Reporting lost or stolen medicine

Position Statement - s226 MPMR

Purpose of position statement

The purpose of this position statement is to provide guidance regarding the process for deciding if a report of lost or stolen medicine is required under section 226 of the *Medicines* and *Poisons* (*Medicines*) *Regulation* 2021 (Qld) (MPMR).

This position statement applies to all persons required to report lost or stolen medicines under section 226 of the MPMR. For guidance on requirements for wholesalers to report the loss or theft of a diversion-risk medicine, refer to section 231 of the MPMR¹.

Rationale for reporting lost or stolen medicines

Some medicines may be targeted for unauthorised use, abuse or diversion into illicit activities. The *Medicines and Poisons Act 2019* (Qld) (MPA) and MPMR includes a series of controls such as secure storage systems, reconciling registers and record keeping requirements to deter, delay and detect unauthorised access to medicines. The suspected loss or theft of medicine represents a potential failure of these controls around the secure possession of medicines that may create a risk to public health and safety.

Reporting lost or stolen medicines to the police service will enable investigation of possible diversion of medicines such as pharmaceutical opioids or pseudoephedrine to the illicit drug market.

Reporting lost or stolen medicines to the chief executive [Director-General, Queensland Health, or delegate] may assist with identifying situations of misuse which might result in self-harm using stolen medicines or situations where staff access to medicines may present a risk to patients.

Requirement to report

Section 226(2) of the MPMR requires that the chief executive [Director-General, Queensland Health, or delegate] and the police service must be notified about 'incidents', as defined in section 226(1)(a)-(d) of the MPMR, where a person, in the course of acting as an 'approved person' [defined in section 54(3) of the MPA], **reasonably suspects** (a type of medicine) has been lost or stolen.

The online form to report loss or theft of a diversion-risk medicine from a wholesaler before the loss or theft is located at Notification of loss or theft (wholesaler) – s231 MPMR.



¹ Section 231 of the MPMR requires that a wholesaler must report the loss or theft of a diversion-risk medicine that was in the possession of the wholesaler immediately before the loss or theft to the police service and the chief executive [Director-General, Queensland Health, or delegate]. The report must be made as soon as practicable, but no later than the end of the next business day after the loss or theft.

Guidance for deciding whether to report a lost or stolen medicine

'Reasonably suspects' that the medicine has been lost or stolen

'Reasonably suspects' is defined in the MPA as meaning 'suspects on grounds that are reasonable in the circumstances.' Circumstances may differ, and accordingly, there is no standard or fixed rule as to what grounds are 'reasonable in the circumstances' that applies to all cases.

By way of guidance only, the following may be considered when determining if you 'reasonably suspect' that a medicine has been lost or stolen such that it should be reported:

- whether there is a reasonable explanation for the discrepancy other than suspected loss or theft e.g. a medicine is missing but theft is not suspected.
 - See Box 1 for some examples of reasonable explanations for a discrepancy.
- whether theft or misuse is reasonably suspected in the circumstance.
 - See Box 2 for examples of circumstances where theft or misuse may be reasonably suspected.

The examples of circumstances described in Box 1 and Box 2 below are not exhaustive and there are other circumstances where an 'approved person' may reasonably suspect medicine has been lost or stolen.

Irrespective of whether a report is made, any loss or discrepancies in medicines should be documented, including in compliance with relevant provisions of the MPA and MPMR (e.g. in medicine registers).

Box 1: Examples of reasonable explanations for a discrepancy

- There was a documentation error e.g. a validated incorrect calculation that can be corrected by a new record in accordance with legislative requirements.
- A small quantity of a medicine was destroyed accidentally when it was under the supervision of an 'approved person' who was attempting to conduct regular, lawful activities e.g. a liquid was spilled, a tablet was dropped, a bottle was broken; and it is clear the items were not misused, it is an infrequent occurrence and the destruction has been recorded compliantly.
- There are minor discrepancies of liquid medicines which are within the expected tolerance variance limits associated with liquid preparations (e.g. ullage) and there is no other evidence to reasonably suspect unlawful activity.
- There is a discrepancy with a patient's medicine e.g. a fentanyl patch was placed on a patient in a
 nursing home and the patch is unable to be located it is an infrequent occurrence and there is no
 other evidence to reasonably suspect unlawful activity.
- The packaging for medication was damaged during transit, which may result in damaged medicines, however, all of the medication is fully accounted for; and there have been no previous incidents or patterns of loss.

Box 2: Examples of circumstances where theft or loss from misuse may be reasonably suspected

- Theft of the medicine was witnessed and reported at the location.
- There are clear signs of a break-in and medicine/s is/are missing.
- There has been repeated unexplained loss of medicine and staff involvement is possible.
- There have been multiple occasions at the same facility where a particular type of medicine e.g. fentanyl patches, are unable to be located.
- Medication packaging has been damaged during transit and medication cannot be fully accounted for.
- The discrepancies of liquid medicines (ullage) are outside of expected tolerance variance limits –
 definitive guidelines and amounts are not legislated for in Queensland.
- There is concern about the integrity of the preparation, such as 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).

Actions to be taken

If a person has considered the circumstances and a reasonable explanation for the loss cannot be found and misuse or theft is reasonably suspected, the matter must be reported to the chief executive and police.

If after considering the circumstances a person decides that there is a reasonable explanation for the discrepancy, then a report of lost or stolen medicine may not be required.

The facts around the reasonable explanation for a discrepancy should be documented for the missing medicine and monitoring of similar discrepancies should occur. Recurrence of similar discrepancies may provide grounds for reasonably suspecting loss or theft that must be reported.

Further information:

Information about reporting matters to the chief executive can be found here <u>Reporting</u> medicines matters to the chief executive | Queensland Health.

The online form to report lost or stolen medicines is located at <u>Reporting lost or stolen</u> medicines - s226 MPMR.