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); and

(d) Holds a current first aid certificate (to be updated every three years); and

(e) Holds a current cardiopulmonary resuscitation certificate (to be updated annually).

OR

(f) Is currently completing clinical practice 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.
(g) Holds a current first aid certificate (to be updated every three years); and
(h) Holds a current cardiopulmonary resuscitation certificate (to be updated annually).

2. The Pharmacist Immuniser 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. A general practice or immunisation clinic in which clinical practice is being undertaken in accordance with paragraph 1(f) to the extent that the supervising health professional is authorised to administer the Schedule 4 poison on those premises.

(ii) Be registered with the Department of Health and Human Services to hold a government funded vaccine account.

(iii) Meet the guidelines for facilities for immunisation services described in the Victorian Pharmacy Authority Guidelines that are current at the time of the administration if administering on premises defined in paragraphs 3(a)(i), II or III.

(b) The pharmacist who administers the Schedule 4 poisons:

(i) 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 Victorian Pharmacist-Administered Vaccination Program Guidelines, as issued by the Department of Health and Human Services, that is current at the time of the administration.

(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), II or III.

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 16 years and over, excluding those circumstances listed in Column 3.</td>
<td>• Vaccination for travel purposes, • Vaccination of people aged 15 years and under;</td>
</tr>
</tbody>
</table>

4 Current version available online.
5 Travel medicine is a specialist area that is outside the scope of this approval.
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</tr>
</thead>
<tbody>
<tr>
<td>Pertussis-containing vaccines</td>
<td>• Vaccination of people aged 16 years and over, excluding those circumstances listed in Column 3.</td>
<td>• Vaccination for travel purposes(^5); • Vaccination of people aged 15 years and under; • Vaccination for the express purpose of achieving immunity against diphtheria, tetanus or poliomyelitis(^6); • Vaccination of inpatients in hospitals; • Vaccination of people that are contacts in the event of a case of pertussis, unless directed by the Department of Health and Human Services(^7); or • Vaccination of people with contraindications defined in the current edition of the <em>Australian Immunisation Handbook</em>(^8).</td>
</tr>
<tr>
<td>Measles-mumps-rubella vaccine (MMR)</td>
<td>• Vaccination of people aged 16 years and over, excluding those circumstances listed in Column 3.</td>
<td>• Vaccination for travel purposes(^5); • Vaccination of people aged 15 years and under; • Vaccination of inpatients in hospitals; • Vaccination of people with contraindications defined in the current edition of the <em>Australian Immunisation Handbook</em>(^8).</td>
</tr>
</tbody>
</table>

This approval supersedes the Secretary Approval Pharmacist vaccination published in the Government Gazette G16 pp 730 – 732 19 April 2018.

This approval takes effect on 22 October 2018.

Approved ANNA PEATT: 

Date: 23/9/2018

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

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\(^5\) Pertussis vaccine is only available in Australia in combination with diphtheria and tetanus, or diphtheria, tetanus and poliomyelitis.

\(^6\) A case of this vaccine-preventable disease is notifiable to the Department of Health and Human Services under the Public Health and Wellbeing Regulations 2009. The Department of Health and Human Services will advise on management of the case and contacts.