

# Medicines and Poisons Act 2019

Factsheet – current as at September 2021

## Wholesale representatives

### How are wholesale representatives authorised to deal with medicines?

Under previous legislation, the *Health (Drugs and Poisons) Regulation 1996 (HDPR)*, an individual who was a wholesale representative, employed by a licensed wholesaler either in Queensland or another State or Territory, required a licence.

The requirement for the individual to hold a licence is no longer required under the *Medicines and Poisons Act 2019 (MPA)* and the *Medicines and Poisons (Medicines) Regulation 2021 (MPMR)*.

Wholesale representatives are now 'authorised' to carry out certain regulated activities with regulated substances as an 'approved person' under the MPA and MPMR.

An approved person is a member of a class of persons prescribed under a regulation for a regulated activity with a regulated substance for the class of persons.

For wholesale representatives, such authority is given under Schedule 14, Part 4 of the MPMR. It will be their employer who has responsibility for the wholesale representative under the MPA.

### What dealings does this authority allow?

Under the MPMR, a wholesale representative is defined as a person employed to display or give starter packs of medicines for an entity that is authorised to supply medicines by wholesale (excluding a pharmacist) either under the MPA or a corresponding law. This means they will be employed by a licensed wholesaler or manufacturer either in Queensland or another State or Territory.

A starter pack means a small pack of the medicine supplied as a sample or at no cost.

Schedule 14, Part 4 of the MPMR allows the following dealings by a wholesale representative:

- Supply stock of an S2, S3 or S4 medicine in a starter pack, other than a monitored medicine, to a health practitioner or veterinary surgeon who is authorised to either prescribe the medicine or supply the medicine without a prescription from another practitioner. The health practitioner or veterinary surgeon must give a purchase order to the wholesale representative for the medicines to be supplied.

- Possess an S2, S3 or S4 medicine in a starter pack, other than a monitored medicine, so long as they do not possess more than is reasonably necessary to meet the business needs of the representative for a 6-month period.

## What is the role of the employer of the wholesale representative?

A wholesale representative must be employed by an entity that is authorised to supply medicines by wholesale.

That employer must:

- make and keep records showing the details of any stock they give to a wholesale representative;
- ensure each wholesale representative complies with the MPA and MPMR;
- ensure a person employed by the supplier (including a wholesale representative) complies with the 'Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 and 8' dated 1 April 2011 and published by the Therapeutic Goods Administration.

## Other obligations

A wholesale representative must comply with storage, record keeping and reporting requirements relevant to the schedule of the medicine.

## What happens to the wholesale representative licences?

Wholesale representative licences granted under the HDPR cease when the MPA commences as the *Health Act 1937* and HDPR are repealed. No fees will be refunded as there is no power under the HDPR or MPA to do so.

## Associated guidance documents

- Authorisations and activities – factsheet
- Substance authorities – factsheet
- Commonwealth law manufacturers – factsheet
- Wholesale suppliers – factsheet
- Carriers, transport and logistics – factsheet

## Further information

For further information, contact the Healthcare Approvals and Regulation Unit:

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