Application form – Manufacturing licence (medicines) – Renewal application

August 2022

Information about this application form

This application form is to be used to apply to renew a licence to **manufacture medicines** and prohibited substances for therapeutic use under section 82 of the *Medicines and Poisons Act 2019* (**MPA**).

To renew a licence to manufacture poisons or prohibited substances for non-therapeutic use, please complete the Application for a manufacturing licence – poisons.

THIS FORM CAN ONLY BE USED FOR LICENCES GRANTED UNDER THE MPA.

Applicants seeking to renew a licence granted under the *Health (Drugs and Poisons) Regulation 1996* (**HDPR**) must complete an **initial application** in the first instance, however only the renewal fee is payable.

Applying for a renewal of a manufacturing licence

Timing

A renewal application must be made using the attached application form within the period starting 90 days before the term of the substance authority ends (s82(2) of the MPA). In exceptional circumstances, a late application may be accepted up to 30 days after the term of the current authority ends (s82(3) of the MPA).

If an application to renew a substance authority is accepted, the authority continues in force until the application is decided or taken to have been withdrawn (s85 the MPA).

Under chapter 3, part 3, division 4 of the MPA, applications are decided within 90 days of the application (final consideration day – section 86 of the MPA), or the latest day the chief executive of Queensland Health (or delegate) receives information from the applicant (section 89 of the MPA), unless a later date is agreed (s88 of the MPA). Applications not decided by this time are taken to have been refused (s89(4) of the MPA).

Fees

Licences may authorise the holder to carry out regulated activities at multiple sites, however a separate licence fee is payable for each site. The fees payable for medicines licences are in accordance with chapter 9, part 2 and schedule 19 of the *Medicines and Poisons (Medicines) Regulation 2021* (**MPMR**). Where a fee has been paid for a licence to manufacture poisons at

the same site (under the *Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021*), no fee is payable for an S2, S3 or S4 medicines manufacturing licence.

There is a fee payable per site per year for a renewal application for a manufacturing licence for an S8 medicine and a separate fee payable per site per year for a renewal application for a manufacturing licence for an S2, S3 or S4 medicine. Where a manufacturing licence covers both S8 medicines and S2, S3 or S4 medicines at a site, then both fees are payable.

Payment of the correct application fee is required for an application to be valid. See our page on fees, which contains the current schedule of fees and further information on calculating the fee payable including a simple calculator.

Once an application is ready to submit, an applicant should **submit the payment prior to submitting the application** using BPOINT: www.bpoint.com.au/pay/qldmedpoisonlicences. Applicants should enter the following details:

Biller Code: 1616440 - Payment of Medicines and Poisons Act 2019 Fees

Application number: Your application number as advised to you by us

Contact name: Your name and the name of the entity applying for the licence (licensee)

Contact phone / email: Contact details of the person authorised to submit the application

Proof of payment (a receipt) must be attached as part of an application.

Assessment

The chief executive of Queensland Health (or delegate) must decide whether or not to grant a renewal application. In determining the application, the matters described in section 83 of the MPA may be taken into consideration, including any changes to matters that were considered by the chief executive of Queensland Health (or delegate) when the substance authority was granted.

Queensland Health assesses all information relevant to an application including:

- whether a relevant person under the application is a fit and proper person, which may take into consideration any prior compliance history, and also the background, skills and qualifications of persons who will be responsible for overseeing activities to be carried out or will have access to regulated substances;
- which regulated substances are to be included in the substance authority;
- proposed activities and locations where regulated substances are to be used and stored; and
- the documented governance arrangements in place relevant to the substance authority.

To apply, submit via email the **attached** application form, accompanied by all supporting documents (certified where required) including proof of payment, to:

The Chief Executive, Queensland Health
c/o Healthcare Approvals and Regulation Unit (HARU)
medicines.applications@health.qld.gov.au

Queensland Government

Queensland Health

Medicines and Poisons Act 2019

MPA-82MML
Version 2:08/2022

APPLICATION TO RENEW A MANUFACTURING LICENCE – MEDICINES

Privacy statement – please read carefully

Personal information collected by Queensland Health is handled in accordance with the *Information Privacy Act 2009*. Queensland Health is collecting your personal information on this form under authority of the *Medicines and Poisons Act 2019*. The information is being collected to ensure that health risks arising from the use of regulated substances are appropriately managed. All personal information will be securely stored and only accessible by Queensland Health. Your personal information will not be disclosed to any other third parties without consent unless the disclosure is authorised or required by law. For information about how Queensland Health protects your personal information or to learn about your right to access your own personal information, please see our website at www.health.qld.gov.au/global/privacy.

Section 1 – Applicant (entity) details

*Provide **current** details of the substance authority to be renewed (to update details, submit an amendment application)*

Substance authority (licence) reference		Name of substance authority holder	
Entity phone		Entity email	

Section 2 – Changes to matters (s83 MPA)

Provide details of any changes to matters considered by the chief executive of Queensland Health (or delegate) when the substance authority was granted – this is for consideration of this application. In addition to describing any changes for the purpose of this renewal, please note that you are required under s42 of the Medicines and Poisons (Medicines) Regulation 2021 (MPMR) to give a notice to the chief executive of Queensland Health (or delegate) of the changes in the approved form Notification of particular changes affecting authority (MPMR-42). Should you wish to amend your licence, submit an amendment application (MPA-78MML).

Changes to premises e.g. storage, security of places where medicines are to be manufactured

Changes to personnel e.g. manufacturing supervisors, management and key staff

Changes to substances being manufactured

Changes to operations

APPLICATION TO RENEW A MANUFACTURING LICENCE – MEDICINES

Section 3 – Substance management plan (s93 MPA, Chapter 6 and Schedule 17 MPMR)

The responsible person for a place where a medicine is manufactured under a manufacturing licence (regulated place), must make a substance management plan before any regulated activity happens with a regulated substance at, or in connection with, a regulated place, unless the person has a reasonable excuse.

The substance management plan must:

- state the following:
  - the day the plan starts;
  - the location of the place;
  - the regulated activities and regulated substances to which the plan applies;
  - the persons (staff) to whom the plan applies; and
- address the matters specified in the Departmental standard: 'Substance management plans for medicines' under the MPMR; and
- be written in a way that is likely to be easily understood by staff.

The responsible person must ensure the substance management plan:

- is made available to staff when it is made; and
- is reviewed at the time specified by the MPMR.

NOTE: A SUBSTANCE MANAGEMENT PLAN IS NOT REQUIRED UNTIL 27 SEPTEMBER 2022 (s280 MPA)

Have you prepared a substance management plan that meets (and continues to meet) the criteria above and the Departmental standard: 'Substance management plans for medicines' of the MPMR?	☐ Yes	☐ No

Section 4 – Duration of the substance authority (s69 MPA)

Please specify the desired term or end date for the renewal of the manufacturing licence, providing justification for another term. Applicants should note that typically manufacturing licences will not be issued for more than two years.

Please specify the term of licence sought:

☐ 1 year ☐ 2 years ☐ Another term, please specify

Section 5 – Additional information and attachments

Provide any additional information (new/updated) to support your application

Provide/specify which attachments are attached to support this application:

☐ **Proof of payment** made using the BPOINT platform

☐ A current **company extract** from the Australian Securities and Investments Commission (ASIC)

☐ Other **relevant documents** please specify

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Section 6 – Consent and declaration

By making this application:

- ☐ I declare that I have authority to make this application on behalf of the applicant.
- ☐ I consent to Queensland Health making enquiries of, and exchanging information with, the authorities of any Australian state or territory, or of the Commonwealth, regarding any matters relevant to this application. If relevant information cannot be obtained from other entities, Queensland Health will determine the application on the information available.
- ☐ I consent to Queensland Health collecting, using and disclosing information submitted with this application including to, for example, the Medicines Expert Advisory Group (or similar) for the purpose of determining this application and any matters relevant to the related substance authority.
- ☐ I declare that, to the best of my knowledge, all information provided in and with this application form is true and correct in every detail.
- ☐ I understand that if anything has been stated in this application form, or in an attachment provided with this application, that is false or misleading, any substance authority granted may be suspended or cancelled.

Full name of applicant or authorised representative (where applicant is a body corporate or another entity)	Designation (position) of applicant or authorised representative

Signature of applicant or authorised representative (where applicant is a body corporate or another entity)	Date (DD/MM/YYYY)

Clear form