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] to assist *responsible persons*[i] make a Substance Management Plan (**SMP**) for a *regulated place*[ii] 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[iii] 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[iv] before any *dealings*[v] [e.g. possessing, manufacturing, prescribing or administering] are undertaken with a *regulated substance*[vi] [e.g. S4 and S8 medicines] at a *regulated place*. Further, section 93(2)[vii] 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)*.

[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.

General information

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

[2] Not all dealings will be relevant to this SMP. Only complete information for the dealings relevant to your entity at the stated regulated place.

	MPA / MPMR requirement	Details	DSSMP reference	Included
	[s.93(3) of the MPA]			

Responsible person making this SMP

	MPA / MPMR requirement	Details	DSSMP reference	Included
1.	Name of responsible person making this SMP *[Schedule 17 of the MPMR - who is a responsible person]*			☐ Yes ☐ No
2.	Designation/role of responsible person *[Schedule 17 of the MPMR - who is a responsible person]*			☐ Yes ☐ No
3.	Date this SMP must be reviewed by *[s.93(3)(b) of the MPA and s.174[viii] of the MPMR]*		1.3	☐ Yes ☐ No
4.	Signature of responsible person listed in section 1 above	*Insert signature here – digital signature is acceptable.*		☐ Yes ☐ No
5.	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

	MPA / MPMR requirement	Details	DSSMP reference	Included
6.	Review *[s.93(3)(b) of the MPA and s.174[ix] 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[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

[3] See the definition of 'review incident' on page six of the DSSMP.

How known and foreseeable risks with regulated substances are to be managed[x]

Dealing	Outcomes required by the DSSMP	Details[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.*	2.3		☐ Yes ☐ No

[4] 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.

Dealing	Outcomes required by the DSSMP	Details[4]	DSSMP reference	MPA/MPMR reference	Included
		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			
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.*	3.3		☐ Yes ☐ No

Dealing	Outcomes required by the DSSMP	Details[4]	DSSMP reference	MPA/MPMR reference	Included
		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			
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[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

[5] Refer to the requirements of the *Departmental Standard - Secure storage of S8 medicines* and legislative requirements regarding medicine stores and S8 safes.

Dealing	Outcomes required by the DSSMP	Details[4]	DSSMP reference	MPA/MPMR reference	Included
	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* • *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.*	4.5		☐ Yes ☐ No

Dealing	Outcomes required by the DSSMP	Details[4]	DSSMP reference	MPA/MPMR reference	Included
		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			
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

Dealing	Outcomes required by the DSSMP	Details[4]	DSSMP reference	MPA/MPMR reference	Included
	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[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		6.1		☐ Yes ☐ No

[6] If applicable, Refer to the *Departmental Standard - Requirements for an electronic prescription management system.*

Dealing	Outcomes required by the DSSMP	Details[4]	DSSMP reference	MPA/MPMR reference	Included
	animal by appropriate persons				
	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* • *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

Dealing	Outcomes required by the DSSMP	Details[4]	DSSMP reference	MPA/MPMR reference	Included
	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.[7] Otherwise, delete this section.*	7	Definitions in Schedule 1 of the MPA	

[7] If applicable, refer to the *Departmental Standard - Requirements for an electronic prescription management system.*

Dealing	Outcomes required by the DSSMP	Details[4]	DSSMP reference	MPA/MPMR reference	Included
	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* • *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)*	7.3		☐ Yes ☐ No
	Incidents, including potential incidents, are deterred, identified and	*Include details of reporting pathways - who incidents must be reported to, what incidents must*	7.4		☐ Yes ☐ No

Dealing	Outcomes required by the DSSMP	Details[4]	DSSMP reference	MPA/MPMR reference	Included
	reported in a timely manner	*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			
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	*https://www.health.qld.gov.au/clinical-practice/guidelines-*	8.3		☐ Yes ☐ No

Dealing	Outcomes required by the DSSMP	Details[4]	DSSMP reference	MPA/MPMR reference	Included
	reported in a timely manner	*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			
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[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

[8] 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.

Dealing	Outcomes required by the DSSMP	Details[4]	DSSMP reference	MPA/MPMR reference	Included
	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

[i] 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.

[ii] 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.

[iii] 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.*

[iv] See section 92 definition above.

[v] 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).

[vi] Section 17 of the MPA defines 'regulated substance' as follows:
A ***regulated substance*** is a medicine, poison, prohibited substance, fumigant or pesticide.

[vii] 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.

[viii] 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'.

[ix] 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'.

[x] 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.