Medicines and Poisons Act 2019

Factsheet – current as at September 2021

Manufacturers – medicines

What is manufacture?

Under section 21 of the *Medicines and Poisons Act 2019* (MPA), manufacture a regulated substance (a medicine, poison or prohibited substance)—

a) means carry out any activity using any substance for the purpose of making the regulated substance; and
b) includes any process or step undertaken to produce the regulated substance or to prepare the regulated substance for supply to the public or a person, including for administration to an animal.

Examples for paragraph (b)—

- testing batches of manufactured substances
- compounding medicines in preparation for supply
- repackaging poisons for supply

How does the scheme regulate manufacturers?

The MPA regulates the manufacture of medicines, poisons and prohibited substances (collectively 'regulated substances') in Queensland jointly with Commonwealth agencies including the Therapeutic Goods Administration (TGA), the Office of Drug Control (**ODC**) or the Australian Pesticides and Veterinary Medicines Authority (APVMA).

To reduce duplication and simplify administration, section 50 of the MPA provides that persons who hold a permission to manufacture regulated substances granted under a Commonwealth law (e.g. a licence, permit or other authority from the TGA, ODC or APVMA) **do not** require a manufacturing licence under the MPA to manufacture the same substances at the same place within the same conditions – see Commonwealth law manufacturers fact sheet for more information.

Where a person is not a Commonwealth law manufacturer, the person must be authorised under the MPA to manufacture, either as an 'approved person' authorised to manufacture by compounding (e.g. a pharmacist or a veterinary surgeon), or as the holder of, or a person working under, a manufacturing licence.

What is a manufacturing licence?

A manufacturing licence is a licence that authorises a person to carry out the following regulated activities with a regulated substance stated in the licence—

a) manufacture of the regulated substance at a place stated in the licence;
b) possession of the regulated substance at a place stated in the licence;
c) possession of the regulated substance for transportation to a place where a person is authorised, or where it is not unlawful for a person, to possess the substance;
d) supply of the regulated substance, primarily by wholesale, to—
   (i) if the licence states a class of persons to whom the substance may be supplied—a person who is a member of the class; or
   (ii) otherwise—a person who is authorised, or for whom it is not unlawful, to carry out a regulated activity with the substance;
e) disposal of waste from the regulated substance.

Furthermore, a manufacturing licence may, if stated in the licence, authorise—

a) the buying and possession of another stated regulated substance for manufacturing the regulated substance to be manufactured under the licence (the final product); or
b) the manufacture of, and disposal of waste from, another stated regulated substance that is a by-product of the manufacture of the final product.

Are there different kinds of manufacturing licences?

Yes. Licences to manufacture medicines are dealt with under the Medicines and Poisons (Medicines) Regulation 2021 (MPMR). Licences for manufacturing poisons and prohibited substances are dealt with under the Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021.

For medicines manufacturers, there are different requirements and standard conditions that apply to manufacturers of medicated feed and particular requirements for manufacturers of medicines other than medicated feed – see our fact sheet on medicated feed for more information.

What are the requirements for manufacturers?

There are requirements and standard conditions that apply to all manufacturing licences, as well as particular requirements and standard conditions that apply to manufacturers of medicated feed and particular requirements for manufacturers of medicines other than medicated feed.

Unless stated otherwise in the licence, the requirements and standard conditions specified in the following chapters of the MPMR, apply to manufacturing licences:

- chapter 3 of the MPMR ‘Standard conditions for substance authorities’ – part 2 ‘Manufacturing licences’ and part 6 ‘All substance authorities’;

- chapter 4 of the MPMR 'General requirements for dealings' – part 3 'Buying by giving purchase orders', part 4 'Supplying stock', part 5 'Possessing stock for delivery' and part 11 'Disposing of waste from diversion-risk medicines';
- chapter 5 of the MPMR 'Special requirements for dealings' – part 5 'Wholesale representatives'; and
- chapter 8 of the MPMR 'Offences' – part 2 'Secure storage systems', part 4 'Recording and keeping information', and part 5 'Reporting particular matters'.

What is a substance management plan and do manufacturers need to have one?

A substance management plan (SMP) is 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. SMPs must comply with the Departmental Standard: 'Substance management plans for medicines'. To support persons to meet this new requirement, a transitional period of one (1) year has been afforded to develop and implement a compliant SMP and guidelines and templates for SMPs will be made available.

An SMP for medicines is required for any place specified as a regulated place under the MPMR (Schedule 17). Accordingly, manufacturers will be required to prepare an SMP, as an SMP is required for 'a place where a medicine is manufactured under a manufacturing licence' and also 'a place where a medicine is stored for supply by wholesale'.

How do I apply for a manufacturing licence?

To apply for a manufacturing licence, please complete and submit an initial application form for a medicines manufacturing licence available on our website. For existing manufacturing licence holders (granted under the *Health (Drugs and Poisons) Regulation 1996* (HDPR)), please submit a renewal application (if required).

Are there fees for manufacturing licences?

Yes. A fee is required for a manufacturing licence and must be paid with an application. Separate fees are payable for licences that authorise the manufacture of S8 medicines and those that authorise the manufacture of an S2, S3 or S4 medicine. A processing fee is also payable for initial applications.

What if I currently have a manufacturing licence?

On the commencement of the MPA, what occurs concerning existing licences for manufacturing granted under the HDPR depends on the scenario:

- Licence holders that no longer need authorisation (i.e. Commonwealth law manufacturers) will have their HDPR licence cease on commencement. No fees will be refunded as there is no power under the HDPR or MPA to do so.

- Licence holders that manufacture medicated feed for animals will gain MPA manufacturing licences, authorising a holder to manufacture medicated feed:
  - with each substance that was approved under the HDPR licence
  - under the supervision of the person responsible for supervising the manufacture under the HDPR licence
  - at the place that was approved for manufacturing the feed under the HDPR licence
  - for the term of the HDPR licence.
- All other manufacturing licences granted under the HDPR will have their licences continue to be valid until expired, surrendered or cancelled, subject to the conditions of the licence and the HDPR continues to apply until such time.

Key points for manufacturers

- Most manufacturers will no longer need a Queensland manufacturing licence.
- Manufacturers of medicated feed (or S4 medicines) for a group of animals will still require a Queensland manufacturing licence, however there are new requirements specific to manufacturing medicated feed.
- To apply for a manufacturing licence, or to renew or amend a manufacturing licence, applicants must complete the relevant application form and submit the relevant fee.
- Existing licence holders will transition across to the MPA in different ways. For manufacturers of medicated feed, your licence will be taken to be a manufacturing licence issued under the MPA.
- Before 27 September 2022 (in one year), manufacturers must prepare an SMP setting out how known and foreseeable risks associated with any dealing with a regulated substance are to be managed at, or in connection with, any place where a medicine is manufactured under a manufacturing licence.

Associated guidance documents

- When is a wholesale licence required – factsheet
- Carriers, transport and logistics – factsheet
- Substance management plans – factsheet
- Medicinal cannabis wholesalers – factsheet
- Wholesale representatives – factsheet
- Commonwealth law manufacturers – factsheet
- Medicated feed – factsheet
- Fees – factsheet
- Categories of medicines and dealings – factsheet
- Substance authorities – factsheet
- Manufacturing licence (medicines) – initial application form and guideline
- Manufacturing licence (medicines) – renewal application form and guideline

Further information

For further information, contact the Healthcare Approvals and Regulation Unit (HARU): HARU@health.qld.gov.au.