Government of Western Australia
Department of Health

Guidelines for dealing with a Schedule 4 Restricted and Schedule 8 Medicines Discrepancy

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Part 1 – Performing an Initial Review into a Medicines Discrepancy

1. Background

Wherever an inventory balance of S8 or S4R medicine is kept, there is potential for a discrepancy to occur. A discrepancy is a mismatch between the physical stock on hand and the expected stock as indicated in the respective medicines register. That is, the counted physical balance of stock on hand is not equal to the stated expected balance in the register.

A discrepancy can be either more stock than expected, or less, but all discrepancies should follow the same overall process of review, noting that actions undertaken may differ with the circumstances (e.g. tablet or liquid, more stock or less, etc).

There are a number of potential causes of a discrepancy. In many cases, the cause may be a simple calculation or counting error. Clinical errors, such as selecting and administering the wrong drug or strength, are also possible.

However, discrepancies can also be the result of deliberate theft, diversion or abuse.

These guidelines are provided to assist clinical staff conduct an initial review of a medicine discrepancy. They are not exhaustive and additional actions may be appropriate based on local policy for storage and handling of medicines. Local Health Service Provider policy relating to managing discrepancies should be consulted.

2. Performing an Initial Review

After identifying a discrepancy exists, an Initial Review should be immediately performed, by staff in the area, who are normally responsible for the day to day management of those medicines.

This should systematically work through the most common operational causes. At least two staff members from the area should be involved to confirm any findings, wherever possible.

The table below provides a list of common operational causes to consider.

Each possible cause should be considered, in turn. If the missing medicines are located, the appropriate corrective action should be taken to resolve the discrepancy, and the register records adjusted.

Other causes may be possible at individual sites. For example, operational errors associated with automated supply devices.

Where the discrepancy can be resolved within 24 hours, no report is required. Individual Health Service Providers may have local policies that require repeated or frequent discrepancies to be reported, even when resolved, for quality purposes.

3. Where the discrepancy is not resolved

If the review does not identify a clear cause, then the discrepancy must be considered to be a confirmed loss and/or potential misconduct.

If, at any time, it becomes apparent that a discrepancy is suspected to be the result of theft, then this should be immediately reported as potential misconduct and escalated to senior staff.

In these circumstances, evidentiary materials, such as drug registers and CCTV footage, should be securely stored, in a manner that minimises the risk of tampering.

4. Verifying a cause

The cause of a discrepancy must be verified through appropriate evidence. This should be witnessed by two staff members, both of whom should sign the entry in the register and provide their full name.

If a suspected cause cannot be identified with objective evidence, then other causes, including potential misconduct remain a possibility. In these cases, the discrepancy must be reported.

For example, if it is suspected an item “fell in the bin”, unless this was directly observed and/or the missing stock can be retrieved, then the discrepancy is not resolved and it must be reported (complete and submit the Medicines Discrepancy Report Form), as a reasonable suspicion of misconduct cannot be ruled out.

5. Making register corrections

If the medicines can be accounted for, then the S8 or S4R register records should be corrected, with the cause of the discrepancy provided. Any corrections must be complete, legible, and clearly explain what occurred.

Incorrect entries must not be deleted, crossed out or obscured. Instead they should be annotated by making a note in the margin of the register, identifying the entry that is incorrect and the reason for this.

Missing entries should be entered as usual. Where these are not in correct date or time order, an explanatory note should be included.

6. Policy or systems failure

A discrepancy may be due to failure to correctly follow mandatory Health Service Provider systems and policies. This may include non-compliance with requirements for the recording, storage, security, or use of a medicine.

Unintentional non-compliance may require action to increase awareness or additional education of staff. Intentional non-compliance may be a misconduct matter.

Whether or not the discrepancy is resolved, if S4R / S8 policy is not being followed, then this should be escalated for further action by the Health Service Provider as appropriate.

7. Matters that are not a discrepancy

There may be occasions where a S8 or S4R medicine may be unusable. This can include stock that is expired, where tablets fall on the floor, oral liquids that are spilt, ampoules that are dropped or broken, and so on.

If the stock is not missing and the cause is known, the circumstances were witnessed and it can be verified by two staff members, then there is no discrepancy and a report is not required.

Where a cause of this nature is suspected, but cannot be verified, then the matter should be classified as a confirmed loss and/or potential misconduct and reported. For example, if an ampoule is found broken or empty in the original packaging, but this was not directly witnessed, then a report is still required. This enables tracking of separate events where potential misconduct may be involved.

Unusable stock should be safely disposed of according to local policy. Full records of destruction/disposal should be made in the register with appropriate annotations. For example, if an ampoule is dropped prior to use, there must be a record of the broken ampoule with a note, and an additional record of the ampoule that was ultimately administered to the patient.

8. Patient’s-own medicines

Where there is a discrepancy with patient’s-own medicines, the guidelines should be followed as outlined above.

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Common Operational Causes of Discrepancy		
Possible Cause	**Review Activity to Perform**	**Corrective Action to Take**
Incorrect counting	• Recount stock	• Correct register, if required
Stock not counted, incorrectly returned to storage or misplaced	• Recheck S8 safe / S4R cupboard for additional uncounted stock • Check drug rooms and surrounds for misplaced stock	• Correct register, if required
Incorrect calculation	• Review subtraction and addition for all transaction entries since last correct balance	• Correct balance with appropriate annotation • Do not obscure prior entries.
Entry transposition (i.e. entries written on wrong page or for wrong medicine)	• Check balance of other S8 / S4R items	• Make correct register entries • Correct balance, if required • Annotate incorrect entries (do not delete or obscure any records)
Missing entries	• Check with clinical staff on shift since last correct balance • Review medication charts of patients since last correct balance • Check with patient	• Add missing register entry • Correct balance, if required
Clinical error (i.e. incorrect medicine drug selected and given to patient)	• Check balance of other S8 / S4R items • Check with clinical staff • Review medication charts of most recent patients	• Make correct register entries • Correct balance, if required • Annotate incorrect entries as erroneous (do not delete or obscure) • Follow usual procedure for clinical error
Manufacturer error	• Stock received from manufacturer with lower quantity than stated on label • All manufacturer seals must be intact	• Contact pharmacy for assistance • Validate error derived from manufacturer • Make report to manufacturer • Correct register

Common Operational Causes of Discrepancy		
Possible Cause	**Review Activity to Perform**	**Corrective Action to Take**
Broken, damaged or unusable stock	• Ensure no portion has been removed • Validate other causes not involved • Photograph of stock may be taken	• Destroy/dispose of stock according to local policy • Discrepancy report may not be required
Software error (i.e. automated supply device at fault)	• Contact local administrator to interrogate device records • Review may take longer than 24 hours.	• Administrator to correct, as appropriate • Records must reflect actual transaction events

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Part 2 – Performing a Preliminary Inquiry into a Medicines Discrepancy

1. Background

Wherever an initial review of a medicines discrepancy has failed to locate the missing stock, potential loss or theft must be considered and the discrepancy investigated further.

The Initial Review is intended to exclude common operational causes or errors that can be readily resolved. Once it is identified that the discrepancy is not resolved and the discrepancy has been reported, a Preliminary Inquiry must then be undertaken.

The Preliminary Inquiry is intended to confirm that a medicine has been lost and that all efforts have failed to resolve the discrepancy. The inquiry should explore all possible causes of the loss and determine, on balance, the most likely cause(s).

It should also consider if theft or misconduct is potentially involved and, if so, whether a person, or persons, responsible can be identified.

These guidelines are provided to assist with the Preliminary Inquiry. They should be applied in conjunction with any relevant Health Service Provider policy. Individual circumstances will dictate the inquiry and the steps taken may need to be expanded or amended, as required.

2. Assigning an officer for the inquiry

The Health Service Provider should assign an officer to conduct the inquiry. Under previous Policy versions this officer was termed the Medicines Incident Coordinator; consult local Policy in regard to procedures for selecting and appointing this officer.

The officer should not have been part of the discrepancy itself or any Initial Review already performed for a discrepancy. Ideally they will be independent of the local area/unit where the discrepancy has occurred.

It is recommended that inquiry officers have suitable training in conducting an investigation, wherever possible. Where this is not possible, inquiry officers should still have access to specialist advice and support on conducting an investigation.

3. Performing the inquiry

The table below provides a list of possible inquiry actions. The inquiry officer should systematically perform these in turn, based on the nature of the discrepancy.

The inquiry should be commenced as soon as possible, while records and staff accounts of events are still recent. Ideally the inquiry should be completed and reported within 7 days. This will allow further actions to be performed without delay, if required.

The inquiry officer should confirm the Initial Review of the discrepancy is complete and accurate. The review should be repeated as necessary. If an operational error or cause is identified then this should be verified, and the discrepancy resolved accordingly.

An operational cause may be suspected, but unless there is evidence that can verify an operational cause, then theft or misconduct should be considered further by the inquiry officer.

More thorough audits of register records, medication drug charts and inspection of physical storage conditions may be required. Review of other sources of information such as additional staff interviews, patient interviews and CCTV may indicate that a specific cause is responsible for the medicines loss.

Records of all reviews, audits, interviews, actions and decisions should be made and retained.

Where misconduct is being considered, evidentiary materials, such as drug registers and CCTV footage, should be securely stored, in a manner that minimises the risk of tampering.

4. Policy non-compliance or systems failure

The officer may observe that Health Service Provider policies and procedures, or legislation, is not being adhered to: e.g. storage conditions, register recording, etc. This may be unintentional, due to awareness or training, or through deliberate non-compliance.

Incidents of non-compliance may constitute misconduct and should be addressed accordingly. This should be referred back to the local area in the first instance, and managed in accordance with the relevant policy.

The inquiry officer may wish to escalate any instance where they believe that procedures and practices require systematic review or other improvement to the appropriate unit within the Health Service Provider for further action.

5. Analysis of results and conclusions

Analysis of likely causes should be confined to the available evidence.

An assessment of risk should be performed to guide any follow up actions for the local area and Health Service Provider. The inquiry officer should consider the individual loss in light of the medicine involved, the form, its schedule and classification, the quantities missing and other relevant circumstances. System control improvements to minimise re-occurrence across the site / HSP should also be considered and local risk policies should be consulted for further guidance.

The loss should be compared to prior similar discrepancies for the local area itself and the Health Service Provider as a whole. Where the same ward, drug, staff or circumstances are involved, this should guide decisions and follow-up actions.

6. Reporting

The findings of the Preliminary Inquiry, any analysis and recommendations are to be reported to the Health Service Provider and the Department of Health using Part 2 of the Medicines Discrepancy Report Form. Documents and other records relating to the Preliminary Inquiry can be provided as attachments to the Form.

Data from reports assist with future Health Service Provider investigations and is used to identify trends and issues within, and across Health Service Providers.

7. Suspected misconduct

As S4R/S8 drugs are kept in a controlled environment designed to prevent unauthorised access, where a discrepancy cannot be resolved and the subsequent inquiry cannot further identify an explainable cause of the loss, then misconduct is a possible (but not necessarily the only) cause.

Health Service Providers are required to undertake an assessment as to whether the discrepancy is one of either 'serious' or 'minor' misconduct. Minor misconduct may require reporting to the Public Sector Commission.

Any medicine discrepancy that is suspected, on reasonable grounds, to concern serious misconduct must be notified in writing to the Corruption and Crime Commission. Notifications must be made to the Corruption and Crime Commission in accordance with *MP 0125/19 Notifiable and Reportable Conduct Policy*. A person responsible for the loss does not need to be specifically identified in order to make a notification of potential misconduct.

Reasonable suspicion of theft must be immediately dealt with in accordance with *MP 0127/20 Discipline Policy* and *MP 0125/19 Notifiable and Reportable Conduct Policy,* including reporting to Police and notifying other authorities as appropriate. Specific advice should be sought from Health Service Provider Integrity Units in each case.

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Performing a Preliminary Inquiry	
Component	**Suggested Activity**
Review information sources to identify potential causes	• Verify the Initial Review was conducted sufficiently and repeat as needed
	• Perform audit of relevant drug register(s) or electronic system
	• Reconcile recent register entries with medication charts (or other orders)
	• Inspect physical storage and security conditions
	• Interview staff involved and/or any direct witnesses to the discrepancy
	• Identify any other staff with access to the safe/cupboards/area over period and interview as required
	• Interview patients, as required (for patient's own discrepancy) or to verify administration/supply
	• Consult other experts as required - CNS, ward pharmacist, security staff, integrity unit
	• Review any available CCTV footage of the storage area
	• Review recent discrepancies for the unit / hospital and compare for any similar patterns
Assess compliance with policy, procedure & legislation	• Seek opinion of Chief Pharmacist, NUM/DON, security, other experts
	• Identify policy or procedural breaches: unintentional or deliberate
	• Consider whether procedural gaps/weaknesses exist
	• Refer any quality or compliance issues identified to the appropriate HSP area for action
Analysis of evidence	• Perform an analysis of all the evidence collected

Performing a Preliminary Inquiry	
Component	**Suggested Activity**
collected	• Consider the inherent risk of the loss (medicine, s4/S8, form, quantity, etc.)
	• Consider if a person of interest can be identified
	• Make an assessment of most probable explanation(s) for loss
	• Consider if there are reasonable grounds to suspect misconduct has occurred
Reporting	• Complete a final report on the discrepancy (fill in part 2 of the reporting form)
	• Escalate any deliberate policy non-compliance to appropriate area of HSP for action
	• Consult with the HSP integrity unit for additional guidance
	• Escalate all disciplinary issues to appropriate area of HSP according to policy
	• Inform Medicines and Poisons Regulation Branch of confirmed theft or legislative breaches
	• Consider informing Police, for criminal conduct, as required
	• Inform AHPRA where practitioner misconduct or impairment (due to drugs or other) is suspected
	• Keep full records of all actions taken, decisions and recommendations

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