 1, 2, 3, 4 and 5 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 intern pharmacists. These guidelines contain best practice guidance for the administration of all Schedule 4 poisons listed in Appendices 1, 2, 3, 4 and 5 (whether government-funded or not) by intern pharmacists.

Note: Intern pharmacists who administer the Schedule 4 poison, as listed in Appendix 3 are referred to the edition of the *Victorian mpox (monkeypox) vaccination program guidelines*, current at the time of administration and issued by the Department of Health.

Note: Pharmacists (including intern pharmacists) are permitted to possess and administer Schedule 3 poisons pursuant to Regulation 141 of the Regulations. Accordingly, intern pharmacists are permitted to possess and administer Schedule 3 poisons that are necessary for the treatment of anaphylactic reactions to the Schedule 4 poison. Those Schedule 3 poisons should be kept on hand and utilised should they be required at the time the Schedule 4 poison is administered.

Note: Supervision means that the intern pharmacist must be supervised as referred to in clause 3(d), by an experienced pharmacist immuniser, with the supervising pharmacist immuniser required to always be physically present in the workplace while the intern pharmacist immuniser is undertaking immunisation activities, and available during those times to observe and discuss management of people receiving vaccines and/or the performance of the intern pharmacist when necessary.

Appendix 1

Column 1: Generic name of vaccine	Column 2: Approval for intern pharmacists to vaccinate with this vaccine applies to	Column 3: Approval for intern pharmacists to vaccinate with this vaccine excludes
Herpes zoster (shingles) Human papillomavirus (HPV) Influenza Measles-mumps-rubella (MMR) Meningococcal ACWY Pneumococcal	<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 <i>Australian Immunisation Handbook</i>⁵.

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

Column 1: Generic name of vaccine	Column 2: Approval for intern pharmacists to vaccinate with this vaccine <i>applies to</i>	Column 3: Approval for intern pharmacists to vaccinate with this vaccine <i>excludes</i>
Diphtheria-tetanus-pertussis vaccines	<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 that are contacts in the event of a case of pertussis, unless directed by the Department of Health⁷; ● Vaccination for the express purpose of post-exposure prophylaxis in people with a tetanus-prone wound⁸; ● Vaccination of people with contraindications defined in the current edition of the <i>Australian Immunisation Handbook</i>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 webpage⁹ 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 Victorian Department of Health's Japanese encephalitis webpage^{6,9}; ● Vaccination of people aged 4 years and younger; ● Vaccination of people with contraindications defined in the current edition of the <i>Australian Immunisation Handbook</i>⁵.
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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 Pertussis vaccine is only available in Australia in combination with diphtheria and tetanus, or diphtheria, tetanus and poliomyelitis.

⁹ Victorian Department of Health, Japanese encephalitis, available at: www.health.vic.gov.au/infectious-diseases/japanese-encephalitis

Appendix 3

Mpx (monkeypox/ vaccinia virus)	<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 Mpx (monkeypox) webpage¹⁰ 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 Victorian Department of Health's Mpx (monkeypox) webpage^{6,10}; • Vaccination of people aged 4 years and younger; • Vaccination of people with contraindications defined in the current edition of the <i>Australian Immunisation Handbook</i> (or current recommendations issued by the Australian Technical Advisory Group on Immunisation (ATAGI))⁵.
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Appendix 4

Column 1: Generic name of vaccine or therapeutic product	Column 2: • Approval for intern pharmacists to immunise with this vaccine or therapeutic product <i>applies to</i>	Column 3: • Approval for intern pharmacists to immunise with this vaccine or therapeutic product <i>excludes</i>
Respiratory syncytial virus (RSV) vaccine or RSV therapeutic product as listed on the Victorian Department of Health's Respiratory syncytial virus (RSV) immunisation webpage ¹	<ul style="list-style-type: none"> • Immunisation of people aged 5 years and older that are recommended for immunisation as listed on the Victorian Department of Health's Respiratory syncytial virus (RSV) immunisation webpage¹ at the time of administration. 	<ul style="list-style-type: none"> • Immunisation of people not recommended for immunisation; • Immunisation for travel purposes other than those people recommended for immunisation as listed on the Victorian Department of Health's Respiratory syncytial virus (RSV) immunisation webpage^{1,6}; • Immunisation of people aged 4 years and younger; • Immunisation of people with contraindications defined in the current edition of the <i>Australian Immunisation Handbook</i> (or current recommendations issued by the Australian Technical Advisory Group on Immunisation (ATAGI))⁵.

¹⁰ Victorian Department of Health, Mpx (monkeypox), available at: www.health.vic.gov.au/infectious-diseases/mpox-monkeypox

Appendix 5

Column 1: Generic name of vaccine	Column 2: Approval for pharmacists to immunise with this vaccine or therapeutic product <i>applies to</i>	Column 3: Approval for pharmacists to immunise with this vaccine or therapeutic product <i>excludes</i>
SARS-CoV-2 (COVID-19)	<ul style="list-style-type: none"> ● Vaccination of persons aged 5 years and older, and included in the patient group for which that COVID-19 vaccine has been approved for by the Therapeutic Goods Administration, or the patient group as recommended by the Australian Technical Advisory Group on Immunisation (ATAGI)², 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 (or current recommendations issued by the Australian Technical Advisory Group on Immunisation (ATAGI))⁵.

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