Queensland Health

Application form – General approval (immunisation program) – Renewal application

February 2022

Information about this application form

This application form is to be used to apply to renew a general approval for an **immunisation program** under section 82 of the *Medicines and Poisons Act 2019* (**MPA**).

Applicants **must include with the application** a complete up-to-date list of all locations where immunisation program services have been carried out, including the dates of the services provided.

Applying for a renewal of a general approval for an immunisation program

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authority is accepted, the authority continues in force until the application is decided or taken to have been withdrawn (s85 the MPA).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

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:

- prior compliance history;
- 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), 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-82GIP
Version 2:02/2022
APPLICATION TO RENEW A GENERAL APPROVAL (IMMUNISATION PROGRAM)

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 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 titled Notification of particular changes affecting authority (MPMR-42). Should you wish to amend your approval, submit an amendment application (MPA-78GIP).

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

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

Changes to substances being used

Changes to operations

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

The holder of a general approval for an immunisation program *may* be required, as a condition on the approval, to make a substance management plan before any regulated activity happens with a regulated substance at, or in connection with, a regulated place (e.g. a location stated in the approval), unless the person has a reasonable excuse.

If a substance management plan is required, it 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' made under the MPMR; and
- be written in a way that is likely to be easily understood by staff.

The approval holder (as 'responsible person') must ensure any substance management plan prepared:

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

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)

General approvals for immunisation programs may be issued for up to two years, but a **shorter term** may be requested/granted.

Please specify the term of approval sought

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

Section 5 – Additional information and attachments

Provide any additional information to support your application

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

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

☐ A complete up-to-date **list of all locations** where immunisation program services have been provided, including the dates of services provided

☐ Details of **relevant person** forms for each person relevant to the application (directors etc.)

☐ Other **relevant documents** (e.g. operational procedures) please specify

Section 6 – Consent and declaration

By making this application:

☐ I declare that I have authority to make this application on behalf of the applicant.

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