

# Medicines and Poisons Act 2019

Factsheet – current as at September 2021

## Substance management plans

### What is a substance management plan?

The Act introduces the concept of a *substance management plan*, which is a co-regulatory tool to assist substance authority holders to consider and manage known and predictable risks specific to regulated activities with regulated substances. The requirement for a substance management plan supports a risk-management system for regulated substances proportionate to the risk.

Substance management plans are outcome-focused and are required to contain minimum risk management, accountability benchmarks and governance criteria that must be established by certain persons and entities in their dealings with regulated substances.

The Act defines *substance management plan* as follows:

- *substance management plan*, for a regulated place, means a document setting out how known and foreseeable risks associated with any dealing with a regulated substance are to be managed at, or in connection with, the regulated place.

The following definitions are also important:

- *regulated place* means a place:
  - (a) where a dealing happens, or is proposed to happen, with a regulated substance; and
  - (b) prescribed by regulation to be a regulated place.
- *responsible person*, for a regulated place, means the person prescribed by regulation to be the responsible person for the regulated place.

### Who is required to make a substance management plan?

The Act states that the *responsible person for a regulated place* must make a substance management plan for the place that contains a number of prescribed components, before any dealing happens with a regulated substance at the place, unless the person has a reasonable excuse.

Failure to comply with this requirement can attract a significant penalty.

# What must a substance management plan contain?

The Act prescribes what a substance management plan must contain.

A substance management plan for a regulated place must:

- state the following matters:
  - the day the plan starts;
  - the location of the place;
  - the dealings and regulated substances to which the plan applies;
  - the persons (staff) to whom the plan applies; and
- address the matters prescribed by regulation; and
- be written in a way that is likely to be easily understood by staff.

The responsible person must also ensure the substance management plan:

- is made available to staff when it is made; and
- is reviewed at the time prescribed by regulation.

Staff must comply with substance management plans unless they have a reasonable excuse.

# What is the substance management plan Standard?

The *Medicines and Poisons (Medicines) Regulation 2021 (MPMR)* prescribes six (6) departmental standards, with one being on substance management plans – ‘*Substance management plans for medicines*’.

The matters to be addressed in a substance management plan are contained in the standard.

# What are regulated places and who are responsible persons?

Schedule 17 of the MPMR prescribes a list of regulated places and the corresponding responsible person for the regulated place.

# How often does a substance management plan need to be reviewed?

A substance management plan for a regulated place must be reviewed:

- as soon as practicable after a *review incident* happens in relation to the place; and

- at least every 5 years after the day the substance management plan starts or if the plan is reviewed in any 5-year period after the plan starts—the day the plan was last reviewed.

A *review incident* in relation to a regulated place, means an incident stated to be a review incident for the place in the departmental standard called '*Substance management plans for medicines*'.

## Associated guidance documents

- Departmental standards – factsheet
- Departmental Standard - Substance management plans for medicines

## Further information

For further information, contact the Healthcare Approvals and Regulation Unit:

- Email: [HARU@health.qld.gov.au](mailto:HARU@health.qld.gov.au)