DRUGS, POISONS AND CONTROLLED SUBSTANCES REGULATIONS 2006

Approval Under Regulation 49B

Pursuant to Regulation 49B of the Drugs, Poisons and Controlled Substances Regulations 2006 ('the Regulations'), I, Graeme Gillespie, Chief Officer, Drugs and Poisons Regulation and Delegate of the Secretary of the Department of Health and Human Services, hereby approve the Schedule 4 poisons listed in Appendix 1 for administration by pharmacists, subject to the following conditions:

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 Australia and:
   (a) has satisfactorily completed the assessment of an ‘Immuniser program of study’ recognised by the Chief Health Officer; and
   (b) has recency of practice and continuing professional development in immunisation (as defined from time to time by the Pharmacy Board of Australia); and
   (c) holds a current first aid certificate (to be updated every three years); and
   (d) holds a current cardiopulmonary resuscitation certificate (to be updated annually);

   OR

   (e) 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’ that is compliant with Regulation 5(3) of the Regulations; or
      (iv) Pharmacist that is compliant with Regulation 49A of the Regulations;

   AND

   (f) holds a current first aid certificate (to be updated every three years); and
   (g) 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 on which clinical practice is being undertaken in accordance with paragraph 1(e) 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.

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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.
(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)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’³ that is current at the time of the administration; and

II. the edition of the ‘National Vaccine Storage Guidelines: Strive for 5’³ 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)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>
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<tbody>
<tr>
<td>Influenza vaccines</td>
<td>• Vaccination of people aged 18 years and over, excluding those circumstances listed in Column 3.</td>
<td>• Vaccination for travel purposes⁴; • Vaccination of people aged 17 years and under; • Vaccination of inpatients in hospitals; or • Vaccination of people with contraindications defined in the current edition of the ‘Australian Immunisation Handbook’³.</td>
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| Pertussis-containing vaccines | • Vaccination of people aged 18 years and over, excluding those circumstances listed in Column 3. | • Vaccination for travel purposes⁴; • Vaccination of people aged 17 years and under; • Vaccination for the express purpose of achieving immunity against diphtheria, tetanus or poliomyelitis⁵; • 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 Services⁶; or • Vaccination of people with contraindications defined in the current edition of the ‘Australian Immunisation Handbook’³. |

³ Current version available online.
⁴ Travel medicine is a specialist area that is outside the scope of this approval.
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 Health (Infectious Diseases) Regulations 1990. The Department of Health and Human Services will advise on management of the case and contacts.
This approval takes effect from the date of publication in the Victoria Government Gazette.

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