

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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