Medicines and Poisons Act 2019

Factsheet – current as at July 2024

Departmental standards - medicines

What is a departmental standard?

The *Medicines and Poisons Act 2019* (MPA) allows the chief executive (or delegate), to make a *departmental standard* about carrying out a regulated activity with a regulated substance and other matters relating to the purposes and administration of the Act.

A departmental standard may be about any of the following matters:

- procedures for carrying out regulated activities;
- procedures for keeping, storing and managing regulated substances;
- training and competency requirements for persons carrying out regulated activities with regulated substances;
- procedures to ensure products containing regulated substances are safe and suitable for the intended use of the products; and
- requirements for tracing the movement of regulated substances from their manufacture to final disposal, including requirements about documentation and electronic transactions.

The chief executive may make a departmental standard by adopting all or part of another entity's code, guideline, protocol or standard.

Before making a departmental standard, the chief executive must take reasonable steps to consult with entities that:

- are proposed to be subject to the standard; or
- have expertise about the matters proposed to be dealt with by the standard.

The chief executive must publish each departmental standard on the department's website.

The departmental standards provide task-specific guidance for professions and industries that perform regulated activities with regulated substances. Due to the technical and scientific nature of the regulated activities and substances that develop over time with best practice and consultation, the departmental standards themselves are not included in the Act or the *Medicines and Poisons (Medicines) Regulation 2021* (MPMR).

What are the departmental standards?

The MPMR prescribes the following six (6) departmental standards:

- Compounding;
- Secure storage of S8 medicines;

- Monitored medicines;
- Pseudoephedrine recording;
- Substance management plans for medicines; and
- Requirements for an electronic prescription management system.

Who do the departmental standards apply to?

The MPMR provides guidance as to what persons/entities the relevant departmental standard applies to. The departmental standards should be read in their entirety for complete guidance.

A person compounding a medicine for a patient must compound the medicine in accordance with the departmental standard called 'Compounding'.

The standard on 'Secure storage of S8 medicines' is relevant to S8 safe establishers.

The standard on 'Monitored medicines' is relevant to prescribers and dispensers who must prescribe and dispense a monitored medicine in accordance with the departmental standard called 'Monitored medicines'.

The standard on 'Pseudoephedrine recording' is relevant to pharmacists who sell S3 medicines which contain pseudoephedrine.

The standard on 'Substance management plans for medicines' is relevant to responsible persons for regulated places and staff working for relevant entities.

The standard on 'Requirements for an electronic prescription management system' is relevant to system managers who are appointed by entities to set up and maintain an electronic prescription management system.

Associated guidance documents

- *Compounding* – departmental standard (version 1);
- *Secure storage of S8 medicines* - departmental standard (version 2);
- *Monitored medicines* - departmental standard (version 2);
- *Pseudoephedrine recording* - departmental standard (version 1);
- *Substance management plans for medicines* - departmental standard (version 1); and
- *Requirements for an electronic prescription management system* - departmental standard (version 1).

Further information

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

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