

|  |
| --- |
| Refrigerated storage for Schedule 8 poisons  |
| Requirements in Victoria |
|  |

# 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.

# Security requirements for Schedule 8 medicines

Regulation 74(2) states that Schedule 8 poisons are to be stored in a lockable storage facility that provides **security** **at least equivalent** to a storage facility that is—

* + 1. constructed of mild steel plate of 10 mm thickness; and
		2. constructed with continuous welding of all edges; and
		3. fitted with a door constructed of mild steel plate of 10 mm thickness, swung on hinges welded to the door and body of the cabinet, the door being flush fitting with a clearance around the door of not more than 1·5 mm; and
		4. fitted with a fixed locking bar, welded to the inside face of the door near the hinge edge, which engages in a rebate when the door is closed; and
		5. fitted with a 6 lever lock securely affixed to the rear face of the door; and
		6. securely attached to a wall or floor in such a manner that it will resist attack by hand tools for 30 minutes or power tools for 5 minutes.
* This level of security is commonly achieved by a facility that is described, by knowledgeable tradespersons, as a ‘drug cabinet’.

## Storage that provides ‘at least equivalent’ security

It is possible that other storage facilities could achieve (or exceed) the level of security provided by a fixed drug cabinet; e.g. a large free-standing safe (350 kg mass) or a vault will commonly provide greater security.

**Note**: It is advisable to seek a written assessment from an independent, professional security advisor to confirm that any immediate storage facility, intended for Schedule 8 medicines, provides security that equates to or exceeds the parameters indicated in regulation 74(2).

# Refrigerated storage of Schedule 8 medicines

Providing refrigerated storage conditions (2° to 8° Celsius), in addition to adequate security for Schedule 8 medicines, can present a challenge.

This document provides clarification of requirements and a number of options that might facilitate compliance with both security and refrigerated storage requirements.

## Small refrigeration units within compliant safes or vaults

It is possible to place a small refrigeration device within a larger safe or vault, which provides adequate ventilation. For example:

* A ‘shoe-box’ sized refrigeration device, designed to hold pharmaceutical products, within a safe.
* A ‘bar-fridge’ sized refrigerator, designed to hold pharmaceutical products, within a vault.
	+ Many pharmaceutical wholesalers and larger hospital pharmacies already use this arrangement.

## Compliant storage that provides refrigeration

Some storage facilities for Schedule 8 medicines have been designed to provide refrigeration; these facilities include ventilation that ensure the adequate operation of refrigeration.

## Within certain health services

Regulation 74(3) allows larger health services (such as hospitals) and pharmacies (co-located with hospitals) to use electronic storage and recording equipment to provide additional security (to achieve security ‘at least equivalent’) when the immediate storage facility for Schedule 8 medicines is less physically resistant than a drug cabinet or a large safe.

Sub-regulation 74(3)(c) requires such storage facilities to incorporate staff access restrictions, notices of discrepancies and/or forced entry, audible alerts or more. Examples of storage facilities that may satisfy these requirements include Pyxis® Medstations and Omnicell® products.

Establishments of this kind could potentially install refrigerated storage facilities with similar properties.

# Other circumstances

## Long acting injectable buprenorphine (LAIB) products

LAIB products are Schedule 8 medicines that have entered the market in recent years as an innovative treatment for opioid-dependence. These products do not necessarily require refrigeration; for example, the following information was obtained from the Therapeutic Goods Administration in March 2021.

* Buvidal® modified release solution for injection.
	+ Buvidal® products do not require refrigeration.
* Sublocade® modified release solution for injection.
	+ Sublocade® products should normally be refrigerated
	+ However the registered product information for these products also states that “once outside the refrigerator this product may be stored in its original packaging at room temperature (below 25°C) for up to 28 days prior to administration.”

**Note**: Reference should be made to the product information that pertains to the relevant batch or formulation to ensure that appropriate storage conditions are provided.

## Consideration of ‘same-day collection’

It **might** be possible to overcome the need to provide refrigerated storage for a Schedule 8 medicine by arranging for the medicine to be obtained from a supplier and delivered (or administered) to a patient on the same day.

However, if considering such arrangements, one would need to consider:

* the storage conditions (i.e. temperature) of the medicine during transit;
* the need to transport the Schedule 8 medicine in a lockable receptacle; regulation 74(6);
* whether suitably secure, temperature-controlled storage is available if the Schedule 8 medicine is not promptly delivered from the supplier to the recipient;
* what happens if the patient does not attend the pharmacy or clinic as originally planned?

# Possible exceptions

The regulations allow for a less physically-resistant storage facility to be used to store a limited number of Schedule 8 medicines, in the circumstances indicated below. Conceivably, compliance could be achieved by having a lockable refrigerator or a refrigerator with an internal lockable compartment, possibly within a lockable room – provided all conditions of the noted circumstances are applicable.

## Six divided doses – for emergency use only

Regulation 74(7) allows some health practitioners and organisations to possess Schedule 8 medicines) to store Schedule 8 medicines within a less physically-resistant, lockable storage facility – **provided:**

* **the total number of doses does not exceed six**; and
* the Schedule 8 medicines are demonstrably **for emergency use only**
* the facility is used only for the of Schedule 8 and Schedule 9 poisons plus drugs of dependence.

**Note**: Whilst this provision could be applicable to a medical practitioner, pharmacist, veterinary practitioner, dentist, nurse practitioner, authorised midwife or the holder of a licence or permit (e.g. Health Services Permit); it should be noted that the provision could only be applicable if the Schedule 8 medicine could be required for emergency use (i.e. where any delay in accessing the medicine might represent undue suffering or a risk to the life or wellbeing of a patient.

## Aged care services

Regulation 75 allows approved providers of aged care services to store Schedule 8 medicines (dispensed and supplied for specific residents), within a lockable room or in a lockable storage facility that is firmly fixed to the floor or wall – **provided** the Schedule 8 medicines have been lawfully dispensed and supplied for administration to a specific resident.

* In such circumstances, any dispensed and supplied Schedule 8 medicines would need to be retained in the original container, labelled with the name of the specific resident (i.e. by the pharmacy at which the corresponding prescription was dispensed).

# For further information

## Department of Health (DH)

### Medicines and Poisons Regulation

GPO Box 4057

Melbourne 3001

Fax: 1300 360 830

Email: dpcs@health.vic.gov.au

Web: www2.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 page 7); 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) and indicate, in the ‘Subject’ field, that your query is to be directed to:
	+ The Health Practitioner Compliance team – for matters relating to compliance by medical practitioners, veterinary practitioners, dentists and pharmacists.
	+ The Licence and Permit team – for matters relating to Health Services Permit holders (e.g. hospitals) and licence holders.

## 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.

|  |
| --- |
| To receive this document in another format, phone 1300 364 545, using the National Relay Service 13 36 77 if required, or email dpcs@health.vic.gov.auAuthorised and published by the Victorian Government, 1 Treasury Place, Melbourne.© State of Victoria, Australia, Department of Health, October 2023. |