Regulation 99(c) of the Drugs, Poisons and Controlled Substances Regulations 2017 authorises pharmacists to administer a Schedule 4 poison without an instruction from a registered medical practitioner, dentist, nurse practitioner or authorised midwife provided that the Secretary has approved the poison under regulation 163 and the pharmacist has taken all reasonable steps to ensure a therapeutic need exists for the poison.

Secretary Approval Pharmacist Immuniser

Approval under Regulation 99(c) Drugs, Poisons and Controlled Substances Regulations 2017

1. This approval applies to a pharmacist who at the time of the administration of the Schedule 4 poisons\(^1\) holds general registration with the Pharmacy Board of Australia\(^2\) and:
   
   (a) Has satisfactorily completed the assessment of an ‘Immuniser program of study’ recognised by the Chief Health Officer;

   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’\(^3\) that is compliant with Regulation 8(1) of the Drugs, Poisons and Controlled Substance Regulations 2017; or

   (iv) Pharmacist that is compliant with Regulation 99(c) of the Drugs, Poisons and Controlled Substances Regulations 2017;

AND

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\(^1\) Included in Schedule 4 of the Poisons Standard.

\(^2\) This does not include limited registration, provisional registration, non-practising registration, or student registration.

\(^3\) ‘Nurse Immuniser’ is a nurse acting in accordance with a Secretary Approval to administer certain vaccines.
(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).

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

(a) Vaccines listed in Appendix 1.

3. The following circumstances apply:

(a) The premises on which a pharmacist administers the Schedule 4 poisons must:

   (i) be one of the following premises:
       (I) A hospital; or
       (II) A pharmacy as defined in the Pharmacy Regulation Act 2010; or
       (III) A pharmacy depot, as defined in the Pharmacy Regulation Act 2010, that is a stand-alone business in premises owned or leased by the licensee of the related pharmacy;

OR

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

(b) Any premises referred to in paragraphs 3(a)(i)(I), (II) or (III) on which a pharmacist administers a Schedule 4 vaccine must meet the guidelines for facilities for immunisation services described in the Victorian Pharmacy Authority Guidelines that are current at the time of the administration.

(c) All pharmacists administering Schedule 4 poisons:

   (i) must do so in accordance with:
       (I) The edition of the Australian Immunisation Handbook\(^4\) that is current at the time of the administration; and
       (II) The edition of the National Vaccine Storage Guidelines: Strive for 5\(^4\) that is current at the time of the administration; and

   (ii) Must ensure that at least one other staff member that holds a current first aid and cardiopulmonary resuscitation certificate is on duty in the pharmacy when the Schedule 4 poisons are administered and for a minimum period of 15 minutes afterwards, where administering on premises defined in paragraphs 3(a)(i)(I), (II) or (III).

NOTE: Pharmacists who administer Schedule 4 poisons, as listed in Appendix 1, 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 and Human Services, which apply to the administration of all government-funded vaccines by pharmacists. These guidelines contain best practice guidance for the administration of all vaccines listed in Appendix 1 (whether government funded or not) by pharmacists.

\(^4\) Current version available online.
## Appendix 1

<table>
<thead>
<tr>
<th>Column 1: Generic name</th>
<th>Column 2: Approval for pharmacists to vaccinate with this vaccine applies to</th>
<th>Column 3: Approval for pharmacists to vaccinate with this vaccine excludes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza vaccines</td>
<td>• Vaccination of people aged 10 years and over, excluding those circumstances listed in Column 3.</td>
<td>• Vaccination for travel purposes;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Vaccination of people aged 9 years and under;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook.</td>
</tr>
<tr>
<td>Pertussis-containing vaccines</td>
<td>• Vaccination of people aged 15 years and over, excluding those circumstances listed in Column 3.</td>
<td>• Vaccination for travel purposes;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Vaccination of people aged 14 years and under;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Vaccination for the express purpose of achieving immunity against diphtheria, tetanus or poliomyelitis;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Vaccination of people that are contacts in the event of a case of pertussis, unless directed by the Department of Health and Human Services; or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook.</td>
</tr>
<tr>
<td>Measles-mumps-rubella vaccine (MMR)</td>
<td>• Vaccination of people aged 15 years and over, excluding those circumstances listed in Column 3.</td>
<td>• Vaccination for travel purposes;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Vaccination of people aged 14 years and under;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook.</td>
</tr>
<tr>
<td>Meningococcal ACWY</td>
<td>• Vaccination of people aged 15 years and over, excluding those circumstances listed in Column 3</td>
<td>• Vaccination for travel purposes;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Vaccination of people aged 14 years and under;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Vaccination of people with contraindications defined in the current edition of the Australian Immunisation Handbook.</td>
</tr>
</tbody>
</table>

* Current version available online.  
* Travel medicine is a specialist area that is outside the scope of this approval.  
* Pertussis vaccine is only available in Australia in combination with diphtheria and tetanus, or diphtheria, tetanus and poliomyelitis.  
* A case of this vaccine-preventable disease is notifiable to the Department of Health and Human Services under the Public Health and Wellbeing Regulations 2019. The Department of Health and Human Services will advise on management of the case and contacts.
This approval supersedes the Secretary Approval Pharmacist vaccination published in the Government Gazette G39 pp 2080 – 2082 27 September 2018.

This approval takes effect on Wednesday 1 April 2020.

Approved ANNA PEATT:

Date: 27/2/2020

Chief Officer, Medicines and Poisons Regulation, Delegate of the Secretary, Department of Health and Human Services