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| Criteria for lawful prescriptions |
| Requirements in Victoria |
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# Introductory notes

The *Drugs Poisons and Controlled Substances Act 1981* (the Act) and the Drugs Poisons and Controlled Substances Regulations 2017 (the regulations) indicate who may possess Schedule 4 and 8 poisons; the extent to which possession is lawful; and the legislative requirements for use, storage, prescribing and supply of Schedule 4 and 8 poisons. Current versions of the Act and the regulations, which should be considered in concert and not in isolation, can be accessed at [Victorian Law Today](http://www.legislation.vic.gov.au/) <http://www.legislation.vic.gov.au/>.

This is one of a series of documents prepared by Medicines and Poisons Regulation (MPR) to assist multiple or specific categories of health practitioners to understand the more common legislative requirements. Refer to the [Medicines and poisons webpage](http://www.health.vic.gov.au/dpcs) <http://www.health.vic.gov.au/dpcs> on the Health.Vic website for other ‘Documents to print or download’ and for a link to the Poisons Standard, which contains details of poisons schedules plus labelling and packaging requirements.

# Drugs of dependence

In Victoria, the term ‘**drug of dependence**’ is used to describe substances, listed in Schedule 11 of the Act, which are known to be subject to misuse and trafficking. **Note**: The term is not limited to Schedule 8 poisons; some Schedule 4 poisons (e.g. benzodiazepines, pseudoephedrine, phentermine, testosterone and other anabolic steroids) are also classified as drugs of dependence. Whereas most regulations relate primarily to whether a drug is a Schedule 4 or Schedule 8 poison, regulatory requirements for prescriptions and prescribing are often stricter for Schedule 4 drugs of dependence than for other Schedule 4 medicines.

# Issuing prescriptions

An **original prescription** is a document that authorises a pharmacist to supply prescribed medicines; pharmacists are not authorised to supply on the basis of facsimiles or other scanned copies of prescriptions, except in emergency circumstances that are detailed in another document in this series, *‘Prescribing requirements for health practitioners’.*

Health practitioners are not authorised to prescribe a Schedule 3, Schedule 4 or Schedule 8 poison **merely** because a person requests a prescription.

Before issuing a prescription, a prescriber must take **all reasonable steps** toensure a **therapeutic need** exists and, before issuing a prescription for a **drug of dependence**, a prescriber must take all reasonable steps to **confirm the identity** of the patient. Issuing a prescription, merely because another prescriber has done so, is unlikely to satisfy these requirements.

# Handwritten prescriptions for Schedule 4 and 8 poisons

Regulation 24 specifies the required form of a prescription for Schedule 4 and Schedule 8 poisons; required components, which must be **in the prescriber’s own handwriting**, include:

* full details of the prescriber (i.e. name, address **and contact phone number**)
* the name and address of the patient
  + **Note**: The patient’s **date of birth** must also be included on each prescription when a **Schedule 8 poison** or a **Schedule 4 monitored poison** is prescribed
  + Veterinary practitioners must also include the species, age, breed and sex of the animal plus the name and address of the owner or person having the custody of the animal on the prescription
* full particulars of the medicine
* the quantity to be supplied
* precise directions for use except:
  + where complex directions are provided separately, in writing, or the medicine is to be administered by a registered health practitioner (e.g. injection to be administered by a nurse or medical practitioner)
  + where a variable dosage regimen is directed, in which case a statement specifying a maximum frequency of administration is to be included;
* the signature of the prescriber and the date on which the prescription was written

## Prescriptions for Schedule 8 poisons

In addition to the requirements for a prescription for a Schedule 4 poison, regulation 24 requires the following details on a prescription for a Schedule 8 poison:

* a statement of the quantity to be supplied, written in both words and figures; **and**
* a statement that:
  + there is to be no repeat supply, specified in words and not just figures; **or**
  + the number of times that the prescribed quantity may be supplied or repeated (written in words and figures)

# Alternatives to handwritten prescriptions

If a practitioner wishes to issue a prescription that is not handwritten, it must comply with the criteria, approved by the Secretary (of the Department of Health) for electronic prescriptions or computer-generated prescriptions, the latter of which must also include handwritten specified handwritten particulars when a Schedule 8 medicine or other drug of dependence is prescribed.

# Software

The Victorian Department of Health (DH) does **not** approve software for use by health practitioners; there is no legislative provision to do so. Accordingly, any claims by a software supplier, that the department has approved its software for use in Victoria, are not correct.

It is the responsibility of health practitioners to comply with the provisions of the Act and regulations and to ensure that any selected software enables them to do so. Therefore, it is advisable to seek confirmation, from prospective software suppliers, that software will enable the health practitioner to comply with the legislation **and** that following the provided operating instructions will ensure compliance with the legislation.

# Criteria for computer-generated prescriptions

Note: A ‘computer-generated prescription’ is a paper prescription that has been printed using computer software and includes handwritten requirements, as described below.

1. The Secretary has given approval, in general, for an authorised prescriber to issue computer-generated prescriptions under circumstances which satisfy the criteria set out below.
2. The computer program will restrict access to the prescription-printing module to authorised prescribers.
3. Prescriptions will be generated only by persons authorised to issue prescriptions.
4. 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.
5. 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.
6. 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.
7. The prescription will not be pre-signed.
8. 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.
9. 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.
10. 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.
11. **Alterations will not be made to printed prescriptions**. Where an alteration is required a new prescription will be generated and the initial prescription will be immediately destroyed.

## Additional requirements for drugs of dependence

1. 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 for Schedule 8 poisons)
       - the number of repeats authorised (in both words and figures)
       - adequate directions for use

* The software program will automatically indicate that such handwriting is required. (This will commonly be printed on the prescription or displayed as a message on the computer screen).

**Note:**

* A computer-generated prescription must also comply with the requirements of regulation 24.

### Handwritten components on computer-generated prescriptions

* In addition to Schedule 8 poisons, Victoria requires handwritten particulars of a computer-generated prescription for Schedule 4 drugs of dependence; including benzodiazepines, pseudoephedrine, phentermine (Duromine®), testosterone and other anabolic steroids. This is not the case in other states.
  + As requirements for computer-generated prescriptions may vary in different states. Health practitioners are strongly advised to seek, prior to purchase, verification from the software supplier that their software enables compliance with the specified criteria in Victoria. Examples have been identified in which practitioners have contravened the regulations by using software that is in common use in other states but which does not satisfy Victorian requirements.
* Stationery for computer-generated prescriptions is provided by Medicare Australia to satisfy the requirements of the Pharmaceutical Benefits Scheme. These documents include provision for two copies, which are identified as the PBS copy (which the pharmacist may need to submit to Medicare Australia) and the Patient/Pharmacist copy (which must be retained by the pharmacist or attached to a repeat authorisation form).
* To satisfy the requirements of the Pharmaceutical Benefits Scheme, a prescriber must sign both copies of the prescription.
* To satisfy Victorian regulations, additional handwritten components (as indicated above) are required on all computer-generated prescriptions for drugs of dependence.
  + These handwritten components are only required on the patient/pharmacist copy.
  + There is no requirement for a prescription to be provided in duplicate unless the prescription relates to a Pharmaceutical Benefits medicine.

# Criteria for electronic prescriptions

Note: An ‘electronic prescription’ is a paperless prescription. There are no handwritten requirements for an electronic prescription.

A person who issues an electronic prescription must comply with the Criteria for Electronic Prescriptions, listed below in addition to any requirements under the National Health (Pharmaceutical Benefits) Regulations 2017 (Commonwealth Regulations), the Drugs, Poisons and Controlled Substances Act 1981 and the Regulations.

1. The software used to issue or receive the prescription must be listed on the Register of Conformance by the Australian Digital Health Agency with a current conformance identifier; and must comply with the current version of the Australian Digital Health Agency Electronic Prescribing Participating Software Conformance Profile.
2. The digital prescription message for each prescription must include:
   * + the Healthcare Provider Identifier – Organisation (HPI-O) of the practice or organisation from which the prescription is issued (Electronic Prescribing Conformance Profile requirement PRES-18), and
     + the Healthcare Provider Identifier – Individual (HPI-I) (Electronic Prescribing Conformance Profile requirement PRES-19) or for an electronic prescription that is transmitted within a hospital a unique identifier that is managed and audited by that hospital, and
     + a unique prescription number (Electronic Prescribing Conformance Profile requirement PRES-18), and
     + the conformance identifier, except those electronic prescriptions that are transmitted within a hospital.
3. The electronic prescription must include information that confirms the identity of the authorised prescriber.
4. The software used to issue the prescription must:
   * + manage defined roles with access rights that will only allow authorised persons to issue or receive electronic prescriptions for all medications, and
     + display the prescription and obtain a final approval from the prescriber prior to issuing a prescription for electronic distribution, and
     + utilise Electronic Prescribing Conformance Profile requirements to protect against fraud.
5. The software audit requirements (Electronic Prescribing Conformance Profile requirements PRES-10, PRES-38, PRES-39) will be capable of being accessed when required and must be produced on demand to an authorised officer.
6. The electronic prescription must comply with other requirements of the Drugs, Poisons and Controlled Substances Regulations 2017.

# Prescription pads and pages

Prescription pads plus pages for computer-generated prescriptions are known to be misappropriated by patients (sometimes by other practitioners, staff members and family members) and used to create fraudulent prescriptions for drugs of dependence. These items should not be stored in unlocked areas or left in printers, where they might be subject to opportunistic theft.

## Loss or theft

For the loss or theft of prescription pads or prescription pages, health practitioners are requested to submit the ‘*Notification of lost and stolen prescriptions*’ form, which is available on the MPR website in the section for ‘*online forms*’.

## Other matters to be reported to MPR and/or police

For information about other matters to be reported and how to submit reports, please refer to the document ‘Possession and storage of Schedule 4 and 8 poisons’.

# For further information

## Department of Health (DH)

### Medicines and Poisons Regulation

50 Lonsdale Street

Melbourne, 3000

Fax: 1300 360 830

Email: dpcs@health.vic.gov.au

Web: www.health.vic.gov.au/dpcs

For queries relating to the Act or regulations, please:

* refer to the ‘Documents to print or download’ that are available on the MPR website (see below); or
* if you are unable to address your query by referring to those documents, please forward your query via e-mail to [dpcs@health.vic.gov.au](mailto:dpcs@health.vic.gov.au)

## Documents to print or download from the MPR website

The [Medicines and poisons webpage](http://www.health.vic.gov.au/dpcs) <http://www.health.vic.gov.au/dpcs> on the Health.Vic website in the section for ‘Documents to print or download’, contains summaries of legislative requirements that have been prepared in relation to issues that relate to multiple categories of health practitioner as well as to individual categories of health practitioner.

## Other possible sources of information

### Medicare Australia (Pharmaceutical Benefits Scheme)

* Web: [www.medicareaustralia.gov.au/provider/](http://www.medicareaustralia.gov.au/provider/)
* General inquiries - 132 290
* Authorities - 1800 888 333

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