New regulatory requirements
DPCS Regulations 2017
Prescribers and pharmacists
May 2017

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Explanatory notes
The legislation that defines lawful actions in relation to scheduled poisons is contained in the Drugs Poisons and Controlled Substances Act 1981 (the Act) and, when it takes effect on 23 May 2017, the Drugs Poisons and Controlled Substances Regulations 2017 (the 2017 Regulations). The regulations complement the Act by authorising actions that would otherwise be unlawful and define the outcomes required of lawful actions. For full details of legislative requirements, current versions of the Act and the regulations, which can be accessed at Victorian Law Today (www.legislation.vic.gov.au), should be considered in concert and not read in isolation. There is a link to the Poisons Standard, which contains details relating to poisons schedules plus labelling and packaging on the DPR website (at www2.health.vic.gov.au/dpcs).

This document has been prepared by Drugs and Poisons Regulation (DPR) to highlight key regulatory requirements that differ from those contained in the Drugs, Poisons and Controlled Substances Regulations (the 2006 Regulations).

Note: Although the structure of the 2017 Regulations differs significantly from the 2006 Regulations, there are relatively few changes that impose new requirements on registered health practitioners.

Documents relating to requirements for individual categories of practitioner will be located on the DPR website (at www2.health.vic.gov.au/dpcs).

Clarifying the meaning of key terms
In the 2006 Regulations, it was common to see references to registered health practitioners being able to prescribe, administer and supply scheduled poisons within the same regulation. This is not the case in the 2017
Regulations. The following explanations clarify the meaning of these and other terms that are used in the 2017 Regulations or that are in common use.

- **Administer** means to personally introduce a medication to a person’s body (or personally observe its introduction).
- **Supply** means to provide a medication to be administered at a later time.
- **Dispense** is a term that can have different meanings to different health practitioners; the terms administer and supply are preferred to minimise misunderstandings.
- **Prescribe** is a term that commonly relates to the action of a practitioner who authorises treatment that may be carried out by another person. The 2017 Regulations describe this action in accordance with the three different mechanisms by which the treatment may be authorised; to prescribe – meaning ‘issuing a prescription’, writing a chart instruction’ and ‘authorising administration’.

**Chart instructions and prescriptions**

‘Chart instructions’ can serve to authorise administration by other health practitioners (e.g. nurses) and to authorise pharmacists to supply medicines.

‘Prescriptions’ are documents that authorise pharmacists to supply medicines.

The terms ‘prescription’ and ‘chart instruction’ are defined or explained in regulations 5 – 6. The practitioners that can write chart instructions, within the meaning of the term in the 2017 Regulations, are authorised to do so in regulation 28 and regulation 29. Chart instructions are written on hospital medication charts and residential medication charts. Regulation 28(3) and regulation 29(2) make it clear that the 2017 Regulations do not preclude other matters being written on medication charts.

Provision for chart instructions was included to accommodate the Commonwealth National Health (Pharmaceutical Benefits) Regulations 2017. The Commonwealth regulations enable pharmacists to supply medicines under the Pharmaceutical Benefits Scheme (PBS). The 2017 Regulations do not limit the provisions to medicines that are listed on the PBS or to prescribers who are authorised to prescribe PBS items.

**Note:** A standard PBS Hospital medication chart was introduced nationally on 1 July 2016 to accompany the introduction of PBS claiming from an instruction on the chart. The 2017 Regulations will not preclude the use of an electronic PBS Hospital medication chart.

**Additional components for prescriptions**

Regulation 24 lists the required components of a prescription, including the following additional requirements.

- Where directions for the precise dose or frequency of administration cannot be included or a variable dosage regimen is directed (e.g. 1 to 2 tablets when necessary); the prescriber must include a statement specifying a maximum frequency of administration (e.g. not more than 4 tablets daily).
- Prescriptions from veterinary practitioners will be required to include additional information in relation to the identity of the animal (i.e. species, age, breed and sex).

**Prescriptions for Schedule 8 and Schedule 9 poisons**

Regulation 24 requires that prescriptions for Schedule 8 and Schedule 9 poisons contain the following additional information:

- The date of birth of the patient (not including an animal in the case of a veterinary prescription)
- A statement in words (not just figures) indicating that the drug is to be supplied on only one occasion (e.g. NIL repeats) unless repeats are authorised
How pharmacists might deal with non-compliant prescriptions

Note: This section is included to clarify a pharmacist's responsibilities in the event that a prescription does not contain all components required by the regulations.

It is the responsibility of the prescriber to comply with the regulatory requirements for the components of a prescription.

It is the responsibility of the pharmacist to accurately interpret the prescriber’s intentions and, in doing so, to ensure the prescribed medicine is safe and appropriate for administration by the patient.

A pharmacist who is presented with a prescription that does not contain every required component need not send the prescription back to the prescriber to have it amended. The steps that might be taken by a pharmacist are a matter of professional judgement; to be decided after considering relevant factors, for example:

- If it is necessary to confirm or clarify a prescriber’s intentions, it is often sufficient to communicate with the prescriber. In such cases, a contemporaneous note, in the form of a professional message in the dispensing records and/or an endorsement on the prescription (especially if repeat supplies are authorised), is strongly recommended.
- Sometimes the absence of a required component (e.g. a warrant number on a prescription for an ovulatory stimulant) could raise doubts about whether the medicine should have been prescribed by the noted prescriber and/or whether it is safe or appropriate to supply the prescribed medicine.
- Sometimes an omission will be trivial and the pharmacist will not need to contact the prescriber at all.

Pharmacists wishing to vary from instructions on a prescription

To address concerns that pharmacists have been supplying Schedule 4 and Schedule 8 poisons on prescriptions contrary to prescribers’ intentions, regulations 50 and 51 have been drafted to make it clear that such conduct represents a contravention of the regulations other than in the exceptional circumstances set out in regulation 53.

In summary, a pharmacist must not supply a Schedule 4 or Schedule 8 poison contrary to the instructions written on a prescription other than in accordance with the exceptional circumstances set out in regulation 53. Specific examples of the instructions that are not to be varied unless exceptional circumstances apply include:

- supplying a quantity that exceeds the quantity authorised for supply on the first occasion  
  – e.g. supplying multiple repeats when the prescriber has not endorsed the prescription
- providing a repeat supply before an interval specified in the prescription (if any) has elapsed
- if the prescription specifies that only a specific brand of the poison is to be supplied, supplying a different brand  
  – supplying a different brand when the prescriber has indicated that ‘brand substitution is not permitted’.

Exceptional circumstances

A pharmacist who believes it is necessary to vary from a prescription’s stated instructions in exceptional circumstances is required to take reasonable steps to obtain the prescriber’s consent first but, if unable to contact the prescriber-

- Where the variation is requested by or on behalf of the person named on the prescription, the pharmacist:
  – must be satisfied that not to vary from the prescription would impose an unreasonable difficulty or inconvenience on the patient; and
  – must take all reasonable steps to ensure that supplying the Schedule 4 or Schedule 8 poison as requested would not represent an unacceptable risk to the health and safety of the patient; and
  – must not supply a quantity that exceeds the quantity requested (if any)
- Where, at the time that the prescription is presented, it is not reasonably practicable for the pharmacist to comply with the instructions written on the prescription:
  – the pharmacist must take all reasonable steps to ensure that supplying the Schedule 4 or Schedule 8 poison as proposed would not represent an unacceptable risk to the health and safety of the patient; and
the patient must consent to the variation from the instructions.

**Recording**

Regulation 68 requires a pharmacist who varies from the instructions on a prescription without the consent of the prescriber to:

- inform the prescriber as soon as practicable after the supply; and
- make a record (i.e. in connection with the corresponding dispensing record) to confirm that the exceptional circumstances existed in relation to that supply.

**Producing prescriptions on demand**

The 2017 Regulations require a pharmacist to produce prescriptions for Schedule 4 poisons that are required to be retained in accordance with Commonwealth Regulations, on demand to an authorised officer (regulation 67). This new requirement is intended to ensure that prescriptions, which might be needed as evidentiary documents, can be readily obtained in a manner similar to the long-established requirement for the provision of prescriptions for Schedule 8 poisons.

**Labelling dispensed medicines**

Most components of a label on a container of a medicine supplied for the treatment of a specific person (or animal) are adopted by reference under section 27A of the Act. The Act defers to the labelling requirements of the Poisons Standard. Labelling of dispensed medicines, including warning statements and sedation warnings, is included in Section 1.5.6(1), Appendix K and Appendix L of the Poisons Standard. Accordingly, these provisions are not included in the Regulations.

The 2017 Regulations contain Supplementary labelling requirements (regulation 72). The regulation stipulates that the following components must be included, meaning in addition to the components that are required under the Act:

- the date of the making of a record of the sale or supply; and
- the directions for use unless—
  - the medicine is being sold or supplied by a pharmacist on a prescription and directions for use have not been included on the prescription; or
  - the dosage regimen or directions for use are so complex that the person supplying the poison has also supplied the patient with separate written instructions; or
  - the poison is being supplied for the purpose of it being administered by a registered health practitioner
- if the poison is for the treatment of an animal, the label must include—
  - the species, age, breed and sex of the animal; and
  - the name of the person who owns or has custody or care of the animal.

**Recording transactions in Schedule 8 poisons**

Whereas records of transactions in Schedule 8 poisons must be completed as soon as practicable after each transaction (regulation 108), the 2017 Regulations also allow the remaining balance of methadone or buprenorphine used for opioid-replacement therapy to be recorded in a Schedule 8 poisons register at least daily (regulation 109).

**Passwords**

Registered health practitioners must take all reasonable steps to ensure that personal access codes, for making electronic records for Schedule 8 poisons and Schedule 9 poisons, are not known or used by other persons (regulation 109).
Destruction of Schedule 8 poisons
To facilitate destruction of selected formulations of Schedule 8 poisons, regulation 115 now provides for the following formulations to be destroyed by a registered medical practitioner, veterinary practitioner, dentist, pharmacist, nurse or midwife without requiring a witness:

- the unused contents of a previously sterile container (e.g. ampoule) containing a Schedule 8 poison (or Schedule 9 poison) that are not required for administration to a patient
- the unused portion of a tablet or lozenge containing a Schedule 8 poison (or Schedule 9 poison) that is not required for administration to a patient.

Notification of loss or theft of poisons
The 2017 Regulations (regulation 152) require prescribers and pharmacists to notify both the Secretary (through DPR) and Victoria Police immediately they become aware of the loss or theft of a poison or controlled substance.

Veterinary practitioners
Accurately identifying an animal
Veterinary prescriptions and dispensing labels on containers must now include the species, age, breed and sex of the animal for which a medicine is prescribed or supplied.
Note: animal may include animals.

Bulk supplies
Regulation 43 allows for veterinary practitioners to order the supply of Schedule 4 poisons (i.e. in stock food) in bulk transport without labelling the container.

However, where multiple containers make up a bulk supply, the veterinary practitioner will need to label each container. The exception that existed in the 2006 Regulations (regulation 29(7)) has been removed.

The 2017 Regulations do not limit wholesale supplies of stock food to ‘flocks or herds’ of animals and allow such supplies to animals generally.

Orders for stock food manufacture
The 2017 Regulations specify the particulars to be included in a written order from a veterinary practitioner to a stock food manufacturer to manufacture and supply a Schedule 4 poison as part of a stock food preparation (regulation 27). The veterinary practitioner must retain a record of the order for three years.

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