

Medicines Wholesalers, Opioid Dependency Treatment, and Pharmacy Medicines Rural Communities Licence Applications

This summary has been prepared by the Health Protection Service to assist applicants in understanding key application requirements and licensing provisions. Before completing the relevant licence application form, you are strongly urged to read the *Medicines, Poisons and Therapeutic Goods Act 2008 and Regulation 2008* (at www.legislation.act.gov.au) to ensure full compliance. Failure to comply with ACT legislation renders a person liable to prosecution.

Please ensure that:

- All the information on the form is correct;
- All sections of the form have been completed;
- All necessary documentation to support the licence application is attached;
- You have signed the required declarations on the form; and
- The required fee is being paid.

Cheques should be made payable to ACT Health. GST is not applicable under section 81-5 of the *A New Tax System (Goods and Services Tax) Act 1999 (Cth)*.

Key legislative provisions:

The key provisions for the application and granting of a licence are included in the *Medicines, Poisons and Therapeutic Goods Act 2008* Chapter 6 and the *Medicines, Poisons and Therapeutic Goods Regulation 2008* at part 14.4 for a medicines wholesalers licence, 14.5 for an opioid dependency treatment licence and 14.6 for a medicines rural communities licence. If granted, a licence will confer the following authorisations and responsibilities on the licence holder and to other persons authorised under the licence.

Medicines Wholesalers Licence

A medicines wholesalers licence-holder (unless otherwise stated) is authorised to:

- Issue a complying purchase order for a licensed medicine.
- Obtain a licensed medicine on a purchase order for sale by wholesale from the licensed premises.
- Possess a licensed medicine for sale by wholesale from the licensed premises.
- Sell a licensed medicine by wholesale (whether or not for resale) from the licensed premises to a person authorised to issue a purchase order for the medicine; or someone in another state who may obtain the medicine by wholesale under the law of the other state; or someone in another country who may lawfully obtain the medicine by wholesale in the other country (unless a prohibited export under the *Customs Act 1901*).
- Unless it is a controlled medicine, supply the licensed medicine in accordance with the *Medicines Australia Code of Conduct* provisions for product starter packs.

Authorisation conditions for medicines wholesalers licences:

- Dealings with a medicine will be carried out under the supervision of the approved individual stated in the licence.
- The licence-holder, their agents and employees must comply with the *Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4, and 8* and the *Medicines Australia Code of Conduct*.
- Medicine obtained under the licence is purchased on a complying purchase order.
- Medicine sold under licence is sold on a complying purchase order.

Opioid Dependency Treatment Licence

An opioid dependency treatment licence-holder or any other registered pharmacist at the licensed community pharmacy is authorised to:

- Issue a purchase order for buprenorphine or methadone.
- Obtain buprenorphine or methadone on a purchase order for administration at the licensed pharmacy.
- Possess buprenorphine and methadone.
- Dispense buprenorphine and methadone in accordance with a prescription.
- Supply buprenorphine and methadone to a registered nurse at the licensed pharmacy for administration at the licensed pharmacy under the supervision of a pharmacist and in accordance with a prescription.
- Administer buprenorphine and methadone at the licensed pharmacy in accordance with a prescription.

Authorisation conditions for opioid dependency treatment licences:

- The licence-holder must be a registered pharmacist in the ACT.
- Licence-holder must ensure that a person to whom buprenorphine or methadone is administered under the licence signs a written (including in electronic form) acknowledgement (approved name and brand of medicine administered; form, strength and quantity of medicine administered; and date medicine administered) that the medicine has been administered to that person.
- Buprenorphine and methadone must be obtained on a complying purchase order.

Pharmacy Medicines Rural Communities Licence

A pharmacy medicines rural communities licence-holder is authorised to:

- Issue a purchase order for a licensed pharmacy medicine stated in the licence for retail sale from the licensed premises.
- Obtain the licensed medicine on a purchase order for retail sale from the licensed premises.

- Possess the licensed medicine at the licensed premises for retail sale from the licensed premises.
- Sell the licensed medicine by retail from the licensed premises to customers attending in person (and not over the internet or by mail).

An employee of a pharmacy medicines rural communities licence-holder is authorised to:

- Possess a licensed medicine at the licensed premises for retail sale from the licensed premises.
- Sell a licensed medicine by retail from the licensed premises to customers attending in person (and not over the internet or by mail).

Authorisation conditions for rural community licences:

- The rural business must be more than 25km by the shortest practical route to the nearest community pharmacy.
- Customers must attend in person to the licensed premises to purchase the medicines.
- Pharmacy medicines must be purchased on a complying purchase order.
- The licensee must retain an invoice for the purchase of a pharmacy medicine for not less than 2 years.
- Pharmacy medicines must be sold in manufacturer's packs with complying labelling.
- Pharmacy medicines must be stored for retail sale so that public access to the medicines is restricted.
- Pharmacy medicines must be stored within the manufacturer's recommended storage temperature range and in any other environmental condition that is necessary to preserve the medicine's stability and therapeutic quality.
- Expired or unwanted medicines should be returned to the wholesaler for disposal. It is an offence under the Act to discard a medicine in a way that puts the health or safety of people at risk or is likely to cause damage to property or the environment.

Related Documents

Guidelines for Medicines Wholesalers and Pharmacy Medicines Rural Communities Licences

Accessibility

If you have difficulty reading a standard printed document and would like an alternative format, please phone 13 22 81.



If English is not your first language and you need the Translating and Interpreting Service (TIS), please call 13 14 50.

For further accessibility information, visit: www.health.act.gov.au/accessibility

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