Substance Management Plan - Checklist

*Insert name of regulated place*

*Medicines and Poisons Act 2019* (Qld)

Medicines and Poisons (Medicines) Regulation 2021(Qld)

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### Purpose of this checklist

This checklist has been developed by Queensland Health[[1]](#footnote-1) to assist *responsible persons[[2]](#endnote-2)* make a Substance Management Plan (**SMP**) for a *regulated place[[3]](#endnote-3)* as required under the *Medicines and Poisons Act 2019* (Qld)(**MPA**). This checklist is intended as a guide only and should be used in conjunction with the *Guide to developing a substance management plan for medicines (https://www.health.qld.gov.au/\_\_data/assets/pdf\_file/0026/1110788/guide-smp-medicines.pdf).*

The purpose of this checklist is to support the *responsible person* and provide prompts around the areas to consider when preparing SMPs. However, it is the responsibility of the *responsible person* to ensure all legislative requirements are addressed as part of preparing an SMP. **For clarity, this checklist may become the SMP itself.**

Where applicable, terms used in this checklist have the same meaning as that in the MPA and Medicines and Poisons (Medicines) Regulation 2021 (Qld) (**MPMR**). Relevant provisions in the MPA and MPMR are reproduced in full within the Appendix at the end of the checklist.

### Substance Management Plans

SMPs[[4]](#endnote-4) are documents *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*, and are a mandatory requirement under the MPA.

Section 93(1) of the MPA requires a *responsible person* to make an SMP[[5]](#endnote-5) before any *dealings[[6]](#endnote-6)* [e.g. possessing, manufacturing, prescribing or administering] are undertaken with a *regulated substance[[7]](#endnote-7)* [e.g. S4 and S8 medicines] at a *regulated place*. Further, section 93(2)[[8]](#endnote-8) of the MPA details what information must be included in an SMP.

Section 94 of the MPA provides that a person to whom the SMP applies [section 93(2)(a)(iv) of the MPA] must comply with the SMP unless the person has a reasonable excuse. Failure to comply with an SMP can attract a significant penalty (up to 200 penalty units).

SMPs 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*.

In developing an SMP, a *responsible person* should ensure consideration is given to:

* the specific legislative requirements in the MPA and MPMR;
* the Departmental Standard - *Substance management plans for medicines* (**DSSMP**) (<https://www.health.qld.gov.au/__data/assets/pdf_file/0023/1108940/ds-substance-management-plans-medicines.pdf>);
* the *Guide to developing a Substance management plan for medicines (*[*https://www.health.qld.gov.au/\_\_data/assets/pdf\_file/0026/1110788/guide-smp-medicines.pdf*](https://www.health.qld.gov.au/__data/assets/pdf_file/0026/1110788/guide-smp-medicines.pdf)*).*

### General information

|  | **MPA / MPMR requirement** | **Details**  | **DSSMP reference** | **Included** |
| --- | --- | --- | --- | --- |
|  | Name of regulated place*[see Schedule 17 of the MPMR for a list of the regulated places]* |  |  | [ ]  Yes  |
|  | Day this SMP starts*[s.93(2)(a)(i) of the MPA]* |  | 1.1 | [ ]  Yes  |
|  | Location/s of regulated place to which this SMP applies*[s.93(2)(a)(ii) of the MPA]* |  | 1.1 | [ ]  Yes  |
|  | Regulated substance/s to which this SMP applies*[s.93(2)(a)(iii) of the MPA]* |  | 1.1 | [ ]  Yes  |
|  | Regulated activities (dealings) to which this SMP applies[[9]](#footnote-2)*[s.93(2)(a)(iii) of the MPA]* |  | 1.1 | [ ]  Yes  |
|  | Person/s (staff) this SMP applies to*[s.93(2)(a)(iv) of the MPA]* |  | 1.1 | [ ]  Yes  |
|  | The SMP is available to all staff at the time it is made and when it is revised*[s.93(3) of the MPA]* |  | 1.1.3 | [ ]  Yes  |

### Responsible person making this SMP

|  | **MPA / MPMR requirement** | **Details**  | **DSSMP reference** | **Included** |
| --- | --- | --- | --- | --- |
|  | Name of responsible person making this SMP*[Schedule 17 of the MPMR - who is a responsible person]* |  |  | [ ]  Yes [ ]  No |
|  | Designation/role of responsible person*[Schedule 17 of the MPMR - who is a responsible person]* |  |  | [ ]  Yes [ ]  No |
|  | Date this SMP must be reviewed by*[s.93(3)(b) of the MPA and s.174[[10]](#endnote-9) of the MPMR]* |  | 1.3 | [ ]  Yes [ ]  No |
|  | Signature of responsible person listed in section 1 above | *Insert signature here – digital signature is acceptable.* |  | [ ]  Yes [ ]  No |
|  | Version control of this SMP | *Insert the version history of the SMP, date of review(s) of the SMP, the name(s) of the person who completed any review of the SMP and the reason/s for the review(s) of the SMP* | 1.1 | [ ]  Yes [ ]  No |
|  | Review*[s.93(3)(b) of the MPA and s.174[[11]](#endnote-10) of the MPMR]* | *The SMP must reference or describe the processes/procedures for conducting a review of the SMP in the event a review incident[[12]](#footnote-3) occurs.**The SMP must describe or reference how a routine review of the SMP will be undertaken at least every 5 years to ensure that all known and foreseeable risks have been identified and appropriate controls are in place to mitigate those risks.* | 1.3 | [ ]  Yes [ ]  No |

### How known and foreseeable risks with regulated substances are to be managed[[13]](#endnote-11)

| **Dealing** | **Outcomes required by the DSSMP** | **Details[[14]](#footnote-4)**  | **DSSMP reference** | **MPA/MPMR reference** | **Included** |
| --- | --- | --- | --- | --- | --- |
| **Manufacture***[s.21 MPA]* |  | *Only provide details if this dealing is undertaken at the regulated place specified in this SMP. Otherwise, delete this section.* | 2 | *Chapter 3, part 2 of the MPMR – ‘Manufacturing licences’* |  |
|  | *Medicines manufactured are fit for purpose* |  | 2.1 |  | [ ]  Yes [ ]  No |
|  | *Access to the manufacturing area and storage areas for raw materials and finished products is controlled to prevent theft and tampering* |  | 2.2 |  | [ ]  Yes [ ]  No |
|  | *Incidents, including potential incidents, are deterred, identified and reported in a timely manner* | *Include details of reporting pathways - who incidents must be reported to, what incidents must be reported, when incidents must be reported, how incidents must be reported.**Consider application of ss 226(1)d) [lost or stolen medicine], 228(1)(a) [unlawful purchase order], 230 [false purchase order] of the MPMR.*See also information about reporting medicines matters to the chief executive - <https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines/reporting-medicines-matters> | 2.3 |  | [ ]  Yes [ ]  No |
| **Buy***[s.22 of the MPA]* |  | *Only provide details if this dealing is undertaken at the regulated place specified in this SMP. Otherwise, delete this section.* | 3 | *Chapter 4, part 3 of the MPMR – ‘Buying by giving purchase orders’* |  |
|  | *Purchase orders for medicines are made by appropriate persons or their delegates* |  | 3.1 |  | [ ]  Yes [ ]  No |
|  | *The stock received is secure and fit for purpose* |  | 3.2 |  | [ ]  Yes [ ]  No |
|  | *Incidents, including potential incidents, are deterred, identified and reported in a timely manner* | *Include details of reporting pathways - who incidents must be reported to, what incidents must be reported, when incidents must be reported, how incidents must be reported.**Consider application of ss 226(1)d) [lost or stolen medicine], 228(1)(a) [unlawful purchase order], 230 [false purchase order] of the MPMR.*See also information about reporting medicines matters to the chief executive - <https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines/reporting-medicines-matters> | 3.3 |  | [ ]  Yes [ ]  No |
| **Possess***[s.23 of the MPA]* |  | *Only provide details if this dealing is undertaken at the regulated place specified in this SMP. Otherwise, delete this section* | 4 |  |  |
|  | *Medicines are only accessible and possessed by appropriate persons* |  | 4.1 | *See also ss. 23 and 62 of the MPA* | [ ]  Yes [ ]  No |
|  | *Medicines are stored in secure and appropriate storage[[15]](#footnote-5)* |  | 4.2 | *See also Chapter 8, part 2 of the MPMR – ‘Secure storage systems’; and* *Departmental standard - Secure storage of S8 medicines* | [ ]  Yes [ ]  No |
|  | *Recording and keeping of information enables traceability of medicines* |  | 4.3 |  | [ ]  Yes [ ]  No |
|  | *There is compliance with relevant Departmental Standards* | [*https://www.health.qld.gov.au/system-governance/licences/medicines-poisons/medicines-poisons-act/legislation-standards*](https://www.health.qld.gov.au/system-governance/licences/medicines-poisons/medicines-poisons-act/legislation-standards)* *Departmental standard - Compounding*
* *Departmental standard - Monitored medicines*
* *Departmental standard - Pseudoephedrine recording*
* *Departmental standard - Secure storage of S8 medicines*
* *Departmental standard - Substance management plans for medicines*
* *Departmental standard - Requirements for an Electronic Prescription Management System (EPMS)*
 | 4.4 |  | [ ]  Yes [ ]  No |
|  | *Incidents, including potential incidents, are deterred, identified and reported in a timely manner* | *Include details of reporting pathways - who incidents must be reported to, what incidents must be reported, when incidents must be reported, how incidents must be reported.**Consider application of ss 226(1)d) [lost or stolen medicine], 228(1)(a) [unlawful purchase order], 230 [false purchase order] of the MPMR.*See also information about reporting medicines matters to the chief executive - <https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines/reporting-medicines-matters> | 4.5 |  | [ ]  Yes [ ]  No |
| **Supply of stock***[s.24 of the MPA]* |  | *Only provide details if this dealing is undertaken at the regulated place specified in this SMP. Otherwise, delete this section.* | 5 | *Chapter 4, part 4 of the MPMR – ‘Supplying stock’* |  |
|  | *Medicines are only supplied by appropriate persons* |  | 5.1 |  | [ ]  Yes [ ]  No |
|  | *Medicines are only supplied to persons authorised to buy* |  | 5.2 | *See also Chapter 4, part 3 of the MPMR* | [ ]  Yes [ ]  No |
|  | *Medicines are delivered in a safe, secure and timely manner* |  | 5.3 | *See also ss 64 and 65 of the MPMR* | [ ]  Yes [ ]  No |
|  | *Carriers engaged to deliver medicines are capable and reliable* |  | 5.4 | *See also s. 66 of the MPMR* | [ ]  Yes [ ]  No |
|  | *Recording and keeping of information enables traceability of medicines* |  | 5.5 |  | [ ]  Yes [ ]  No |
|  | *Incidents, including potential incidents, are deterred, identified and reported in a timely manner* | *Include details of reporting pathways - who incidents must be reported to, what incidents must be reported, when incidents must be reported, how incidents must be reported.**Consider application of ss 226(1)d) [lost or stolen medicine], 228(1)(a) [unlawful purchase order], 230 [false purchase order] of the MPMR.*See also information about reporting medicines matters to the chief executive - <https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines/reporting-medicines-matters> | 5.6 |  | [ ]  Yes [ ]  No |
| **Supply for a person or animal[[16]](#footnote-6)** |  | *Only provide details if this dealing is undertaken at the regulated place specified in this SMP. Otherwise, delete this section.* | **6** |  |  |
|  | *Medicines are dispensed, given as a treatment dose or otherwise supplied for a person or animal by appropriate persons* |  | 6.1 |  | [ ]  Yes [ ]  No |
|  | *Medicines supplied for a person or animal are appropriately labelled* |  | 6.2 | *See also s.73 of the MPMR* | [ ]  Yes [ ]  No |
|  | *Records are kept of medicines dispensed, given as a treatment dose or otherwise supplied for a person or animal* |  | 6.3 |  | [ ]  Yes [ ]  No |
|  | *There is compliance with relevant Departmental Standards* | [*https://www.health.qld.gov.au/system-governance/licences/medicines-poisons/medicines-poisons-act/legislation-standards*](https://www.health.qld.gov.au/system-governance/licences/medicines-poisons/medicines-poisons-act/legislation-standards)* *Departmental standard - Compounding*
* *Departmental standard - Monitored medicines*
* *Departmental standard - Pseudoephedrine recording*
* *Departmental standard - Secure storage of S8 medicines*
* *Departmental standard - Substance management plans for medicines*
* *Departmental standard - Requirements for an Electronic Prescription Management System (EPMS)*
 | 6.4 |  | [ ]  Yes [ ]  No |
|  | *Incidents, including potential incidents, are deterred, identified and reported in a timely manner* | *Include details of reporting pathways - who incidents must be reported to, what incidents must be reported, when incidents must be reported, how incidents must be reported.**Consider application of ss 226(1)d) [lost or stolen medicine], 228(1)(a) [unlawful purchase order], 230 [false purchase order] of the MPMR.*See also information about reporting medicines matters to the chief executive - <https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines/reporting-medicines-matters> | 6.5 |  | [ ]  Yes [ ]  No |
| **Prescribe or make a standing order** **for a medicine***[see Schedule 1 MPA for definitions]* |  | *Only provide details if this dealing is undertaken at the regulated place specified in this SMP.[[17]](#footnote-7) Otherwise, delete this section.* |  7 | Definitions in Schedule 1 of the MPA |  |
|  | *Only appropriate persons can prescribe or make a standing order for medicines* | *Refer to the Departmental Standard - Requirements for an electronic prescription management system (reference system manager and system administrator and link to procedures).* | 7.1 | *See also s.38 of the MPA and Chapter 4, part 7 of the MPMR* | [ ]  Yes [ ]  No |
|  | *Standing orders and prescriptions remain appropriate* |  | 7.2 |  | [ ]  Yes [ ]  No |
|  | *There is compliance with relevant Departmental Standards* | [*https://www.health.qld.gov.au/system-governance/licences/medicines-poisons/medicines-poisons-act/legislation-standards*](https://www.health.qld.gov.au/system-governance/licences/medicines-poisons/medicines-poisons-act/legislation-standards)* *Departmental standard - Compounding*
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* *Departmental standard - Secure storage of S8 medicines*
* *Departmental standard - Substance management plans for medicines*
* *Departmental standard - Requirements for an Electronic Prescription Management System (EPMS)*
 | 7.3 |  | [ ]  Yes [ ]  No |
|  | *Incidents, including potential incidents, are deterred, identified and reported in a timely manner* | *Include details of reporting pathways - who incidents must be reported to, what incidents must be reported, when incidents must be reported, how incidents must be reported.**Consider application of ss 226(1)d) [lost or stolen medicine], 228(1)(a) [unlawful purchase order], 230 [false purchase order] of the MPMR.*See also information about reporting medicines matters to the chief executive - <https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines/reporting-medicines-matters> | 7.4 |  | [ ]  Yes [ ]  No |
| **Administer***[s.26 of the MPA]*  |  | *Only provide details if this dealing is undertaken at the regulated place specified in this SMP. Otherwise, delete this section.* | 8 |  |  |
|  | *Medicines are only administered by persons who are competent to administer medicines in the circumstances* | *Persons who administer medicines must be lawfully authorised under the MPA/MPMR to administer the medicines.* | 8.1 |  | [ ]  Yes [ ]  No |
|  | *Records are kept of medicines administered* |  | 8.2 | *See also Chapter 4, part 10 of the MPA* | [ ]  Yes [ ]  No |
|  | *Incidents, including potential incidents, are deterred, identified and reported in a timely manner* | [*https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines/reporting-medicines-matters*](https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines/reporting-medicines-matters)*Include details of reporting pathways - who incidents must be reported to, what incidents must be reported, when incidents must be reported, how incidents must be reported.**Consider application of ss 226(1)d) [lost or stolen medicine], 228(1)(a) [unlawful purchase order], 230 [false purchase order] of the MPMR.*See also information about reporting medicines matters to the chief executive - <https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines/reporting-medicines-matters> | 8.3 |  | [ ]  Yes [ ]  No |
| **Dispose***[s.28 of the MPA]* |  | *Only provide details if this dealing is undertaken at the regulated place specified in this SMP* | **9** |  |  |
|  | *Waste from medicines[[18]](#footnote-8) is disposed of appropriately by appropriate persons* |  | 9.1 | *See also s.42 of the MPA – offence to dispose of waste from diversion-risk medicines* | [ ]  Yes [ ]  No |
|  | *Disposal of S8 diversion-risk medicine waste is recorded* |  | 9.2 | *As above, see s.42 MPA* | [ ]  Yes [ ]  No |
|  | *Incidents, including potential incidents, are deterred, identified and reported in a timely manner* | *Include details of reporting pathways - who incidents must be reported to, what incidents must be reported, when incidents must be reported, how incidents must be reported.**Consider application of ss 226(1)d) [lost or stolen medicine], 228(1)(a) [unlawful purchase order], 230 [false purchase order] of the MPMR.*See also information about reporting medicines matters to the chief executive - <https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines/reporting-medicines-matters> | 9.3 |  | [ ]  Yes [ ]  No |

### Appendix

1. For further information, contact the Healthcare Approvals and Regulation Unit (**HARU**) by email: HARU@health.qld.gov.au. This checklist was prepared by HARU in May 2022. [↑](#footnote-ref-1)
2. Section 92 of the MPA defines ‘responsible person’ as follows:

 ***responsible person****, for a regulated place, means the person prescribed by regulation to be the responsible person for the regulated place.*

See also Schedule 17 of the MPMR which details ‘regulated places’ and ‘responsible persons’ for the regulated places. [↑](#endnote-ref-2)
3. Section 92 of the MPA defines ‘regulated place’ as follows:

***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.

See also Schedule 17 of the MPMR which details ‘regulated places’ and ‘responsible persons’ for the regulated places. [↑](#endnote-ref-3)
4. Section 92 of the MPA 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. [↑](#endnote-ref-4)
5. See section 92 definition above. [↑](#endnote-ref-5)
6. Section 18 of the MPA defines ‘deals’ as follows:

***Meaning of deals with a regulated substance***

A person deals with a regulated substance if the person does

any of the following activities—

(a) manufactures the substance;

(b) buys the substance;

(c) possesses the substance;

(d) supplies the substance;

(e) if the substance is a medicine—

(i) administers the medicine; or

(ii) prescribes or makes a standing order for the medicine;

(f) if the substance is a poison—applies the poison;

(g) if the substance is a prohibited substance—otherwise uses the substance;

(h) disposes of waste from the substance;

(i) asks or directs another person to do something mentioned in any of paragraphs (a) to (h). [↑](#endnote-ref-6)
7. Section 17 of the MPA defines ‘regulated substance’ as follows:

A ***regulated substance*** is a medicine, poison, prohibited substance, fumigant or pesticide. [↑](#endnote-ref-7)
8. Section 93(2) of the MPA provides as follows:

…(2) The substance management plan for the regulated place must—

(a) state the following matters—

(i) the day the plan starts;

(ii) the location of the place;

(iii) the dealings and regulated substances to which the plan applies;

(iv) the persons (staff) to whom the plan applies; and

(b) address the matters prescribed by regulation; and

(c) be written in a way that is likely to be easily understood by staff. [↑](#endnote-ref-8)
9. Not all dealings will be relevant to this SMP. Only complete information for the dealings relevant to your entity at the stated regulated place. [↑](#footnote-ref-2)
10. Section 174 of the MPMR provides as follows:

***Review of plan—Act, s 93***

(1) For section 93(3)(b) of the Act, the following times are prescribed for a substance management plan for a regulated place relating to medicines—

(a) as soon as practicable after a review incident happens in relation to the regulated place; and

(b) at least every 5 years after—

(i) the day the substance management plan starts; or

(ii) if the plan is reviewed in any 5-year period after the plan starts—the day the plan was last reviewed.

(2) In this section—

***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’. [↑](#endnote-ref-9)
11. Section 174 of the MPMR provides as follows:

***Review of plan—Act, s 93***

(1) For section 93(3)(b) of the Act, the following times are prescribed for a substance management plan for a regulated place relating to medicines—

(a) as soon as practicable after a review incident happens in relation to the regulated place; and

(b) at least every 5 years after—

(i) the day the substance management plan starts; or

(ii) if the plan is reviewed in any 5-year period after the plan starts—the day the plan was last reviewed.

(2) In this section—

***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’. [↑](#endnote-ref-10)
12. See the definition of ‘review incident’ on page six of the DSSMP. [↑](#footnote-ref-3)
13. As per section 1.2 of the *Departmental Standard - Substance Management Plans for Medicines*, in the preparation (and review) of the SMP the following risks must be considered and addressed for each dealing in the SMP:

• diversion/theft or other loss

• fraud and tampering

• expiry, cold chain breach, or other substance quality issue

• improper or inappropriate use

• public, patient, or environmental harm

• staff having insufficient training, qualifications or experience to perform an activity

• non-compliance with legislation or codes of practice. [↑](#endnote-ref-11)
14. Refer to the minimum requirements expressed in the DSSMP and ensure they are covered in the SMP. You can and should refer to existing processes and procedures in this SMP. [↑](#footnote-ref-4)
15. Refer to the requirements of the *Departmental Standard - Secure storage of S8 medicines* and legislative requirements regarding medicine stores and S8 safes. [↑](#footnote-ref-5)
16. If applicable, Refer to the *Departmental Standard - Requirements for an electronic prescription management system.* [↑](#footnote-ref-6)
17. If applicable, refer to the *Departmental Standard - Requirements for an electronic prescription management system.* [↑](#footnote-ref-7)
18. It is not necessary to document disposal of waste from hazardous poisons, pesticides or fumigants (section 47 MPA) in this SMP, as this SMP relates to medicines only. [↑](#footnote-ref-8)