Secretary Approval: Community Pharmacist Program

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

Pursuant to regulation 163A of the Drugs, Poisons and Controlled Substances Regulations 2017 (the Regulations), I, **Jenny Atta PSM**, Secretary to the Department of Health hereby:

A. **approve**, subject to the conditions specified below, in respect of pharmacists participating in the Community Pharmacist Program:

- (1) the Schedule 4 poisons listed in Appendix 1 for supply and sale for the treatment of a suspected urinary tract infection (UTI) to a person under the pharmacist's care without a prescription or other instruction or authorisation from a registered medical practitioner, dentist, nurse practitioner, authorised midwife, authorised optometrist or authorised podiatrist; and
- (2) the Schedule 4 poisons listed in Appendix 2 for supply and sale of hormonal contraceptives to a person under the pharmacist's care without a prescription or other instruction or authorisation from a registered medical practitioner, dentist, nurse practitioner, authorised midwife, authorised optometrist or authorised podiatrist; and
- (3) the Schedule 4 poisons listed in Appendix 3 for supply, sale or administration of depot medroxprogesterone injection to a person under the pharmacist's care without a prescription or other instruction or authorisation from a registered medical practitioner, dentist, nurse practitioner, authorised midwife, authorised optometrist or authorised podiatrist; and
- (4) the Schedule 4 poisons listed in Appendix 4 for administration to a person under the pharmacist's care without a prescription or other instruction or authorisation from a registered medical practitioner, dentist, nurse practitioner, authorised midwife, authorised optometrist or authorised podiatrist; and the Schedule 4 poisons listed in Appendix 5 for supply and sale for the treatment of minor skin disorders to a person under the pharmacist's care without a prescription or other instruction or authorisation from a registered medical practitioner, dentist, nurse practitioner, authorised midwife, authorised optometrist or authorised podiatrist; and

B. **revoke** the Secretary Approval made under regulation 163A of the Regulations regarding the Community Pharmacist Program and published in the Vicotria Government Gazette No. G26 dated 26 June 2025.



Conditions

1. This approval applies to:

a pharmacist who at the time of the sale, supply or administration of the Schedule 4 poisons1:

- (a) holds general registration with the Pharmacy Board of Australia²; and
- (b) owns, or is employed, contracted or otherwise engaged at, a pharmacy participating in the Community Pharmacist Program³ (Program) and
- (c) at the time of administering an injection listed in Appendix 3, the pharmacist:
 - (i) has successfully completed the assessment of an 'Administering medicines by injection program of study' recognised by the Chief Health Officer (see Note); and has recency of practice and continuing professional development in administering medicines by injection; and
 - (ii) holds a current first aid certificate (to be updated every three years); and
 - (iii) holds a current cardiopulmonary resuscitation certificate (to be updated annually).
- (d) at the time of administering a vaccine listed in Appendix 4, the pharmacist:
 - (i) has successfully completed the assessment of an 'Immuniser program of study' recognised by the Chief Health Officer (see Note); and
 - (ii) has successfully completed the assessment of an 'Travel healthcare training' recognised by the Deputy Chief Health Officer - Communicable Disease (see Note); and
 - (iii) has recency of practice and continuing professional development in immunisation (as defined from time to time by the Pharmacy Board of Australia); and
 - (iv) holds a current first aid certificate (to be updated every three years); and
 - (v) holds a current cardiopulmonary resuscitation certificate (to be updated annually).

NOTE: For a list of the programs of study that have been recognised by the Chief Health Officer and links to the Travel healthcare training that have been recognised by Deputy Chief Health Officer - Communicable Disease see the Department of Health's Program webpage: Department of Health - Community Pharmacist Program Home.

2. The pharmacist may sell, supply or administer the following Schedule 4 poisons:

- (a) medicines listed in Appendix 1 subject to the conditions set out in the corresponding entry in column 2:
- (b) medicines listed in Appendix 2 subject to the conditions set out in the corresponding entry in column
- (c) medicines listed in Appendix 3, subject to the conditions set out in the corresponding entry in column
- (d) vaccines listed in Appendix 4, to persons listed in the corresponding entry in column 2, subject to the corresponding exclusions in column 3; and

¹ Included in Schedule 4 of the Poisons Standard.

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

³ A pharmacy is participating in the Program when the owner, or other authorised representative of the pharmacy, is a party to a Funding Agreement for the purposes of the Program with the Department of Health.

(e) medicines listed in Appendix 5, for the skin disorder set out in the corresponding entry in Column 2, subject to the conditions set out in the corresponding entry in Column 3;

from a pharmacy as defined in the **Pharmacy Regulation Act 2010**, which meets the requirements of the Victorian Pharmacy Authority Guidelines current at the time of sale, supply or administration of the Schedule 4 poisons, and which is participating in the Program.

NOTE: Pharmacists who sell, supply or administer the Schedule 4 poisons listed in Appendices 1, 2, 3, 4 and 5 should regularly refer to the <u>Community Pharmacist Program – Resources for pharmacists</u> webpage to ensure they act in accordance with guidance issued by the Department of Health and Safer Care Victoria from time to time.

NOTE: Clause 2 does not prevent pharmacists from administering a vaccine listed in Appendix 4 as part of a mobile or outreach service offered by a pharmacy participating in the Program.

3. A pharmacist administering a medicine listed in Appendix 3 or a vaccine listed in Appendix 4:

(a) must ensure that, when administering on a pharmacy premises, at least one other staff member that holds a current first aid and cardiopulmonary resuscitation certificate is on duty in the pharmacy when the medicine or vaccine is administered and for a minimum period of 15 minutes afterwards

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.

NOTE: Pharmacists who administer, sell or supply Schedule 4 poisons under this approval must comply with general labelling, storage and record keeping requirements in Parts 7 and 13 of the Regulations.

4. A pharmacist administering a vaccine listed in Appendix 4:

- (a) must do so in accordance with:
 - (i) The edition of the *Australian Immunisation Handbook* that is current at the time of the administration; and
 - (ii) The edition of the *National Vaccine Storage Guidelines: Strive for 5* that is current at the time of the administration; and
 - (iii) The Protocol for Vaccine Administration current at the time of the administration, and as updated from time to time by the Department of Health⁴; and
- (b) must report the administration of the vaccine to the Australian Immunisation Register in a timely manner; and
- (c) must only provide mobile or outreach services connected to a pharmacy referred to in paragraph 2, which they own, are employed, contracted or otherwise engaged at, and from which they source the vaccine.

NOTE: Pharmacists who administer Schedule 4 poisons listed in Appendix 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

⁴ Available from Community Pharmacist Program – Resources for pharmacists | health.vic.gov.au

pharmacists. These guidelines contain best practice guidance for the administration of all vaccines listed in Appendix 3 (whether government funded or not) by pharmacists.

Appendix 1

| Column 1 | Column 2 | | | | |
|-----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|--|
| Medicines for the treatment of suspected UTIs | Conditions of sale or supply without a prescription or other instruction or authorisation | | | | |
| Trimethoprim Nitrofurantoin Cefalexin | Sale or supply must be in compliance with the Protocol for Management of Urinary Tract Infections⁵ as updated from time to time by Safer Care Victoria. The pharmacist has successfully completed the current training requirements specified on the Community Pharmacist website; A medicine listed in column 1 is only supplied or sold for the purpose of treatment of a suspected UTI in a female, aged between 18 and 65 years who is not known to be pregnant. | | | | |

Appendix 2

| Column 1 | Column 2 | | | |
|----------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|
| Medicines for hormonal contraception | Conditions of sale or supply without a prescription or other instruction or authorisation | | | |
| Combined oral contraceptives Progestogens Combined hormonal contraceptive vaginal ring | Sale or supply must be in compliance with the Protocol for Resupply of Hormonal Contraception⁶ as updated from time to time by Safer Care Victoria. The pharmacist has successfully completed the current training requirements specified on the Community Pharmacist Program website; A hormonal contraceptive listed in column 1 must not contain 50 microgram ethinylestradiol equivalent or above; A hormonal contraceptive listed in column 1 is only to be sold or supplied to a female who: is aged between 16 and 50 years; and is not known to be pregnant; and has been prescribed the hormonal contraceptive by a medical practitioner, nurse practitioner, or authorised midwife in the last two years; and has been stabilised on that hormonal contraceptive for at least 12 months if aged 16 to 17 years, or at least 6 months if aged 18 to 50 years; and has had no more than 4 weeks break in the preceding 30 days of use of that hormonal contraceptive. | | | |

 $^{^{5}\} Available\ from\ \underline{Community\ Pharmacist\ Program-Resources\ for\ pharmacists\ |\ health.vic.gov.au$

 $^{^{6} \} Available \ from \ \underline{Community \ Pharmacist \ Program-Resources \ for \ pharmacists \ | \ health.vic.gov.au$

Appendix 3

| Column 1 | Column 2 | | | |
|--------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|
| Medicines for hormonal contraception | Conditions of sale, supply or administration without a prescription or other instruction or authorisation | | | |
| Depot medroxyprogesterone injection | Sale, supply or administration must be in compliance with the Protocol for Resupply of Hormonal Contraception⁷ as updated from time to time by Safer Care Victoria. The pharmacist has successfully completed the current training requirements specified on the Community Pharmacist Program website; A medicine listed in column 1 is only to be sold, supplied or administered to a person who: is aged between 16 and 50 years; and is not known to be pregnant; and has been prescribed the medicine by a medical practitioner, nurse practitioner, or authorised midwife in the last two years; and has been stabilised on that medicine for at least 12 months if aged 16 to 17 years, or at least 6 months if aged 18 to 50 years; and has had no more than 14 weeks break since their previous injection of this medicine. | | | |

Appendix 4

| Column 1 Generic name of vaccine | Column 2 Approval for pharmacists to administer this vaccine applies to | Column 3 Approval for pharmacists to administer this vaccine excludes | | |
|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|
| Influenza vaccine Hepatitis A vaccine Hepatitis B vaccine Poliomyelitis vaccine Typhoid vaccine | Vaccination of people aged 5 years and older, excluding those circumstances listed in Column 3. | Vaccination of people aged 4 years and younger. Vaccination of contacts in the case of hepatitis A, unless directed by the Department of Health⁸. Immunisation with normal human immunoglobulin for the prophylaxis of hepatitis A when in contact with a case⁹. Vaccination of people following acute exposure to potentially infected blood or body fluids¹⁰. Immunisation with hepatitis B immunoglobulin following acute exposure to potentially infected blood or body fluids⁸. | | |

 $^{^{7}\,\}text{Available from } \underline{\text{Community Pharmacist Program}} - \underline{\text{Resources for pharmacists}} \; | \; \underline{\text{health.vic.gov.au}}$

⁸ A case of this vaccine preventable disease is notifiable to the Department of Health under the Health (Infectious Diseases) Regulation 1990. The department will provide advice on the further management of the case and contacts.

⁹ Approval to administer vaccines does not include the administration of immunoglobulin preparations.

¹⁰ Although immunisation is indicated, the final decision that immunisation is indicated should be made by the individual's treating doctor due to the specialist nature of the condition.

| | | Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook¹¹. |
|----------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diphtheria-tetanus- pertussis vaccines ¹² | Vaccination of people aged 12 years and older, excluding those circumstances listed in Column 3. | Vaccination of people aged 11 years and younger; Vaccination with diphtheria antitoxin⁸. Vaccination of people that are contacts in the event of a case of diphtheria or pertussis, unless directed by the Department of Health⁷. Vaccination for the tetanus prophylaxis related to wound management¹³. Immunisation with tetanus immunoglobulin⁸. Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook¹⁰. Error! Bookmark not defined. |
| Human papillomavirus (HPV) vaccine | Vaccination of people aged 12 years and older, excluding those circumstances listed in Column 3. | Vaccination of people aged 11 years and younger. Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook¹⁰. |
| Measles vaccine Mumps vaccine Rubella vaccine (MMR) ¹⁴ Meningococcal ACWY vaccine | Vaccination of people aged 15 years and older, excluding those circumstances listed in Column 3. | Vaccination of people aged 14 years and younger. Vaccination of contacts in the event of a case of measles, mumps, rubella or meningococcal disease unless directed by the Department of Health⁷. Immunisation with normal human immunoglobulin for the prophylaxis of measles, mumps or rubella when in contact with a case⁸. Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook¹⁰. |
| Pneumococcal vaccine Herpes zoster/zoster/ shingles vaccine | Vaccination of people aged 50 years and older, excluding those circumstances listed in Column 3. | Vaccination of people aged 49 years and younger. Immunisation with normal human immunoglobulin for the prophylaxis of herpes zoster when in contact with a case⁸. Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook¹⁰. |

Appendix 5

| Column 1 | Column 2 | Column 3 |
|-----------------------------|---------------|---------------------------------|
| Medicines for the treatment | Skin disorder | Conditions of sale or supply |
| of skin disorder | | without a prescription or other |
| | | instruction or authorisation |

 $^{^{11}\,} Current\, version\, available\, online\, at: \underline{https://immunisationhandbook.health.gov.au/}$

¹² Only available in Australia in combination vaccine with diphtheria, tetanus and pertussis or diphtheria, tetanus, pertussis and poliomyelitis.

 $^{^{\}rm 13}$ Tetanus prone wounds should be reviewed in a medical consultation.

¹⁴ Only available in Australia in combination vaccine with measles, mumps and rubella or measles, mumps, rubella and varicella.

| Valaciclovir Famciclovir Aciclovir | Herpes Zoster | • | Sale or supply must be in compliance with the Protocol for Management of Herpes Zoster (Shingles) ¹⁵ as updated from time to time by Safer Care Victoria. The pharmacist has successfully completed the current training requirements specified on the Community Pharmacist Program website. A medicine listed in column 1 is only supplied or sold for the purpose of treatment of Herpes Zoster in a person aged 18 years or older who presents with signs and symptoms indicative of Herpes Zoster less than 72 hours from onset of symptoms. |
|-------------------------------------------------------------------------------------------------------------------------|---------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Betamethasone valerate Triamcinolone acetate Betamethasone dipropionate Methylprednisolone aceponate Mometasone furoate | Psoriasis | • | Sale or supply must be in compliance with the Protocol for Management of Acute Exacerbation of Mild Plaque Psoriasis ¹⁶ as updated from time to time by Safer Care Victoria. The pharmacist has successfully completed the current training requirements specified on the Community Pharmacist Program website. A medicine listed in column 1 is only supplied or sold for the purpose of treatment of an acute exacerbation of mild plaque psoriasis in a person aged 18 years or older who has previously received a diagnosis of mild plaque psoriasis of the trunk or limbs from a medical practitioner and for whom at least one previous exacerbation of plaque psoriasis has been successfully managed with topical corticosteroids. |
| Mupirocin Dicloxacillin Flucloxacillin Cefalexin Trimethoprim + Sulfamethoxazole | Impetigo | • | Sale or supply must be in compliance with the Protocol for the Management of Impetigo ¹⁷ as updated from time to time by Safer Care Victoria. The pharmacist has successfully completed the current training requirements specified on the |

 $^{^{15} \} Available \ from \ \underline{Community\ Pharmacist\ Program-Resources\ for\ pharmacists\ \ \ |\ health.vic.gov.au$

 $^{^{16} \} Available \ from \ \underline{Community\ Pharmacist\ Program-Resources\ for\ pharmacists\ |\ health.vic.gov.au$

 $^{^{17} \} Available \ from \ \underline{Community\ Pharmacist\ Program-Resources\ for\ pharmacists\ |\ health.vic.gov.au$

| | | Community Pharmacist Program |
|--|---|------------------------------------------|
| | | website. |
| | • | A medicine listed in column 1 is only |
| | | supplied or sold for the purpose of |
| | | treatment of Impetigo in a person aged |
| | | 2 years or older with clearly identified |
| | | non-recurrent, non-bullous impetigo, |
| | | limited to no more than two body |
| | | regions, with no signs of other |
| | | complications, who are not at high risk |
| | | of developing Acute rheumatic fever |
| | | (ARF). |
| | | |

This approval takes effect on the date it is published and remains in effect until revoked.

Approved by Jenny Atta

Date: 10/12/2025

Secretary

Department of Health