Management of Schedule 8 and Restricted Schedule 4 oral liquid medicines
1. BACKGROUND

Legislative requirements for the storage and recording of Schedule 8 (S8) medicines by health practitioners are outlined in the Poisons Regulations 1965. Requirements for public hospitals and health services are set out in the Code of Practice for the Handling of Schedule 8 Medicines (drugs of Addiction) in Hospitals and Nursing Posts: OD 0141/08.

The requirements for storage and recording in public hospitals and health services of Restricted Schedule 4 (S4R) medicines that warrant extra accountability are outlined in the Storage and Recording of Restricted Schedule 4 Medicines: 0215/09.

Where there is a discrepancy in S8 or S4R medicine balances these must be reported per Reporting of medicine discrepancies in public hospitals and licenced private facilities which provide services to public patients in Western Australia: OD 0377/12.

The above requirements apply to all S8 and S4R medicines, including oral liquid formulations.

2. POLICY

2.1. Stockholdings and Supplies

Only the minimum stock holding of S8 and S4R oral liquids required for current usage are to be held in clinical areas. Only one bottle of liquid is to be in use at any one time and new stock only supplied as needed; as soon as practicable prior to the exhaustion of any existing stock.

Any S8 stock no longer required is to be transferred back to pharmacy. A stock inventory is to be performed at the time of transfer (see 2.3). Any suspected discrepancy identified at transfer is to be managed as below (see 2.4 and 2.5) and stock then destroyed as per legislative requirements and Clinical and Related Waste Management – Pharmaceutical Wastes: OD 0260/09.

All oral liquids are to remain in the original manufacturer packaging / containers. Routine repackaging is generally discouraged. Where performed, repackaging is to be on the basis of specific identified clinical need. Hospitals are to maintain a local policy to guide any repackaging practice in operation. Repackaging or unit dose supply is to comply with Good Manufacturing Practice, or be from an accredited TGA facility, or otherwise be on an individual patient dispensing / prescription basis.

Use of methadone oral liquid for opioid dependence is to comply with Management of Community Program for Opioid Pharmacotherapy (C-POP) patients in a hospital setting: OD 0255/09. Methadone oral liquid for this purpose is to be repackaged into unit doses by pharmacy, labelled for individual patient use.
2.2. Dose Measurement Practices

The measurement of S8 and S4R oral liquids is to comply with the Safe Administration of Oral, Enteral or Nebulised Solutions: OD 0443/13. Hospitals and health services are to ensure stocks of bungs and oral dosing syringes are available in all clinical areas handling oral liquid medications. Bungs and syringes are to be visibly distinguishable and not inter-connectable with intravenous or parenteral lines and equipment.

All S8 and S4R oral liquid containers are to have an appropriate size bung fitted upon opening and left in situ for the duration of use. Bungs are not to be reused. An unused, approved, oral dosing syringe is to be used for withdrawal and measurement of each oral liquid dose for patient administration.

The combined use of bung and oral dose syringe is the only acceptable dose measurement method. Intravenous syringes and drawing up needles, cannulas, medicine cups or other equipment are not accurate, lead to discrepancies and are not be used for S8 and S4R oral liquids.

Doses are only to be removed from the original container when required, immediately prior to the scheduled administration time. Removal of liquid for general measurement or other reason is not permitted.

An alternative method of measurement of equivalent or greater accuracy, such as calibrated bottle top dispensers (e.g. socorex® “pump”) may be employed. This method is to be approved by the hospital and a local hospital policy maintained to guide use practices.

2.3. Inventory

An inventory of S8 and S4R oral liquid medicines is to be performed at intervals according to local hospital policy for clinical areas. An inventory is to be performed not less than once daily and an entry recorded in the respective Register.

The inventory is to involve visual inspection and estimation of the container volume. The incremental volume scale included on some bottle labels should be employed, or, where a scale is not included on the label, writable tape or purpose made stickers is / are to be affixed at commencement of use of a new container. The remaining volume level is to be marked as soon as practicable after each required dose is withdrawn.

The inventory check is not to involve transfer, decanting or physical measurement. Unnecessary volume measurement leads to further measurement loss and compounded errors, reduced potency and altered shelf life, and potential contamination.

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.

2.4. Stock Reconciliation

On withdrawing the last dose from a S8 or S4R oral liquid medicine container the actual volume is to be reconciled with the stated volume balance in the S8 or S4R Register. The exact amount of liquid remaining is to be measured using the standard dose measurement technique. Measurement at any other time is to be on the advice and assistance of pharmacy.
A separate entry labelled “balance reconciliation” is to be made in the S8 or S4R Register, adjusting the Register balance to reflect actual balance. The balance reconciliation and volume is to be witnessed by a second authorised person and both persons are to sign the Register entry.

2.5. Discrepancy Reporting

Where the actual balance at reconciliation is more or less than the Register balance then the discrepancy per dose is to be calculated. To calculate the discrepancy per dose, the number of doses since the last reconciliation is counted and then the total volume discrepancy (in ml) is to be divided by the number of doses.

If the discrepancy per dose is less than or equal to 0.2 ml / dose and no other irregularity exists, then no discrepancy report is required. The discrepancy per dose is to be recorded as part of the Register entry at reconciliation. Hospitals and health services are to maintain a system for periodic audit of discrepancy per dose and reconciliations which do not require reporting.

Where the discrepancy is greater than 0.2 ml / dose, then the Reporting of medicine discrepancies in public hospitals and licenced private facilities which provide services to public patients in Western Australia: OD 0377/12 is to be followed.

A significant discrepancy suspected at any time must be reported. Any concern regarding the colour, potency, effectiveness, packaging or other aspect of the integrity of a S8 or S4R oral liquid medicine must be reported.

3. DEFINITIONS

<table>
<thead>
<tr>
<th><strong>Schedule 8 medicine</strong></th>
<th>Also termed Controlled Drugs, Drugs of Dependence or Drugs of Addiction. All substances defined under Poisons Legislation as listed in “Schedule 8”</th>
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<tbody>
<tr>
<td><strong>Restricted Schedule 4 medicine</strong></td>
<td>Any Schedule 4, prescription only medicine listed in Operational Directive 0169/09</td>
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<tr>
<td><strong>Oral liquid medicine</strong></td>
<td>Mixtures, syrups or solutions of medicine intended for administration by the oral route.</td>
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<tr>
<td><strong>Inventory</strong></td>
<td>Balance of stocks of medicine on hand. Act of counting or assessing stock on hand</td>
</tr>
<tr>
<td><strong>Stock Reconciliation</strong></td>
<td>Act of comparing physical balance of stock on hand (inventory) to written record of balance in the Register</td>
</tr>
<tr>
<td><strong>Discrepancy</strong></td>
<td>Any difference in balance between physical stock and Register stock</td>
</tr>
<tr>
<td><strong>Discrepancy Report</strong></td>
<td>Report of discrepancy as required by Operational Directive 0377/12</td>
</tr>
<tr>
<td><strong>Register</strong></td>
<td>Approved written or electronic record of transactions and stock balances as defined under Poisons Legislation</td>
</tr>
<tr>
<td><strong>Bung</strong></td>
<td>Device fitted to the bottle neck of an oral liquid container to allow connection of an oral dosing syringe</td>
</tr>
<tr>
<td><strong>Oral Dose Syringe</strong></td>
<td>Dosing syringe designed for the measurement of oral liquid medicine</td>
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4. ROLES AND RESPONSIBILITIES

All health professionals handling medicines in WA Health and authorised under the Poisons Legislation to obtain or possess Schedule 8 and Schedule 4 medicines are required to adhere to this Policy on management of oral liquid medicines.

5. COMPLIANCE

Compliance with inventory checks and record keeping of Registers is a requirement of Poisons Legislation for all authorised health professionals. Breaches of legislation may result in conditions on professional authorisation to obtain or possess medicines, court prosecution or both.

Compliance with reporting procedures for medicines discrepancies is mandatory. Those who fail to comply with this Policy may face disciplinary action relating to ethical standards and misconduct.

6. EVALUATION

Monitoring of compliance with this Policy is to be carried out by Poisons Permit Holders, nominated Medicines Incident Coordinators, and any person in charge of a Schedule 8 drug safe in a hospital ward, from time to time, as defined In the Poisons Regulations 1965.

7. REFERENCES

Poisons Regulations (WA) 1965

8. RELATED DOCUMENTS

Code of Practice for the Handling of Schedule 8 Medicines (drugs of Addiction) in Hospitals and Nursing Posts: OD 0141/08.

Storage and Recording of Restricted Schedule 4 Medicines: 0215/09.

Reporting of medicine discrepancies in public hospitals and licenced private facilities which provide services to public patients in Western Australia: OD 0377/12.

Clinical and Related Waste Management – Pharmaceutical Wastes: OD 0260/09

Community Program for Opioid Pharmacotherapy (C-POP) patients in a hospital setting: OD 0255/09

Safe Administration of Oral, Enteral or Nebulised Solutions: OD 0443/13