Queensland Health

Factsheet – Universities using regulated poisons

Who is this factsheet for?

This factsheet is for persons who hold an approval to use regulated poisons for non-therapeutic purposes (e.g. research, teaching or analysis) at universities under the Health (Drugs and Poisons) Regulation 1996 (HDPR) and who intend to continue to hold an approval under the *Medicines and Poisons Act 2019* (the MPA) which replaced the HDPR on 27 September 2021.

This factsheet may also be used by persons seeking to apply for a general approval to use regulated poisons for research, teaching or analysis at universities under the MPA.

How will it affect me?

- Regulated poisons include S2, S3, S4, S7 and S8 poisons when not used or intend for use for therapeutic purposes and prohibited substances (S9 and S10 substances).
- A general approval is required to deal (buy, possess, use and dispose) with regulated poisons, other than non-restricted S7 poisons, for non-therapeutic purposes. Restricted S7 (RS7) poisons are prescribed in schedule 1 of the Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021 (the Poisons Regulation).
- S8, S9 and S10 substances used for non-therapeutic purposes are classed as high-risk poisons. Users of high-risk poisons will continue to be required to keep a register for high-risk poisons to record all dealings with theses poisons from purchase to disposal.
- Universities are encouraged to apply for an entity level general approval which can be done at a school, departmental or institute level within the university. An entity level general approval will cover all individuals having dealings with regulated poisons within that area. This includes drugs officers, researchers and their supervisors.
- The entity general approval holder is required to have systems and processes in place to ensure appropriate governance, risk management, and legislative compliance. For example, the head of a department within the university may apply for a general approval to deal with regulated poisons. They will be responsible for ensuring that all users covered by the general approval are competent, carry out their activities with the regulated poisons in a safe and compliant manner.
- The holder of a general approval, e.g. department or a school within the university is required to have a Substance Management Plan (SMP) for dealings with high risk poisons and RS7s. An SMP is a document that identifies and addresses the risks associated with carrying out regulated activities. *Note: An SMP may form a part of other plans or systems including quality and safety management systems*.
- The SMP must comply with the Departmental Standard '*Substance management plans for regulated poisons – version 1.*' A '*Substance Management Plan Checklist – research, analysis & teaching*' is available to assist the development of an SMP. General approval holders will be given until 26 September 2022 to prepare and implement SMPs.

- The general approval holder is required to comply with the standard conditions under the MPA. These include ensuring that regulated poisons are stored and transported to prevent unauthorised access.
- Authorisations under the HDPR will transition as closely as possible to a new authority under the MPA. The authority holder may apply for an amendment to their authority to add additional substances.
- The table below summarises how the authorisations for a manufacturing licence under the HDPR will transition to the new MPA.

Purchase orders, storage, registers and disposal

- The Poisons Regulation requires authority holders for high risk poisons to implement measures to ensure the purchase, storage and transport of such poisons is undertaken in a safe and secure manner and is restricted to persons authorised under the SMP.
- A High-Risk Poison Register (HRPR), which records all dealings in relation to high-risk poisons, must be established as part of the SMP. The HRPR register may be electronic or paper based and must include details such as date, name, form, strength and amount of poison, nature of dealing etc. to be able to reconcile the amount of poison received, applied, supplied or disposed of.
- The Poisons Regulation requires that waste from high risk poison is destroyed under the supervision of an inspector under the MPA or another person authorised by the Chief Executive.
- Loss or exposure (requiring medical treatment) to high risk poisons must be reported to the Chief Executive as soon practicable. If reported orally, the authority holder must submit a written report within seven days (7) of the notification.

Exemptions for reference materials

- Under the Poisons Regulation analytical reference materials are exempt from requiring an authority due to the low risk associated with their use.
- Universities using reference materials in analytical laboratories may purchase and use reference materials containing up to 1 g of regulated poisons without an approval. The reference materials must be manufactured by an accredited laboratory as specified in section 13 of the Poisons Regulation.

How to apply for a licence

To apply for a general approval, go to '[Poisons general approval application forms]'.

For further information

- [Relevant factsheets and supporting document]
  - Transitional arrangements and Poisons terms
  - Substance Management Plan Checklist – research, analysis & teaching
- [Departmental Standard]
  - Substance management plans for regulated poisons – version 1

Transition of authorities under the *Medicines and Poisons Act 2019*

Person	Poison	Type of authority under HDPR	Type of authority Under MPA	Scope
University drug officers	Regulated poisons[1] (excluding non-restricted S7 poisons)	Approvals for one or more Regulated poisons (S7 poisons in appendix 7 of the HDPR), S8, S9 & S10 substances	General approval for regulated poisons issued to the school, department or Institute	• Authorised to buy, possess, supply and dispose of waste. • Entity (e.g. school or dept) must have a substance management plan which may cover multiple sites and personnel at multiple sites • Drugs officer and researchers authorised under the SMP • Exemptions apply for use of reference materials[2]
University researchers or teachers	Regulated poisons[3] (excluding non-restricted S7 poisons)	Approvals for one or more Regulated poisons (S7 poisons in appendix 7 of the HDPR), S8, S9 & S10 substances	General approval for regulated poisons to the school, department or Institute	
Entity (university)	Regulated poisons[4] (excluding non-restricted S7 poisons)	Approvals for one or more Regulated poisons (S7 poisons in appendix 7), S8, S9 & S10 substances	General approval for regulated poisons	

[1] The following regulated poisons - S2, S3, S4, S8 poisons; RS7 poisons; S9 and S10 prohibited substances under the MPA

[2] Refer to section 13 exemption for reference materials under the Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021

[3] The following regulated poisons - S2, S3, S4, S8 poisons; RS7 poisons; S9 and S10 prohibited substances under the MPA

[4] The following regulated poisons - S2, S3, S4, S8 poisons; RS7 poisons; S9 and S10 prohibited substances under the MPA