Commonwealth law manufacturers

Who is a Commonwealth law manufacturer?

Under the Medicines and Poisons (Medicines) Regulation 2021 (**MPMR**), a 'Commonwealth law manufacturer' is defined in Schedule 14 as a person who is permitted under a Commonwealth law to manufacture a medicine.

How does the scheme regulate Commonwealth law manufacturers?

Section 50 of the *Medicines and Poisons Act 2019* (**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 Therapeutic Goods Administration, the Office of Drug Control or the Australian Pesticides and Veterinary Medicines Authority) **do not** require a manufacturing licence under the MPA to manufacture the same substances at the same place within the same conditions.

In addition to being able to possess and manufacture these regulated substances under the Act, Schedule 14 of the MPMR specifies that Commonwealth law manufacturers may carry out a dealing mentioned in column 1 of the table below with a medicine mentioned opposite in column 2, within the scope for the dealing mentioned in column 3.

	Column 1 – dealing	Column 2 – medicine	Column 3 – scope of dealing
1	supply	stock of any medicine	the stock is supplied— (a) the stock is supplied in compliance with any conditions of the person's permission under the Commonwealth law; and (b) the stock is supplied from a place where the person is permitted to manufacture the medicine under the Commonwealth law; and (c) the supply is not otherwise authorised under section 50 of the Act

	Column 1 – dealing	Column 2 – medicine	Column 3 – scope of dealing
2	give a purchase order (buy)	stock of any medicine	the purchase order is given for stock required for an activity permitted in the person's permission under the Commonwealth law, to the extent not otherwise authorised under section 50 of the Act

The following terms are important to consider in the context of the table above:

- **permission** includes approval, licence, permission or other authority issued under a law of the Commonwealth that permits the person to do something that is, or involves, carrying out a regulated activity with a regulated substance.
- **stock**, means—

  a regulated substance that is intended for supplying a place or a person who is authorised to carry out a regulated activity with the substance; or

  b a regulated substance that is not sold or dispensed to a particular person.

How does the MPA interact with a Commonwealth permission (e.g. licence)?

The MPA provides the framework that sits around the Commonwealth permission, rather than over the top of what is already covered by the permission. What this means is that although the manufacturing process is not directly regulated by Queensland, the activities that occur before, after and incidental to the manufacturing most likely will be. Commonwealth law manufacturers can therefore consider themselves by and large to be authorised wholesalers under the MPA. As such, Commonwealth licensees should ensure that they adhere to all requirements applying to wholesalers in relation to buying and supplying regulated substances, disposal of waste, secure storage of regulated substances, recording and keeping information, and reporting losses and other particular matters.

Commonwealth law manufacturers are also required to prepare a substance management plan (**SMP**), as an SMP is required for a place where a medicine is stored for supply by wholesale (as a regulated place under the MPMR). An 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. To allow sufficient time to meet this new requirement, a transitional period of one year has been afforded to persons to develop and implement a compliant SMP.

Key points for Commonwealth law manufacturers

- A commonwealth law manufacturer is a person permitted to manufacture a medicine under a Commonwealth law e.g. Therapeutic Goods Act 1989 (Cwlth), Narcotic Drugs Act 1967 (Cwlth), Agricultural and Veterinary Chemicals Code Act 1994 (Cwlth).
- A separate Queensland licence is not required under the MPA. You are authorised to manufacture and supply those substances stated in your Commonwealth licence, but only to the extent permitted by the Commonwealth licence.
- Although no licence is required under the MPA, you must comply with the other aspects of the scheme not explicitly covered by your licence, such as buying and selling, secure storage, labelling, keeping records and reporting.
- You must prepare a substance management plan (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, your premises. This is because an SMP is required for any place where a medicine is stored for supply by wholesale.

Associated guidance documents

- Wholesale suppliers – factsheet
- Carriers, transport and logistics – factsheet
- Substance management plans – factsheet

Further information

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