

Approvals under the Drugs, Poisons and Controlled Substances Regulations 2006

This section has been prepared to assist those who are regulated by the *Drugs, Poisons and Controlled Substances Act 1981* ("Act") and the *Drugs, Poisons and Controlled Substances Regulations 2006* ("Regulations").

Approvals granted by the Secretary of the Department of Human Services

Some regulations allow for the Secretary to approve details that are not contained within the regulations. Approvals contained in this document are as follows:

- Schedule 4 poisons approved for use by **optometrists**
- Schedule 4 poisons approved for use by **podiatrists**
- Schedule 4 poisons approved for use by a qualified **ski patroller**
- Schedule 4 poisons approved for use by **dental hygienists or dental therapists** (12 March 2008)
- Approval for a **midwife**
- Schedule 4 poisons approved for use in the **tuberculosis** program
- Schedule 4 poisons approved for use in **vaccinations** (10 May 2007)
- Schedule 4 poison approved for use in **forensic nurse examinations** (17 December 2008)
- Criteria for **computer-generated prescriptions** (20 August 2009)

Details of matters "Approved by the Secretary" may change from time to time, so care should be taken to refer to the current version.

Should further explanation or clarification of any aspect of the Regulations be needed, officers of the Department of Human Services can be contacted on telephone 1300 364 545.

Regulations 5 and 6

Regulation 5 authorises persons (other than those authorised by the Act) to be in possession of Schedule 4, Schedule 8 or Schedule 9 poisons. In some cases, the extent of the authorisation is clear. In others, the extent of the authorisation is set by the approval of the Secretary.

Pursuant to regulation 6, the Secretary has approved the following:

Schedule 4 poisons approved for use by any optometrist

The Secretary has given approval in general for a registered **optometrist carrying on the lawful practice of his or her profession** to be in possession of, and administer, the following Schedule 4 poisons for use in the eyes of patients in the practice of his or her profession:

- **Anaesthetics Local** - being synthetic cocaine substitutes - when prepared and packed in the form of eye drops containing 0.5 per cent or less of such anaesthetics local;
- **Tropicamide** when prepared and packed in the form of eye drops containing 1 per cent or less of tropicamide;

- **Cyclopentolate hydrochloride** when prepared and packed in the form of eye drops containing 1 per cent or less of cyclopentolate hydrochloride;
- **Pilocarpine nitrate** when prepared and packed in the form of eye drops containing 2 per cent or less of pilocarpine nitrate; and
- **Physostigmine salicylate** when prepared and packed in the form of eye drops containing 0.5 per cent or less of physostigmine salicylate.

Note: Pursuant to section 13 of the *Drugs, Poisons and Controlled Substances Act 1981*, the Minister for Health has approved a list of Schedule 4 poisons, in preparations for topical use in the eye, for use by Optometrists endorsed under section 23 of the *Health Professions Registration Act 2005*. This list may be examined at the website for the Optometrists Registration Board of Victoria, which is linked to this site.

Schedule 4 poisons approved for use by any podiatrist

The Secretary has given approval in general for a **podiatrist carrying on the lawful practice of his or her profession** to be in possession of, and administer, the following Schedule 4 poisons in the practice of his or her profession for the treatment of conditions of the human foot:

- **Anaesthetics Local** - the following only - lignocaine hydrochloride in preparations containing 2 per cent or less of lignocaine hydrochloride;
- **Prilocaine hydrochloride** in preparations containing 2 per cent or less of prilocaine hydrochloride.

Schedule 4 poisons approved for use by an Australian Ski Patrol Association Inc. qualified ski patroller

The Secretary has given approval in general for an **Australian Ski Patrol Association Inc. qualified ski patroller** to be in possession of the following Schedule 4 Poisons and administer them to persons in the performance of his or her duties for the treatment of emergencies

- Methoxyflurane.

Schedule 4 poisons approved for use by dental hygienists or dental therapists (12 March 2008)

The Secretary has given approval in general for a **registered dental hygienist or registered dental therapist** to have in his or her possession the Schedule 4 poisons listed in Appendix 1 that are required for the provision of dental care by the registered dental hygienist or registered dental therapist.

Appendix 1

Adrenaline
 Articaine
 Demeclocycline and triamcinolone in combination for topical endodontic use
 Felypressin
 Lignocaine
 Mepivacaine
 Mercury (metallic) for human therapeutic use
 Prilocaine

Regulation 5(3)

The Secretary may approve the possession and administration of a Schedule 4, Schedule 8 or Schedule 9 poison by a **nurse or class of nurses** if the Secretary considers that the possession and administration—

- (a) is necessary for the provision of health services; and
- (b) is within the competence of a nurse to do so without the direct supervision of a medical practitioner, dentist, nurse practitioner or authorised optometrist (as the case requires).

Pursuant to regulation 5(3), the Secretary has approved the following:

A midwife

The Secretary has given approval in general for a nurse who is a midwife employed at a hospital to possess and administer to a pregnant woman in labour, in an emergency if unable to contact a medical practitioner, a single dose of morphine or pethidine if such practice is in accordance with the written instructions of the medical practitioner under whose care the patient is, provided that the practice has been approved by the governing body of the hospital concerned or a committee to which the responsibility has been delegated by the governing body.

Tuberculosis program

The Secretary has given approval in general for a nurse who is approved by the Manager, Communicable Diseases Section, in vaccine and skin testing administration and technique and as having satisfactorily completed a course in the management of acute reactions associated with vaccination, may possess and administer the Schedule 4 poisons:

1. BCG vaccination, for administration as recommended by the National Health and Medical Research Council.
2. Purified Protein Derivative (PPD) Human, for Tuberculin Skin Testing.
3. Such other Schedule 4 poisons as are necessary for the treatment of anaphylactic reactions to the vaccine and PPD.

under the following circumstances:

- a) the nurse is employed by the Department of Human Services, Tuberculosis Program.
- b) the Tuberculosis Program medical advisor or medical officer is available to provide advice to the nurse on the use of the Schedule 4 poisons.
- c) The nurse administers the Schedule 4 poisons in:
 - i. the performance of his/her duties with the Department of Human Services, Tuberculosis Program,
 - ii. accordance with the current edition of the National Health and Medical Research Council Immunisation Handbook, that is current at the time of the administration, and
 - iii. accordance with any guidelines issued by the Department of Human Services.

Vaccinations – (updated 10 May 2007)

A nurse registered in division 1 of the register of nurses established under the *Nurses Act 1993*, who in the preceding three years has satisfactorily completed a course of training accredited by the Nurses Board of Victoria in all aspects of vaccine administration, vaccination

technique and management of acute reactions, may possess and administer the Schedule 4 poisons:

1. vaccines listed in Appendix 1, and
2. such other Schedule 4 poisons as are necessary for the treatment of anaphylactic reactions to the vaccines,

under the following circumstances:

- a) the nurse is employed or contracted by:
 - i. a municipal council which employs or contracts a medical practitioner,
 - ii. a health services permit holder who employs or contracts a medical practitioner, or
 - iii. a medical practitioner,
- b) the medical practitioner referred in paragraph (a) is available to provide advice to the nurse on the use of the Schedule 4 poisons,
- c) the nurse possesses and administers only vaccines obtained by the municipal council, health services permit holder or medical practitioner by whom he or she is employed or contracted, and
- d) the nurse administers the Schedule 4 poisons in:
 - i. the performance of his or her duties with the municipal council, health services permit holder or medical practitioner (as the case requires),
 - ii. accordance with the edition of the Australian Immunisation Handbook that is current at the time of the administration, and
 - iii. accordance with any guidelines issued by Department of Human Services.

Appendix 1

Diphtheria
Haemophilus influenzae type B
Hepatitis A
Hepatitis B
Human papillomavirus
Influenza
Measles
Meningococcus
Mumps
Pertussis
Streptococcus pneumoniae
Polio
Rotavirus
Rubella
Tetanus
Varicella

Victorian Institute of Forensic Medicine - Forensic Nurse Examiner (updated 17 December 2008)

A nurse registered in division 1 of the register of nurses established under the *Health Professions Registration Act 2005* may possess and administer a single oral dose of the following Schedule 4 drug:

- azithromycin

under the following circumstances:

- a) the nurse is employed or contracted by Victorian Institute of Forensic Medicine (VIFM) to undertake forensic medical examinations;
- b) a medical practitioner employed or contracted by VIFM is available to provide advice to the nurse on the use of the Schedule 4 drug; and
- c) the nurse administers the Schedule 4 drug in:
 - i. the performance of his or her duties as a forensic nurse examiner
 - ii. a designated Centre Against Sexual Assault ⁽¹⁾ Crisis Care Unit providing services to adults
 - iii. accordance with a treatment protocol approved by VIFM, and
 - iv. accordance with any guideline issued by the Department of Human Services

(1) Designated Centres Against Sexual Assault are DHS funded services and are listed at: <http://www.office-for-children.vic.gov.au/family-violence-sexual-assault/library/casa>

Regulation 26

The Secretary has given approval in general for a person referred to in regulation 25 to issue computer-generated prescriptions under circumstances which satisfy the criteria set out below.

Note that as of 20 August 2009 for **drugs of dependence** it is no longer a criterion that only one item appears on a prescription.

Criteria for computer-generated prescriptions

1. The computer program will restrict access to the prescription-printing module to authorised persons.
2. Prescriptions will be generated only by authorised persons.
3. The prescription will be either printed with the prescriber's name, address and contact telephone number OR with the address and contact telephone number of the practice.
4. The prescription will be personalised to the prescriber by the addition at the time of printing of the name of the prescriber below the last prescribed item when the prescription is being generated.
5. The prescriber will sign, in his or her own handwriting, the prescription form beneath and as near as practicable to the last item prescribed on the form.
6. The prescription will not be pre-signed.
7. The total number of items prescribed on the prescription will be either stated on the prescription or the area on the prescription below the prescriber's signature will be scored, hatched or otherwise marked in some way to prevent any other item being printed in that area.
8. The particulars of any prescription issued will be included in the clinical or medication record of the person or animal for whom the prescription was generated.
9. The clinical or medication record of the person or animal for whom the prescription was issued will be preserved for at least one year from the date on which the prescription was generated and will be capable of being accessed when required.

10. Alterations will NOT be made to printed prescriptions. Where alteration is required a new printed prescription will be generated and the other prescription will be immediately destroyed.

Drugs of dependence

In addition, in the case of drugs of dependence (which includes all Schedule 8 poisons and some Schedule 4 poisons):

11. In addition to the printed particulars on the prescription, the prescriber will in his/her own handwriting write all of the particulars required under the Regulations (**other than** the date and the patient's or animal owner's name and address), namely:
- the name of the substance or the proprietary product containing it,
 - the strength where more than one strength is available,
 - the quantity being prescribed (in both words *and* figures),
 - adequate directions for use,
 - the number of repeats authorised (in both words *and* figures).

The software program will automatically indicate that such handwriting is required.

NOTE:

- A computer-generated prescription must comply with the requirements of regulations 26(3), 26(4), 26(5) and 26(6).
- As the criteria for computer-generated prescriptions may vary in different states, medical practitioners, veterinary practitioners, dentists, nurse practitioners and authorised optometrists are strongly advised to seek, prior to purchase, verification from the software supplier that their software enables compliance with the specified criteria.

Version: August 2009