Government of Western Australia
Department of Health

Guideline on oral liquid Schedule 4 Restricted and Schedule 8 medicines

1. Background

Schedule 8 (S8) and some higher-risk Schedule 4 medicines (designated as Schedule 4 Restricted, S4R) may be targeted for unauthorised use, abuse or diversion into illicit activities. Suitable controls are required to minimise the risk of misappropriation and theft. This includes reporting requirements for unexplained stock discrepancies and losses.

The Medicines and Poisons Regulations 2016 include specific requirements for the storage of and record keeping associated with both Schedule 8 and Schedule 4 medicines.

Multiple dose bottles of oral liquid medicines require individual measurement of each dose and are therefore subject to minor, but unavoidable, measurement errors. Liquid oral medicines are acknowledged to present extra challenges when recording and reporting discrepancies of Schedule 8 and Schedule 4 Restricted medicines.

MP 0139/20 *Medicines Handling Policy* includes a requirement for public health service facilities to have a policy for managing S8 and S4R oral liquid medicines.

This guidance document provides information to support adequate practices in the storage, measurement and record keeping of Schedule 8 and Schedule 4 Restricted oral liquid medicines.

This Guideline is intended to be read in conjunction with MP 0139/20 *Medicines Handling Policy*. The Guideline is not intended to be used as a substitute for compliance with legislation, Policy Frameworks or the policies and procedures of health service providers (HSP).

2. Stockholdings and Supplies

Only the minimum stock holding of S8 and S4R oral liquids required for current usage should be held in clinical areas.

Where containers of S8 and S4R oral liquid medicines contain multiple doses, only one container of liquid should be in use at any one time. For multiple dose containers, new stock should only be supplied to clinical areas as needed; as soon as practicable prior to the exhaustion of any existing stock whilst maintaining sufficient stock for patient requirements.

Any stock of S8 and S4R oral liquid medicines no longer required should to be transferred back to pharmacy at the earliest opportunity. A stock inventory should be performed at the time of transfer. See Section 5 for Guidelines on managing any suspected discrepancy identified at transfer.

2.1 Repackaging into smaller multiple dose containers

Repackaging into smaller multiple dose bottles, for use within public health service facilities, is discouraged. Although using a smaller multiple dose container may reduce the risk of accumulation of measurement errors, it may introduce other errors, such as incorrect product selection, due to removal of the manufacturer's original labelling and packaging. The use of smaller multiple dose bottles may also encourage the concurrent use of multiple bottles, which may in turn increase the risk of discrepancies. Smaller bottles may also be more easily diverted.

2.1.1 Repackaging into single use containers

Any repackaging should only be into single use containers. The preferred type of single use container is a unit dose pod, which is labelled in a manner that distinguishes each individual product and which is packaged in a way that allows unused/unopened pods to be readily distinguished from used/opened pods. Ideally, the amount contained in a single use container should be the dose to be administered to the patient. Any remaining content in a single use container after the dose has been administered to the patient must be discarded in accordance with standard practice for other S8 discards.

Single use containers should be recorded separately to multiple dose containers. Rather than recording total volume, the number of single use containers of each type can be recorded.

2.1.2 Doses for treating patients with Opioid Substitution Therapy (OST)

Due to the risk of dosing errors and consequent overdose, methadone oral liquid for opioid pharmacotherapy should be repackaged into unit doses by the Pharmacy Department and labelled for the individual patient, or if required due to logistics, by a community pharmacy participating in the Community Program for Opioid Pharmacotherapy (CPOP)[1].

Alternatively, unit dose pods can be used (see Section 2.1.1 above). However, unit dose pods are only suitable for methadone oral liquid for opioid pharmacotherapy, where the exact dose for the individual patient can be obtained from the contents of one or more whole unit dose pods. Unit dose pods are unsuitable for OST dosing if part pods would need to be used to obtain the correct dose, as the risk of dosing errors and consequent overdose is considered too high.

All doses of methadone oral liquid for OST use, including unit dose pods, should to be labelled for individual patient use with the patient's name, the dose to be administered, the day/date the dose is to be administered and that the dose is intended for use as OST, as it is critical that OST dosing only be administered under supervision.

Patient care areas should not be supplied with multiple dose containers of methadone oral liquid for dosing patients for the purpose of opioid pharmacotherapy. The consequences of incorrect dosing in the opioid pharmacotherapy setting means it is not appropriate to have multiple dose containers available for dosing these patients.

[1] Although CPOP pharmacies receive OST stock free of charge, the pharmacy will incur costs when preparing OST doses. A community pharmacy authorised to dispense CPOP is not obligated to provide CPOP doses for patients at public health service facilities.

3. Dose measurement practices

In accordance with Action 4.2 of the National Medication Safety Standard[2], oral dispenser devices should be used for measuring and administering oral liquid doses to avoid wrong route errors.

If multiple dose containers (that are not formulated to be administered as drops)[3] are being used for S8 and S4R oral liquids, public health service facilities should ensure:

- stock of oral dosing devices and accessories are available in all clinical areas where these medicines will be administered
- bungs and oral dosing syringes are visibly distinguishable and not inter-connectable with intravenous or parenteral lines and equipment
- all multiple dose S8 and S4R oral liquid containers have an appropriately sized bung fitted upon opening and left in situ for the duration of use
- bungs are not re-used
- an unused approved, oral dosing syringe is used for withdrawal and measurement of each oral liquid dose for patient administration
- the combination of bung and oral dose syringe is the only acceptable dose measurement method used
- intravenous syringes and drawing up needles, cannulas, medicine cups or other equipment are not used as they are inaccurate and lead to discrepancies
- doses are only removed from the original container immediately prior to the scheduled administration time.

In patient care areas, liquid should not be removed from multiple dose containers except to administer doses to patients. See Section 4 about measuring oral liquids for the purpose of performing an inventory.

Where S8 or S4R oral liquid medicines are supplied to patient care areas in unit dose pods, the public health service facility should have local procedures for dealing with doses that do not equate to the entire contents of a single unit dose pod or to the entire contents of multiple unit dose pods, where an unusable amount must be discarded. See also Section 3 of the Guideline on administration and record-keeping for Schedule 4 Restricted and Schedule 8 medicines.

If public health service facilities wish to use other methods of measurement of equivalent or greater accuracy, such as a calibrated bottle top dispenser (e.g. Socorex® “pump”), this should be approved by the public health service facility and local policy and procedures maintained to guide use practices.

4. Inventory

In patient care areas, it is recommended an inventory of S8 and S4R oral liquid medicines be performed at least daily, unless automated dispensing cabinets (ADCs) are in use.

If ADCs are in use and require a count each time a transaction occurs, with immediate alerting to discrepancies, less frequent inventories may be sufficient to manage the risk of misappropriation and diversion. For example, a weekly inventory may suffice.

---

[2] Australian Commission on Safety and Quality in Health Care. National Safety and Quality Health Service Standards. 2nd ed. Sydney: ACSQHC; 2017. (Standard 4: Medication Safety Standard).

[3] Oral liquid medicines formulated to be measured as “drops”, such as clonazepam liquid, are not suitable for measurement using a bung and oral dose syringes. Doses should be measured by counting into a measuring cup or onto a spoon. Drops should not be administered directly into the mouth from the bottle.

Where ADCs are designed such that medicines that have been accessed can be differentiated from those that have not been accessed, it may be reasonable to only perform a monthly inventory, in accordance with the requirements of the Medicines and Poisons Regulations 2016, for medicines that have not been accessed.

An inventory should also be performed when stock is transferred back to pharmacy.

4.1 Performing an inventory

The inventory is to involve visual inspection and estimation of the container volume.

The inventory check is **not** to involve:

- Transfer
- decanting or
- physical measurement.

Unnecessary volume measurement may result in:

- further measurement loss and compounded errors
- reduced potency and altered shelf life and
- potential contamination.

The incremental volume scale included on some bottles should be employed, or, where a scale is not included on the label, writable tape or purpose made stickers affixed when a new container is opened.

If a visual inspection leads to suspicion of discrepancy then a reconciliation process is to be performed with pharmacy and the standard process for reporting discrepancies followed.

4.2 Stock Reconciliation

Stock reconciliation is to be performed on withdrawing the last dose from multiple dose S8 or S4R oral liquid medicine containers, in addition to the routine inventory checks:

- measure the exact amount of liquid remaining and
- reconcile the actual volume with the recorded volume balance in the S8 or S4R register.

Measurement at any other time is to be on the advice and assistance of pharmacy.

Stock reconciliation should be recorded in the S8 or S4R register as follows:

- a separate entry labelled “balance reconciliation” is to be made in the S8 or S4R register
- adjust the register balance to reflect the actual balance
- the balance reconciliation and volume is to be witnessed by a second authorised person
- both the person making the entry and witness sign the register entry.

5. Discrepancies

Where the actual balance at reconciliation is different to the register balance, there is a need to consider whether the discrepancy is a consequence of measurement errors or the result of misappropriation or diversion. Triggers for considering whether a discrepancy report should be made in accordance with the MP 0103/19 *Reporting of Schedule 4 Restricted and Schedule 8 Medicines Discrepancies Policy* include:

- the total amount lost per dose is excessive (more than 0.2 mL/dose)
- the total volume difference between the actual balance and the register balance is significant (more than 10 mL)
- the volume difference represents a significant proportion of the total volume of the container (more than 5 percent)
- there is concern about the integrity of the preparation, such evidence of a change in colour, potency, viscosity, effectiveness or packaging (even where the difference per dose and/or the total volume difference are not considered significant)
- there are other concerns such as staff behaviour or patient complaints about effectiveness (even where the difference per dose and/or the total volume difference are not considered significant).

To calculate the discrepancy per dose:

- count the number of doses since the last reconciliation was performed
- divide the total volume of the discrepancy (in mL) by the number of doses
- record the discrepancy per dose as part of the register entry at reconciliation.

If the discrepancy per dose is less than or equal to 0.2mL/dose and no other irregularity exists, this is considered to be acceptable variation due to removal of multiple doses of oral liquid and no discrepancy report is required.

Public health service facilities should maintain a system for periodic audit of:

- discrepancy per dose
- reconciliations which do not require reports.

MP 0103/19 *Reporting of Schedule 4 Restricted and Schedule 8 Medicines Discrepancies Policy* is applicable to the reporting of discrepancies.

6. Definitions

Term	Definition
automated dispensing cabinet (ADC)	Computerised drug storage device or cabinet that allow medications to be stored and dispensed near the point of care, while controlling and tracking drug distribution.
discrepancy report	Report of discrepancy as required by MP 0103/19.
oral dosing syringe	Dosing syringe designed for the measurement of oral liquid medicine. Oral dosing syringes are designed to not connect with equipment used to administer medicines by other routes, such as by injection.
oral liquid medicine	Mixtures, syrups or solutions of medicine intended for administration by the oral route.
unit dose pod	Individual dosage unit of an oral liquid medicine repackaged in a Therapeutic Goods Administration (TGA) compliant facility.
stock reconciliation	Act of comparing physical balance of stock on hand (inventory) with the recorded balance in the register.

This document can be made available in alternative formats on request for a person with a disability.