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# Pharmacy Registration Board of Western Australia

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## GUIDELINES FOR SAFE STORAGE OF MEDICINES IN PHARMACIES

### TOPICS

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Requirements for storage areas of scheduled medicines

Pharmacy only and pharmacist only medicines

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### **BACKGROUND TO GUIDELINES**

The Pharmacy Registration Board of Western Australia (the Board) has produced these Guidelines in the interest of public safety and to assist -

- proprietors of pharmacy businesses,
  - pharmacists with overall responsibility for the pharmacy business carried on at the pharmacy (Responsible Pharmacists), and
  - pharmacists with a proprietary interest in pharmacy businesses,
- collectively the Principals, to understand the Board's view of their responsibilities under the *Pharmacy Act 2010* and the *Pharmacy Regulations 2010* in relation to the safe storage of medicines in pharmacy premises (pharmacies).

The Board's view is the Principals must ensure:

- all scheduled medicines in pharmacies are stored safely in accordance with all relevant legislation;
- all medicines in pharmacies are stored safely in accordance with their recommended storage conditions;
- all returned and unwanted medicines are placed in appropriate containers stored safely in pharmacies and out of reach of the public; and
- all returned and unwanted medicines are disposed of safely to avoid accidental poisoning, misuse and toxic release into the environment.

## **PREMISES**

Regulation 15 of the *Pharmacy Regulations 2010* prescribes –

The pharmacist with overall responsibility for a pharmacy is to ensure that:

- the pharmacy is well lit, adequately ventilated and is air conditioned; and
- the pharmacy and all fixtures and fittings in the pharmacy are maintained in a safe, clean and hygienic condition and in good repair.

Penalty: a fine of \$1 000.

The Board's view is:

- the intent of this regulation is to ensure the premises supports the storage of medicines at room temperature, typically below 25°C; and
- in order to comply with the intent of this regulation, Responsible Pharmacists must –
  - develop and implement procedures, policies and protocols to ensure such medicines are safely stored on the premises in a clean, dry, well lit environment at a temperature below 25°C,
  - install air conditioning equipment capable of maintaining all such storage areas at a temperature below 25°C,
  - routinely monitor and control the temperature of such storage areas to ensure such medicines are stored below 25°C, and
  - maintain and retain documentation to support the storage of -
    - all medicines in accordance with their recommended storage conditions, and
    - all scheduled medicines in accordance with all relevant legislation.

## REFRIGERATOR

*Schedule 1 of the Pharmacy Regulations 2010* prescribes the minimum standards of fitness for the competent and safe practice of pharmacy (**the Minimum Standards**) and includes a requirement for the premises to be equipped with a refrigerator.

The Board's view is:

- the intent of this requirement is to ensure the premises is equipped with a refrigerator that supports the storage of the majority of temperature sensitive medicines between 2°C and 8°C<sup>1</sup>; and
- in order to comply with the intent of this requirement, the Principals must –
  - develop and implement procedures, policies and protocols to manage cold chain storage of such medicines and ensure they are safely stored on the premises in a clean refrigerator at a temperature between 2°C and 8°C,
  - appropriately install a refrigerator, designed to maintain a temperature between 2°C and 8°C, of a size that meets the requirements of the pharmacy business,
  - routinely monitor the temperature of the refrigerator to ensure any malfunction is identified in a timely manner, and
  - be able to provide documentation to support the storage of such medicines at a temperature between 2°C and 8°C.

1. [Australian Government, Department of Health, National Vaccine Storage Guidelines, Strive for 5](#)

## REQUIREMENTS FOR STORAGE AREAS FOR SCHEDULED MEDICINES

The [Medicines and Poisons Regulation Branch](#) at the Department of Health WA requires all scheduled medicines and poisons to be stored:

- out of direct access to the public; and
- out of direct access to children; and
- separately from foodstuffs or beverages.

The Board reminds the Principals to:

- ensure all scheduled medicines in pharmacies – including those delivered, dispensed, compounded, packed in dose administration aids, returned and unwanted - are stored safely in accordance with these requirements;
- develop and implement procedures, policies and protocols to support the safe storage of all scheduled medicines;
- develop and implement procedures, policies and protocols to support appropriate supervision of all storage areas for all scheduled medicines, including where a pharmacist may be unavailable for a short period of time – such as participation in a consultation, involvement in an activity within an area of the

pharmacy that does not provide vision of such storage areas or on a comfort break; and

- ensure all employees adhere to procedures, policies and protocols implemented to support the safe storage of scheduled medicines and the appropriate supervision of their storage areas.

## **PHARMACY ONLY AND PHARMACIST ONLY MEDICINES**

Regulation 86 & Regulation 87 of the *Medicines and Poisons Regulations 2016* prescribes the storage requirements for S2 medicines and S3 medicines respectively.

Regulation 86(2) prescribes -

A medicine that is a Schedule 2 poison that is stored for supply by retail sale must be stored:

- a. in premises specified in a Schedule 2 retail licence or in a pharmacy; and
- b. in an area or in a manner that prevents physical access to the medicine by any person other than a person who is employed in the pharmacy or employed by the licensee.

Regulation 87 of the *Medicines and Poisons Regulations 2016* prescribes the storage requirements for S3 medicines.

Regulation 87(1) prescribes -

A medicine that is a Schedule 3 poison that is stored for supply by retail sale must be stored:

- a. in a pharmacy; and
- b. in an area or in a manner that prevents physical access to the medicine by any person other than a person who is employed in the pharmacy.

The Medicines and Poisons Regulation Branch requires:

- S2 medicines to be stored behind the counter; and
- S3 medicines to be stored to prevent any physical access by the public, for example, behind the counter.

## **RECOMMENDATIONS FOR THE SAFE STORAGE OF PHARMACY ONLY AND PHARMACIST ONLY MEDICINES IN PHARMACIES**

Background

The Board:

- recognises pharmacy only and pharmacist only medicines (Medicines) are commonly stored behind barriers instead of counters;
- considers the suitability of all situations on a case by case basis; and

- makes the following recommendations to assist the Principals to understand its view of their responsibilities in relation to the storage of Medicines in pharmacies.

#### Behind the counter

Where Medicines are stored on shelving located behind a counter and there:

- is potential for the public to enter or reach into this area, the Board recommends storage commences at least one metre in from the end of the counter; and
- is no potential for the public to reach into this area, the Board accepts storage up to the end of the counter.

#### Mobile barrier fixed to a counter or wall

- GATE

Where Medicines are stored on shelving behind a gate, the GATE must:

- be constructed of a rigid material - such as melamine, perspex, safety glass, timber or fine mesh; and
- be secured to a permanent structure, such as a wall, the floor or a counter, or inserted into a rigid and solid frame secured to a permanent structure.

The Board considers the other aspects of a gate – such as height, width and opening – on a case by case basis.

Where Medicines are stored on shelving located behind a GATE and there:

- is potential for the public to reach into this area, the Board recommends storage commences at least one metre in from the gate; and
- is no potential for the public to reach into this area, the Board accepts storage up to the gate.

#### Immobile barrier fixed to the floor

- FENCE

Where Medicines are stored on shelving behind a fence, the FENCE must:

- be constructed of a rigid material - such as melamine, perspex, safety glass, timber or fine mesh;
- be secured to the floor or inserted into a rigid frame secured the floor;
- have a maximum clearance of 150mm from the floor;
- be at least 900mm high;
- be located at least 1000mm from all shelving on which pharmacy only and pharmacist only medicines are stored; and
- must not include rope, cord or Tensabarrier® style material.

Immobile barrier fixed to a wall

- FIN

Where Medicines are stored on shelving adjacent to a fin, the FIN must:

- be constructed of a rigid material - such as perspex, safety glass, timber or fine mesh; and
- be secured to a permanent structure, such as a wall, the floor or a counter, or inserted into a rigid and solid frame secured to a permanent structure.

The Board considers the other aspects of a fin – such as height and width – on a case by case basis.

Where Medicines are stored on shelving adjacent to a FIN and there:

- is potential for the public to reach into this area, the Board recommends storage commences at least one metre in from the fin; and
- is no potential for the public to reach into this area, the Board accepts storage up to the fin.

## **RESTRICTED PHARMACIST ONLY MEDICINES**

Regulation 87 of the *Medicines and Poisons Regulations 2016* prescribes the storage requirements for S3 medicines.

Regulation 87(2) prescribes –

A restricted Schedule 3 poison must not be stored in any part of the retail area of a pharmacy.

The Medicines and Poisons Regulation Branch requires S3R medicines to be stored in the dispensary away from any retail area of the pharmacy.

## **PRESCRIPTION ONLY MEDICINES**

Regulation 90(1) prescribes -

A medicine that is a Schedule 4 poison must be stored for supply by retail sale:

- a. in a pharmacy; and
- b. in an area or in a manner that prevents physical access to the medicine by any person other than a person who is employed in the pharmacy.

The Medicines and Poisons Regulation Branch requires S4 medicines to be stored in the dispensary, to prevent physical access by the public.

## **CONTROLLED PRESCRIPTION DRUGS**

Regulation 96 of the *Medicines and Poisons Regulations 2016* prescribes the storage requirements for S8 medicines in a pharmacy or the pharmacy department of a hospital.

Regulation 96 prescribes -

A medicine that is a Schedule 8 poison stored in a pharmacy or the pharmacy department of a hospital must be stored:

- a. in a secure cabinet access to which is supervised at all times by a pharmacist; or
- b. in a large safe with a detection device; or
- c. in accordance with an approved alternative storage arrangement.

A pharmacist who is supervising access to a secure cabinet in which a medicine that is a Schedule 8 poison is stored must:

- a. if access to the secure cabinet is by use of a key, keep immediate and personal possession of the key; or
- b. if access to the secure cabinet is by way of an access code, take all reasonable measures to ensure that the access code is not given to any other person.

Regulation 94 defines the following terms –

**secure cabinet** means a cupboard or drawer that:

- a. is made from hardwood or metal; and
- b. is lockable; and
- c. is securely fixed to a floor or wall; and
- d. is kept locked at all times except when items are being placed in or removed from it.

**large safe** means a safe:

- a. that —
  - i. is determined in accordance with AS/NZS 3809:1998 to have a resistance grading of at least II; or
  - ii. complies with the requirements for a large safe set out in the Table to Schedule 3 clause 2 of these regulations; and
- b. that is kept locked at all times except when items are being placed in or removed from it; and
- c. that is located in an area that is not accessible by members of the public.

**detection device**, in relation to a safe or strongroom, means a continuously monitored system —

- a. to detect the presence of a person who interferes, or attempts to interfere, with a safe or strongroom or any security measures associated with the safe or strongroom; and
- b. that complies with the requirements in AS 2201.3-1991 *Intruder alarm systems, Part 3: Detection devices for internal use* published by Standards Australia.

**approved alternative storage arrangement** means an arrangement approved by the CEO under regulation 102.

The Medicines and Poisons Regulation Branch requires all Schedule 8 medicines to be stored in approved drug safes at all times and provides information regarding the type of safe required for the storage of S8 medicines in pharmacies.

To access this information:

- go to the [Medicines and Poisons Regulation Branch website](#);
- open Health professionals;
- expand Storage, transport and disposal;
- open Storage of Schedule 8 medicines; and
- open **What type of safe is required**.

## **RETURNED AND UNWANTED MEDICINES**

The Return Unwanted Medicines Project (**the RUM Project**):

- manages and removes unwanted and out-of-date medicines from the community using community pharmacies as collection points; and
- provides protocols for the collection of such medicines at community pharmacies.

To access the Pharmacy Protocol for Western Australia:

- go to the [RUM Project website](#);
- click on “Pharmacists” at the bottom left of the webpage;
- scroll down to “See the Collection Protocol”; and
- click on “WA”.