



# Victoria Government Gazette

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## DRUGS, POISONS AND CONTROLLED SUBSTANCES REGULATIONS 2017 SECRETARY APPROVAL: COMMUNITY PHARMACIST STATEWIDE PILOT

### Approval under Regulation 163A

Pursuant to regulation 163A of the Drugs, Poisons and Controlled Substances Regulations 2017 (the Regulations), I, Professor Euan M Wallace AM, Secretary to the Department of Health, hereby approve in respect of pharmacists participating in the Community Pharmacist Statewide Pilot:

- (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 oral contraceptive pills 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 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
- (4) the Schedule 4 poisons listed in Appendix 4 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.

This approval revokes and replaces the Secretary Approval: Community Pharmacist Statewide Pilot published in the Government Gazette S 74 Tuesday 20 February 2024. The effect of the Secretary Approval is to extend the approval of pharmacists under regulation 163A until 30 June 2025.

### **This approval applies to:**

a pharmacist who at the time of the sale, supply or administration of the Schedule 4 poisons<sup>1</sup>:

- (a) holds general registration with the Pharmacy Board of Australia<sup>2</sup>; and
- (b) owns, or is employed, contracted or otherwise engaged at, a pharmacy participating in the Community Pharmacist Statewide Pilot<sup>3</sup> (Pilot); and
- (c) at the time of administering a vaccine listed in Appendix 3, 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 immuniser 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 Community Pharmacist Statewide Pilot webpage: [www.health.vic.gov.au/primary-care/victorian-community-pharmacist-statewide-pilot-resources-for-pharmacists](http://www.health.vic.gov.au/primary-care/victorian-community-pharmacist-statewide-pilot-resources-for-pharmacists)

<sup>1</sup> Included in Schedule 4 of the Poisons Standard.

<sup>2</sup> This does not include limited registration, provisional registration, non-practising registration, or student registration.

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

**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) oral contraceptive pills listed in Appendix 2 subject to the conditions set out in the corresponding entry in column 2;
- (c) vaccines listed in Appendix 3, to persons listed in the corresponding entry in column 2, subject to the corresponding exclusions in column 3; and
- (d) medicines listed in Appendix 4, 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 Pilot.

Note: Pharmacists who sell, supply or administer the Schedule 4 poisons listed in Appendices 1, 2, 3 and 4 should regularly refer to the Community Pharmacist Statewide Pilot- Resources for Pharmacists 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 3 as part of a mobile or outreach service offered by a pharmacy participating in the Pilot.

**3. A pharmacist administering a vaccine listed in Appendix 3:**

- (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 Health<sup>4</sup>; and
- (b) 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 vaccine is administered and for a minimum period of 15 minutes afterwards; and
- (c) must report the administration of the vaccine to the Australian Immunisation Register in a timely manner; and
- (d) 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 pharmacists. These guidelines contain best practice guidance for the administration of all vaccines listed in Appendix 3 (whether government funded or not) by pharmacists.

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

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

<sup>4</sup> Available from [www.health.vic.gov.au/primary-care/victorian-community-pharmacist-statewide-pilot-resources-for-pharmacists](http://www.health.vic.gov.au/primary-care/victorian-community-pharmacist-statewide-pilot-resources-for-pharmacists)

**Appendix 1**

| <b>Column 1</b><br><b>Medicines for the treatment of suspected UTIs</b> | <b>Column 2</b><br><b>Conditions of sale or supply without a prescription or other instruction or authorisation</b>   |
|---|---|
| Trimethoprim<br>Nitrofurantoin<br>Cefalexin                             | <ul style="list-style-type: none"> <li>● sale or supply must be in compliance with the Protocol for Management of Urinary Tract Infections<sup>5</sup> as updated from time to time by Safer Care Victoria;</li> <li>● the pharmacist has successfully completed the current training requirements specified on the Community Pharmacist Statewide Pilot website;</li> <li>● 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.</li> </ul> |

**Appendix 2**

| <b>Column 1</b><br><b>Classes of oral contraceptive pills</b> | <b>Column 2</b><br><b>Conditions of sale or supply without a prescription or other instruction or authorisation</b>   |
|---|---|
| Combined oral contraceptives<br>Progestogens                  | <ul style="list-style-type: none"> <li>● sale or supply must be in compliance with the Protocol for Resupply of the Oral Contraceptive Pill<sup>6</sup> as updated from time to time by Safer Care Victoria;</li> <li>● the pharmacist has successfully completed the current training requirements specified on the Community Pharmacist Statewide Pilot website;</li> <li>● an oral contraceptive pill listed in column 1 is only to be sold or supplied to a female, aged between 16 and 50 years who is not known to be pregnant;</li> <li>● an oral contraceptive pill listed in column 1 must not contain 50 microgram ethinylestradiol equivalent or above;</li> <li>● an oral contraceptive pill listed in column 1 is only to be sold or supplied to a person who has been prescribed the oral contraceptive pill by a general practitioner or nurse practitioner in the last two years, has been stabilised on that pill for two years and who has been taking the oral contraceptive pill continuously since that prescription.</li> </ul> |

<sup>5</sup> Available from [www.health.vic.gov.au/primary-care/victorian-community-pharmacist-statewide-pilot-resources-for-pharmacists](http://www.health.vic.gov.au/primary-care/victorian-community-pharmacist-statewide-pilot-resources-for-pharmacists)

<sup>6</sup> Available from [www.health.vic.gov.au/primary-care/victorian-community-pharmacist-statewide-pilot-resources-for-pharmacists](http://www.health.vic.gov.au/primary-care/victorian-community-pharmacist-statewide-pilot-resources-for-pharmacists)

## Appendix 3

| Column 1<br>Generic name of vaccine   | Column 2<br>Approval for pharmacists to administer this vaccine applies to   | Column 3<br>Approval for pharmacists to administer this vaccine excludes   |
|---|--|--|
| Influenza vaccine<br>Hepatitis A vaccine<br>Hepatitis B vaccine<br>Poliomyelitis vaccine<br>Typhoid vaccine | <ul style="list-style-type: none"> <li>• Vaccination of people aged 5 years and older, excluding those circumstances listed in Column 3.</li> </ul>  | <ul style="list-style-type: none"> <li>• Vaccination of people aged 4 years and younger;</li> <li>• Vaccination of contacts in the case of hepatitis A, unless directed by the Department of Health<sup>7</sup>;</li> <li>• Immunisation with normal human immunoglobulin for the prophylaxis of hepatitis A when in contact with a case<sup>8</sup>;</li> <li>• Vaccination of people following acute exposure to potentially infected blood or body fluids<sup>9</sup>;</li> <li>• Immunisation with hepatitis B immunoglobulin following acute exposure to potentially infected blood or body fluids<sup>8</sup>; or</li> <li>• Vaccination of people with contraindications defined in the current edition of the <i>Australian Immunisation Handbook</i><sup>10</sup>.</li> </ul> |
| Diphtheria-tetanus-pertussis vaccines <sup>11</sup>   | <ul style="list-style-type: none"> <li>• Vaccination of people aged 12 years and older, excluding those circumstances listed in Column 3.</li> </ul> | <ul style="list-style-type: none"> <li>• Vaccination of people aged 11 years and younger;</li> <li>• Vaccination with diphtheria antitoxin<sup>8</sup>;</li> <li>• Vaccination of people that are contacts in the event of a case of diphtheria or pertussis, unless directed by the Department of Health<sup>7</sup>;</li> <li>• Vaccination for the tetanus prophylaxis related to wound management<sup>12</sup>;</li> <li>• Immunisation with tetanus immunoglobulin<sup>8</sup>; or</li> <li>• Vaccination of people with contraindications defined in the current edition of the <i>Australian Immunisation Handbook</i><sup>10</sup>.</li> </ul>   |

<sup>7</sup> 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.

<sup>8</sup> Approval to administer vaccines does not include the administration of immunoglobulin preparations.

<sup>9</sup> 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.

<sup>10</sup> Current version available online at: [www.immunisationhandbook.health.gov.au/](http://www.immunisationhandbook.health.gov.au/)

<sup>11</sup> Only available in Australia in combination vaccine with diphtheria, tetanus and pertussis or diphtheria, tetanus, pertussis and poliomyelitis.

<sup>12</sup> Tetanus prone wounds should be reviewed in a medical consultation.

|   |  |   |
|---|--|---|
| Human papillomavirus (HPV) vaccine  | <ul style="list-style-type: none"> <li>• Vaccination of people aged 12 years and older, excluding those circumstances listed in Column 3.</li> </ul> | <ul style="list-style-type: none"> <li>• Vaccination of people aged 11 years and younger; or</li> <li>• Vaccination of people with contraindications defined in the current edition of the <i>Australian Immunisation Handbook</i><sup>10</sup>.</li> </ul>   |
| Measles vaccine<br>Mumps vaccine<br>Rubella vaccine (MMR) <sup>13</sup><br>Meningococcal ACWY vaccine | <ul style="list-style-type: none"> <li>• Vaccination of people aged 15 years and older, excluding those circumstances listed in Column 3.</li> </ul> | <ul style="list-style-type: none"> <li>• Vaccination of people aged 14 years and younger;</li> <li>• Vaccination of contacts in the event of a case of measles, mumps, rubella or meningococcal disease unless directed by the Department of Health<sup>7</sup>;</li> <li>• Immunisation with normal human immunoglobulin for the prophylaxis of measles, mumps or rubella when in contact with a case<sup>8</sup>; or</li> <li>• Vaccination of people with contraindications defined in the current edition of the <i>Australian Immunisation Handbook</i><sup>10</sup>.</li> </ul> |
| Pneumococcal vaccine<br>Herpes zoster/zoster/ shingles vaccine  | <ul style="list-style-type: none"> <li>• Vaccination of people aged 50 years and older, excluding those circumstances listed in Column 3.</li> </ul> | <ul style="list-style-type: none"> <li>• Vaccination of people aged 49 years and younger;</li> <li>• Immunisation with normal human immunoglobulin for the prophylaxis of herpes zoster when in contact with a case<sup>8</sup>; or</li> <li>• Vaccination of people with contraindications defined in the current edition of the <i>Australian Immunisation Handbook</i><sup>10</sup>.</li> </ul>  |

<sup>13</sup> Only available in Australia in combination vaccine with measles, mumps and rubella or measles, mumps, rubella and varicella.

## Appendix 4

| Column 1<br>Medicines for the treatment of skin disorder  | Column 2<br>Skin disorder | Column 3<br>Conditions of sale or supply without a prescription or other instruction or authorisation   |
|---|---------------------------|---|
| Valaciclovir<br>Famciclovir<br>Aciclovir  | Herpes Zoster             | <ul style="list-style-type: none"> <li>● sale or supply must be in compliance with the Protocol for Management of Herpes Zoster (Shingles)<sup>14</sup> as updated from time to time by Safer Care Victoria</li> <li>● the pharmacist has successfully completed the current training requirements specified on the Community Pharmacist Statewide Pilot website</li> <li>● 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.</li> </ul>  |
| Betamethasone valerate<br>Triamcinolone acetate<br>Betamethasone dipropionate<br>Methylprednisolone aceponate<br>Mometasone furoate | Psoriasis                 | <ul style="list-style-type: none"> <li>● sale or supply must be in compliance with the Protocol for Management of Acute Exacerbation of Mild Plaque Psoriasis<sup>15</sup> as updated from time to time by Safer Care Victoria</li> <li>● the pharmacist has successfully completed the current training requirements specified on the Community Pharmacist Statewide Pilot website</li> <li>● 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.</li> </ul> |

This approval takes effect on the date it is published and expires on 30 June 2025, unless revoked earlier.

Dated 1 October 2024

Approved by  
PROFESSOR EUAN M. WALLACE AM  
Secretary  
Department of Health

<sup>14</sup> Available from [www.health.vic.gov.au/primary-care/victorian-community-pharmacist-statewide-pilot-resources-for-pharmacists](http://www.health.vic.gov.au/primary-care/victorian-community-pharmacist-statewide-pilot-resources-for-pharmacists)

<sup>15</sup> Available from [www.health.vic.gov.au/primary-care/victorian-community-pharmacist-statewide-pilot-resources-for-pharmacists](http://www.health.vic.gov.au/primary-care/victorian-community-pharmacist-statewide-pilot-resources-for-pharmacists)

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