Queensland Health

Storage and record-keeping requirements for S8 medicines

Introduction

The *Medicines and Poisons Act 2019* (MP Act), the Medicines and Poisons (Medicines) Regulation 2021 (MPMR) and associated legislative instruments commenced on 27 September 2021.

Together, this new suite of legislation defines the lawful actions in relation to medicines (schedule 2 (S2), 3 (S3), 4 (S4) and 8 (S8)) of the Poisons Standard[1]) for therapeutic use in Queensland.

The legislation and associated legislative instruments (including departmental standards and extended practice authorities) can be accessed from the Queensland Health site *Legislation, standards and extended practice authorities*.

Scope

The safe and secure storage and handling of all medicines is essential to ensure public health and safety. The illicit value of Schedule 8 (S8) medicines makes the risk of diversion significant, requiring sound physical and procedural security arrangements to be in place.

This document summarises the requirements for storage and record-keeping for S8 medicines, set out in the MP Act and MPMR, to assist health practitioners, veterinary surgeons and other persons who are authorised to possess S8 medicines in healthcare settings, to understand and implement appropriate security arrangements.

S8 medicines that are obtained by patients pursuant to a prescription and are stored at a patient's own home, or are stored elsewhere temporarily by an agent, are not within the scope of this guidance document

While the storage and record-keeping requirements in the MP Act and MPMR apply to medicines manufacturers and wholesalers, the storage of S8 medicines by these entities is not directly within the scope of this document. Medicines manufacturers and wholesalers should refer to the Australian Code of Good Wholesaling Practice for medicines in schedules 2,3,4 & 8 for requirements specific to this sector, in addition to the relevant sections of the MPMR.

[1] The Standard for Uniform Scheduling of Medicines and Poisons that details the schedules for medicines and poisons and packaging and labelling requirements - The Poisons Standard (the SUSMP) | Therapeutic Goods Administration (TGA).

Storage of S8 medicines

Physical storage arrangements that prevent unauthorised access to S8 medicines are important measures in ensuring the security of these medicines.

S8 medicines (both stock and waste prior to disposal) must be stored in a lockable medicine store (an S8 safe) that meets the requirements of the Departmental Standard: Secure storage of S8 medicines (MPMR section 197).

The Standard describes the outcomes to be achieved by, and minimum requirements for, S8 safes. It presents options for what would be an acceptable S8 safe in defined circumstances, commensurate with the relative risks associated with storing S8 medicines at that place. Considerations include, for example, the quantity of medicines and the strength of intruder resistance mechanisms that are present in the building envelope. This approach allows entities to adapt to local situations and to adopt emerging technologies.

Records of dealings with S8 medicines

Accurate records of dealings with S8 medicines are important because they provide an audit trail for tracking the movement of these medicines from one location to another, facilitating the ready detection of diversion.

Medicine register

A ***medicine register***, for an S8 safe, is a document that states—

a) when each type of medicine is put in, or taken from, the safe for a dealing; and

b) the amount of the type of medicine in the safe at any given time.

A separate medicine register must be kept for each safe. The register must be laid out according to MPMR section 207 and be consistent with the requirements in MPMR section 208 for an electronic register or section 209 for a paper register.

How long are records in a medicine register required to be kept?

A paper medicine register must be kept for 2 years from the date of the last entry made in the register.

A record made in an electronic medicine register must be kept for 2 years from the date the record is made.

TIP: Each entry in a medicine register must state the actual amount of each type of medicine remaining in the safe so there should not be a 'negative balance' in a register. When only a portion of a prescribed quantity is supplied, the portion supplied must be recorded, with the remaining quantity to be recorded in a subsequent, corresponding entry.

Roles and responsibilities at places where S8 medicines are stored

Safe manager and safe establisher

There must be clear lines of responsibility for S8 medicines that are stored at a place. The MPMR introduces the concept of a 'safe establisher', 'safe manager' and 'authorised user' and assigns defined functions to these roles.

At a place where a single person is in possession of S8 medicines (i.e. they are the only person who has access to the S8 safe), that person is an authorised user and is responsible for performing the functions of the *safe establisher* and the *safe manager*.

At a place where more than one person will be accessing stored S8 medicines, the person with overall accountability for the place must appoint, in writing: an appropriately qualified person to be the *safe establisher*; and an appropriately qualified person to be the *safe manager*. The 'person' may be either a named individual or an organisational position that is occupied by a single person.

What does appropriately qualified mean?

Appropriately qualified, for a function or power, means having the qualifications, experience or standing appropriate to perform the function or exercise the power[2].

For the person who is appointed as the **safe establisher,** this means having sufficient seniority, means, skills and knowledge to:

- establish an S8 safe at the place in a way that complies with the departmental standard: Secure storage of S8 medicines; and
- ensure the S8 safe is established and maintained in a way that keeps the medicines in the safe in accordance with the manufacturer's conditions for the medicines; and
- give access to an authorised user of the S8 safe.

For the person who is appointed as the **safe manager**, this means having the skills and knowledge to:

- make and keep a register for an S8 safe that complies with the requirements in sections 207 - 210 of the MPMR; and
- reconcile the register for the S8 safe, at least monthly, against the medicines physically held in the safe and make a record, in the medicine register, that this reconciliation was done (MPMR section 217); and
- report the loss, theft, or destruction of a medicine register for an S8 safe to the chief executive[3] (MPMR section 218).

[2] Defined in the Acts Interpretation Act 1954.

[3] The chief executive of Queensland Health.

Authorised users and assistants

A person who is authorised to deal with a medicine (other than a person who is an assistant as defined below) is, for the purposes of storing S8 medicines, termed an *authorised user*.

An assistant, for possessing a medicine, means a person who is authorised to possess the medicine only under the supervision of another person. For example, pharmacy assistants are authorised to possess S4 and S8 medicines under the supervision of a pharmacist (see Part 2 of Schedule 9 of the MPMR).

Access to an S8 safe

Any device or information (e.g. code, identification number, password) that allows access to an S8 safe, must be strictly controlled to prevent unauthorised access. Penalties apply to authorised users who do not keep a device or information, that they use to access an S8 safe, secure (MPMR section 201).

An authorised user who is supervising an assistant may give the assistant the user's device for accessing an S8 safe (e.g. a key) only if:

a) the device operates solely as a key to open and close the S8 safe, without an additional code or password; and

b) the user gets the device back from the assistant immediately after the assistant uses it.

An S8 safe should only be opened to carry out an essential dealing or function in connection with S8 medicine or waste (e.g. to administer or supply an S8 medicine or to reconcile a register). Authorised users and assistants must close and lock the safe when they are no longer using it.

Recording dealings with S8 medicines in the medicine register

An authorised user or assistant who accesses an S8 safe to deal with an S8 medicine must, as soon as practicable, but no later than 24 hours after the dealing, ensure a record containing the information specified in sections 212 and 213 of the MPMR is made in the medicine register for the safe. **Appendix 1** in this fact sheet has examples, demonstrating the minimum requirements required in a medicine register for common S8 medicine dealings as specified in sections 212 and 213 of the MPMR.

The authorised user (who dealt with the medicine or supervised an assistant dealing with the medicine) must sign the entry. Note. ***Sign*** or ***signature*** includes using initials or signing in an electronic form.

If an authorised user is given a secure system identifier by a safe manager to make an entry in an electronic register, they must take all reasonable steps to keep the identifier secure.

A person may not cancel, delete or obscure an entry in a medicine register but may correct an entry by making a record, of the following information, with the entry -

a) the date the correction is made;

b) the name and position of the person making the correction;

c) the reason for the correction;

d) if the correction relates to the disposal of waste from an S8 medicine by destruction—the name and position of the person who witnessed the destruction of the medicine.

What is the role of a substance management plan?

The responsible person at a place that is required to have a substance management plan (see Schedule 17 of the MPMR) must make a plan by 27 September 2022. It should contain up-to-date policies and procedures that comply with the MPMR covering the management of S8 medicines, such as (but not exclusively) the:

- security, including who can access an S8 safe
- ordering and receipt of medicines
- record-keeping, including register reconciliation requirements
- destroying and disposal, including any witness requirements
- distribution between care settings /wards
- investigation and reporting of discrepancies and other concerns.

A person stated in a substance management plan for a place must comply with the plan unless the person has a reasonable excuse.

Witnessing and recording the destruction of S8 medicines

Health practitioners who destroy S8 medicine waste are required by the MPMR to make a record of the destruction, including the name, signature and authority of the person who witnessed the destruction. This requirement does not apply to the destruction of portions of S8 medicines that are not required for administration, however, local policies (including a substance management plan) may apply a record-keeping and/or witnessing requirement to the destruction of these.

Further detailed instructions for destroying S8 medicine waste are contained in *Disposal and destruction of diversion-risk medicine waste*.

Separate page for recording returned S8 medicines

It is recommended to either use a separate register or designated page/s of the register to record 'S8 medicines for destruction' depending on the amount of medicine waste. This is helpful when accounting for returned or expired S8 medicines.

Reconciliation of medicine register

The safe manager must reconcile the actual stock on hand of S8 medicines and waste with the medicine register. This reconciliation must be performed at least monthly but may be carried out more frequently, as determined by risk assessment, to ensure the timely detection of discrepancies.

The safe manager must promptly investigate all discrepancies and report any that remain unresolved to Queensland Health.

For further information

Contact Healthcare Approvals and Regulation Unit

HARU@health.qld.gov.au

Appendix 1

Examples of minimum requirements required in a medicine register for common S8 medicine dealings

Example of medicine register requirements where an S8 medicine is administered (not under a general approval)

Date	Dealing	Address[4]	Prescriber	Qty in	Qty out	Balance	Unique identifier[5]	Sign	Notes[6]
04/03/22	Jane Doe	Bed 1, Ward A	-	-	1	197	12.30pm	CT	MM

Example of medicine register requirements where an S8 medicine is dispensed or given a treatment dose of on a prescription

Date	Dealing	Address	Prescriber	Qty in	Qty out	Balance	Unique identifier	Sign	Notes
04/03/22	Jane Doe	125 Smith street, Brisbane	Dr Peters	-	28	56	abc123	PT	-

Example of medicine register requirements where an S8 medicine is purchased from a supplier

Date	Dealing	Address	Prescriber	Qty in	Qty out	Balance	Unique identifier	Sign	Notes
04/03/22	Received from Supplier A	46 David Street, Brisbane	-	28	-	56	123456	PT	-

[4] Address refers to previous or future place of custody

[5] Unique identifier can be administration time, prescription reference number, purchase number or invoice number.

[6] Notes relate to countersigning if required or comments on dealings

Example of medicine register requirements where an S8 medicine is distributed out to a ward

Date	Dealing	Address	Prescriber	Qty in	Qty out	Balance	Unique identifier	Sign	Notes
04/03/22	Stock transfer	Ward A, Level 9	-	-	28	56	123456	PT	KC

Example of medicine register requirements where an S8 medicine is destroyed

Date	Dealing	Address	Prescriber	Qty in	Qty out	Balance	Unique identifier	Sign	Notes
04/03/22	Destruction	-	-	-	28	Nil	-	PT P Thomson (BPharm)	KC K Charles (BPharm)

Example of medicine register requirements where an S8 medicine is reconciled

Date	Dealing	Address	Prescriber	Qty in	Qty out	Balance	Unique identifier	Sign	Notes
04/03/22	Stock check	-	-	-	-	56	-	PT	-