Substance authorities

Medicines and Poisons Act 2019 – June 2022

Substance authorities

What is a substance authority?

One of the ways under the *Medicines and Poisons Act 2019* (**MPA**) for a person to be 'authorised' to carry out a regulated activity with a regulated substance is if they are the holder of a substance authority, being either a licence or approval, or they are another person acting under a substance authority.

To obtain a substance authority a person needs to apply for it.

What types of substance authorities are there?

For medicines, a **substance authority** is one of the following—

- a manufacturing licence; or
- a wholesale licence; or
- an S2 retail licence; or
- a prescribing approval which may be general in nature or one of the following specific sub types:
  - prescribing approval for approved opioids to treat a patient under the Queensland Opioid Treatment Program (QOTP)
  - prescribing approval for amfetamines and methylphenidate (psychostimulants)
  - prescribing approval to treat a patient with another restricted medicine (for non-specialists)
- a general approval, which may be general in nature or one of the following specific sub types:
  - general approval (acute health conditions at isolated sites).
  - general approval (emergency first aid).
  - general approval (emergency management of animals).

How do I apply for a substance authority?

A person must apply for a substance authority in the application form that has been approved for that purpose. Each different type of substance authority will have its own specific application form. Some sub types of prescribing or general approvals may have their own specific application form too.

Information about what each substance authority allows the holder to do, is outlined in the guidance material with the application form. The guidance material also provides details about the term of the substance authority, for example limited to 1 year or otherwise.

Each form provides details of how to submit it for consideration.

If a fee is required to be paid, the application is not valid until it is paid.

All forms are accessible from the relevant page: www.health.qld.gov.au/system-governance/licences/medicines-poisons/medicines

What are the fees for a substance authority?

Fees apply to licences, but not to approvals.

The fees for licences for medicines are listed in Schedule 19 of the MPMR. This should be referenced for up to date fee schedules as they may change from time to time. The correct fee is also listed in the relevant application form. Details about fees and refunds can be found in Chapter 9, Part 2 of the MPMR.

What happens after I make my application?

Once you have submitted your application on the correct form and with the correct fee (if applicable), your application will be considered by a delegate of the chief executive of Queensland Health.

If the delegate considers they require further information from the applicant, they will send a notice requesting the additional information. The additional information must be returned by the due date, otherwise the application will be taken to be withdrawn.

The delegate will have 90 days from receipt of the application (or 90 days from receipt of any further information requested) to consider and decide whether or not to grant the substance authority.

If the application is granted, then a notice and the substance authority will be sent to you. The substance authority will be subject to standard conditions (which are specified in the MPMR and advice of these will accompany the substance authority) but may be subject to an additional or changed condition where the delegate deemed this appropriate. Any changed or additional conditions will be stated on the substance authority, so applicants should review the instrument carefully, including for renewals.

If the application is refused, then the applicant will receive a notice outlining the reasons for the refusal and any appeal mechanisms available (refer to factsheet on Review of Decisions).

The above processes also apply when making an application for a renewal or amendment of a substance authority.

Substance authority register

All substance authorities that have been granted will be listed on the substance authority register. The substance authority register contains:

(a) the identification number allocated to the authority;

(b) the name of the holder of the authority;

(c) if the holder of the authority trades as a business—

  (i) the business or trading name of the holder; and

  (ii) the name of the person responsible for overseeing or supervising the regulated activity authorised under the authority;

(d) the type of authority or the regulated activity authorised under the authority;

(e) the term of the authority and the day the authority ends;

(f) the postcode of the place where the regulated activity under the authority will be carried out.

The register may be published by the chief executive on the department's website and information contained in the register may be disclosed to particular persons.

Associated guidance documents

- Authorisations and activities – fact sheet
- Manufacturers – fact sheet
- Commonwealth law manufacturers – fact sheet
- Medicated feed – fact sheet
- Wholesale suppliers – fact sheet
- When is a wholesale licence required by the MPA – fact sheet
- Medicinal cannabis wholesalers – fact sheet
- Carriers, transport and logistics – fact sheet
- Fees (medicines) – fact sheet
- General approvals – fact sheet
- Acute health conditions at isolated sites – fact sheet
- Emergency first aid – fact sheet
- Emergency management of animals – fact sheet
- Immunisation programs – registered nurses – fact sheet
- Reviews of decisions – fact sheet

Further information

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

To submit an application for a licence or approval for medicines, submit the required application and supporting documents to: medicines.applications@health.qld.gov.au