Queensland Health

Application form – Manufacturing licence (medicines) – Amendment application

August 2022

Information about this application form

This application form is to be used to apply to amend a licence to **manufacture medicines** and prohibited substances for therapeutic use under section 78 of the *Medicines and Poisons Act 2019* (**MPA**).

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

Applying for an amendment of a manufacturing licence

Fees

Licences may authorise the holder to carry out regulated activities at multiple sites, however a separate licence fee is payable for each site. If a new site is added as an amendment to the licence, then an additional fee is payable for the period remaining until expiry. 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 an initial application for a manufacturing licence for an S8 medicine and a separate fee payable per site per year for an initial 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 per year per site.

To pay for an application, applicants must **first submit the attached** application form, accompanied by all supporting documents (certified where required) to:

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

Once an application is received, if an additional site is to be added to the licence, then applicants will be given a biller code and a reference number to pay the applicable fees electronically via the BPOINT platform. To avoid delays, applicants should promptly send through their proof of payment.

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.

Assessment

The chief executive of Queensland Health (or delegate) must decide whether or not to grant an amendment application. In determining the application, the matters described in section 79 of the MPA may be taken into consideration.

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.

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).

Queensland Government

Queensland Health
Medicines and Poisons Act 2019

MPA-78MML
Version 2:08/2022
APPLICATION TO AMEND 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.

INSTRUCTIONS:

Sections 1 and 8 must be completed. In addition to this, please complete the relevant sections for which amendment is sought indicating whether the information is to be added, removed or updated.

Section 1 – Applicant (entity) details

*Provide **current** details of the substance authority holder seeking the amendment*

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

Section 2 – Changes to substance authority holder details

*Provide **updated** details of the substance authority holder. Note that substance authorities are not transferrable.*

Name of entity (e.g. individual (surname, given names), partnership, company, incorporated association)			
Trading name (if applicable)		ACN (if applicable)	
Entity phone		Entity email	
Postal address		Town/ Suburb	P/C

Section 3 – Changes to relevant persons (s76 MPA)

To add or update details for relevant persons e.g. partners, executive officers of a body corporate, manufacturing supervisors etc., indicate the changes below and attach a Details of relevant person form (MPA-76) for the person to be added/updated.

To remove a relevant person, provide details below. If more space is required, please attach further details.

Partners/Executive officers (directors, CEO etc.) to add or update (attach relevant person form for each)			
Name		☐ Add	☐ Update
Name		☐ Add	☐ Update
Partners/Executive officers (directors, CEO etc.) to remove			
Name		☐ Remove	
Name		☐ Remove	
Manufacturing supervisors to add or update (attach relevant person form for each)			
Name		☐ Add	☐ Update
Name		☐ Add	☐ Update
Manufacturing supervisors to remove			
Name		☐ Remove	
Name		☐ Remove	

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Section 4 – Changes to premises where manufacturing and possession are to occur (s63(1) MPA)

Provide details of changes to the physical address where substances are to be manufactured and stored. If more space is required, please attach further details.

Manufacturing site 1

☐ Add	☐ Remove	☐ Update

Site Address		Town /Suburb		P/C	

Name of entity conducting operations at this location	

Contact person		Phone		Email	

HDPR / Commonwealth manufacturing licence details for this location (if applicable)	

Have you applied for, or do you currently hold, a licence to manufacture poisons or prohibited substances (non-therapeutic use) at this location?	☐ Yes	☐ No

If yes, provide details e.g. licence number/application number or date	

Does the storage at this location meet the requirements of ss197-199 of the MPMR?	☐ Yes	☐ No

Manufacturing site 2

☐ Add	☐ Remove	☐ Update

Site Address		Town /Suburb		P/C	

Name of entity conducting operations at this location	

Contact person		Phone		Email	

HDPR / Commonwealth manufacturing licence details for this location (if applicable)	

Have you applied for, or do you currently hold, a licence to manufacture poisons or prohibited substances (non-therapeutic use) at this location?	☐ Yes	☐ No

If yes, provide details e.g. licence number/application number or date	

Does the storage at this location meet the requirements of ss197-199 of the MPMR?	☐ Yes	☐ No

Section 5 – Changes to substances proposed to be manufactured under this licence (s63(1) MPA)

Provide details of changes to the final (finished) products to be manufactured, with reference to the schedule and descriptor (name) used in the most current Poisons Standard.
Where a final product is unscheduled (due to, for example, pack size, use, form, strength etc.) state "unscheduled", name the product and provide all other details.

A. Substances to be added

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/Volume/Use
-				
-				
-				

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A. Substances to be added (continued)

-				

B. Substances to be removed

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/Volume/Use
-				
-				
-				
-				

C. Substances to be updated

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/volume/use
-				
Change (for substance above)				
Schedule	Poisons Standard descriptor	Form	Strength	Pack size/volume/use
-				
Change (for substance above)				
Schedule	Poisons Standard descriptor	Form	Strength	Pack size/volume/use
-				
Change (for substance above)				
Schedule	Poisons Standard descriptor	Form	Strength	Pack size/volume/use
-				
Change (for substance above)				

Section 6 – Changes to substances required for manufacturing (s63(2) MPA)

Provide details of any changes to scheduled substances required to manufacture the final products (i.e. raw ingredients).

A. Substances to be added

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/Volume/Use
-				
-				
-				
-				

B. Substances to be removed

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/Volume/Use
-				
-				
-				
-				

C. Substances to be updated

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/volume/use
-				

Change (for substance above)

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/volume/use
-				

Change (for substance above)

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/volume/use
-				

Change (for substance above)

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/volume/use
-				

Change (for substance above)

Section 7 – Changes to manufacture and disposal of waste from by-products (s63(2) MPA)

Provide details of any changes to scheduled substances that are by-products produced from the manufacture of the final products. State which final product the by-product relates to and relevant details, including form and strength of the substance where this impacts on the scheduling.

A. Substances to be added

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/Volume/Use
-				
-				
-				
-				

B. Substances to be removed

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/Volume/Use
-				
-				
-				

C. Substances to be updated

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/volume/use
-				

Change (for substance above)

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/volume/use
-				

Change (for substance above)

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/volume/use
-				

Change (for substance above)

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/volume/use
-				

Change (for substance above)

Section 8 – Changes to supply of substances by wholesale (s63(1) MPA)

*Provide **updated** details of the classes of persons to whom you intend to supply these substances. Select all that apply.*

☐ Manufacturers	☐ Podiatrists
☐ Wholesalers	☐ Optometrists
☐ Other substance authority holders	☐ Nurse practitioners
☐ Farmers	☐ Midwives
☐ Veterinary surgeons	☐ Other health practitioners, please specify
☐ Pharmacists	
☐ Doctors	☐ Other persons, please specify
☐ Dentists	

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Section 9 – Additional information and attachments

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

Provide/specify which attachments (if any) are attached to support this application:

- ☐ A current **company extract** from the Australian Securities and Investments Commission (ASIC)
- ☐ Details of **relevant person forms** for each person relevant to the application (directors, supervisors etc.)
- ☐ Other **relevant documents** please specify

Section 10 – 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