Factsheet – Manufacturing licence – poisons

Who is this factsheet for?

This factsheet is for persons who hold a licence to manufacture regulated poisons under the Health (Drugs and Poisons) Regulation 1996 (HDPR) and who intend to continue to hold a licence under the *Medicines and Poisons Act 2019* (the MPA) which replaced the HDPR on 27 September 2021.

This fact sheet may also be used by persons seeking to apply for a manufacturing licence for hazardous poisons under the MPA.

How will it affect me?

- A manufacturing licence will be required to manufacture **hazardous poisons** under the MPA. Hazardous poisons include substances in schedules 2, 3, 4, 7 and 8, under the Poisons Standard, when not used or intended for use for therapeutic purposes.
- A manufacturing licence will allow the holder to manufacture, buy, possess, supply primarily by wholesale, and dispose of waste from the final manufactured product and precursor substances.
- Queensland-based manufacturers of poisons that are licensed by the Australian Pesticides and Veterinary Medicines Authority (APVMA) will no longer be required to hold a separate manufacturing licence in Queensland for those products covered by the APVMA licence. However, the manufacture of APVMA-registered S7 products (e.g. agricultural chemicals such as paraquat (herbicide)), which are not captured under the APVMA licensing requirements, will require a manufacturing licence under the MPA.
- The poison must be manufactured under the supervision of a manufacturing supervisor who holds qualifications stated in the Departmental Standard '*Competency requirements for authority holders dealing with poisons.*'
- The manufacturers may also apply for an approval to manufacture prohibited substances (S9 and S10 substances under the Poisons Standard).
- The holder of a manufacturing licence who operates from multiple sites may request one licence covering all sites, rather than having separate licences for each site. The licence fee will be calculated based on the number of sites under the licence.

  Authorisations under the HDPR will transition as closely as possible to a new authority under the MPA. A manufacturer can apply for an amendment to their authority to manufacture additional substances. The table below summarises how the authorisations for a manufacturing licence under the HDPR will transition to the new MPA.

Substance management plans (SMP)

- The holder of a manufacturing licence will be required to have a Substance Management Plan (SMP) which identifies and addresses the risks associated with manufacturing the regulated poisons. *Note: An SMP may form a part of other plans or systems including quality and safety management systems or those used to demonstrate compliance with the AgVet scheme.*
- The SMP must comply with the Departmental Standard: '*Substance management plans for regulated poisons.*' Guidelines and templates for an SMP will be made available.
- Authority holders will have up to 26 September 2022 to comply with new obligations such as preparation of a substance management plan under the MPA.

Quality control, batch manufacturing records and security

- The Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021 requires the holder of a manufacturing licence to implement measures to ensure that the manufactured poisons are fit for purpose and free from contamination.
- The holder of a manufacturing licence is required to keep batch manufacturing records which include details such as materials; procedures and controls used in manufacturing the batch of poison; tests carried out during the processing of the final product; and tests for shelf life, etc.
- Licensees must also ensure that adequate physical or electronic security measures are implemented while storing high-risk poisons.

How to apply for a licence

To apply for a licence to manufacture poisons, go to '<u>Poisons licence application forms and fees</u>'.

For further information

- <u>Relevant factsheets</u>
  - Wholesale licence – poisons
  - Transitional arrangements
  - Poisons terms
- <u>Departmental Standard</u>
  - Substance management plans for regulated poisons – version 1
  - Competency requirements for authority holders dealing with poisons – version 1

Table 1. Transition of authorities under the *Medicines and Poisons Act 2019*

Person	Substance	Type of authority under HDPR	Type of authority under MPA	Scope
Poison manufacturers	Hazardous poisons S2, S3, S4, S7 & S8	Poison manufacturer licence for one or more S2, S3 or S7 substances	Manufacturing licence for one or more of S2, S3, or S7 poisons May apply to add S4 or S8 poisons	• Authorised to buy, manufacture, possess, supply (primarily by wholesale) and dispose of waste. • Must have a substance management plan • Must appoint a manufacturing supervisor to oversee the manufacturing of poisons
Poison manufacturers	S9 & S10 prohibited substances	General Approval	Manufacturing licence or General approval for S9 and/or S10 substances	• Authorised to buy, manufacture, possess, supply (primarily by wholesale) and dispose of waste. • Must have a substance management plan • May need to appoint a manufacturing supervisor if required as a condition of General Approval.