Queensland Health

Application form – General approval (naloxone supply) – Initial application

October 2022

Information about this application form

Approval to supply naloxone

This application form is to be used to apply for a general approval to supply (give treatment doses of) **naloxone to individuals** under section 75 of the *Medicines and Poisons Act 2019* (**MPA**), whether or not participating in the Commonwealth Government subsidised national Take Home Naloxone (**THN**) program. To supply *stock* of naloxone, a wholesale licence is required.

What is the THN program?

Under the national THN program being implemented across Queensland, an authorised alternative supplier (**AAS**) can obtain naloxone for free from participating wholesale suppliers (although freight and other holding costs may apply). Naloxone can then be given for free to people who are at risk of an opioid overdose or adverse reaction, their carers, friends and family members following a brief intervention.

Participants in the THN program are required to submit data to the Commonwealth via the Pharmacy Programs Administrator (**PPA**) and comply with national THN program rules and jurisdictional requirements. To find out more about THN in Queensland, including how Queensland AASs can access stock of naloxone, training and other resources, please see our THN page. To find out more about the national THN program rules, including submitting data, please see the PPA's website.

Is it mandatory to participate in the national THN program?

No, however access to subsidised naloxone is only available under the national THN program.

Do pharmacies require a general approval to participate?

No. Public hospital pharmacies (s94) are already registered. Community pharmacies, private hospital pharmacies and non-PBS public hospitals can register directly with the PPA.

Do health professionals practicing individually require a general approval?

No. Individual medical practitioners, nurse practitioners and other health professionals that already have authority under the Medicines and Poisons (Medicines) Regulation 2021 (**MPMR**) to give a treatment dose of S3 naloxone **do not** need a general approval, however you will **need to register** for the THN program to access the subsidised supply via Queensland Health. To register, send an email to medicines.applications@health.qld.gov.au.

Do health professionals practicing at an entity or organisation require a general approval?

Yes. Entities that provide support services will need a general approval to lawfully buy stock and give out naloxone.
If unsure if you need an approval, please email medicines.applications@health.qld.gov.au.

Administering naloxone for first aid

No approval is required under the MPMR for a **first aid provider**, being a person who has a current certificate granted by a registered training organisation for the provision of first aid, to administer naloxone, provided the first aid provider has completed naloxone training.

Under the MPMR, naloxone training means training in the following matters:

- recognition of the symptoms and signs of suspected opioid overdose;
- knowledge of the appropriate use of naloxone, including competency in administering naloxone;
- implementing an opioid first aid plan.

Scope of a general approval for naloxone supply

The holder of a substance authority, including a person acting under a substance authority, is authorised to carry out a regulated activity with a regulated substance in the authorised way (ss31 and 62 of the MPA). A *general approval* is a type of substance authority that may be granted under the MPA (ss61 and 68 of the MPA).

Purpose of general approvals for naloxone supply

General approvals for naloxone supply are granted to facilitate entities giving treatment doses of naloxone to people who are at risk of an opioid overdose or adverse reaction, their carers, friends and family members following a brief intervention. Persons giving naloxone must have completed training to ensure that the brief intervention is conducted in an appropriate and effective manner.

Naloxone training

Free online training has been prepared by Insight in collaboration with the Queensland Injectors Health Network (QuIHN). While not mandatory to use this training option, this is the recommended THN training in Queensland.

Other THN training programs, including those that may be provided through service providers or available in other States and Territories may also be acceptable, however applicants will need to provide details.

Authorisation under a general approval for naloxone supply

A general approval for naloxone supply authorises the holder (including persons stated in the approval to be acting for the approval holder) to carry out the following regulated activities with naloxone:

1. A senior person at an authorised location, to buy stock of naloxone (whether or not the stock is free).
2. Persons authorised at the entity to possess stock of naloxone.
3. Persons who have completed naloxone intervention training to give a treatment dose of naloxone.

What this class of approval does not authorise

A general approval for naloxone supply **does not** authorise:

- the supply of *stock* of naloxone (as this requires a wholesale licence); or
- the administration of naloxone, however this may be carried out by a first aid provider who has completed naloxone training or a person to whom naloxone has been given.

Requirements and conditions

Authorised way – section 31 of the MPA

All substance authorities are subject to the requirements and standard conditions specified in the relevant regulation, in this case, the MPMR, that applies to that type of substance authority, and any additional or varied conditions specified on the substance authority. These conditions may limit or specify how the regulated activities must be carried out.

Any person carrying out a regulated activity with a regulated substance must do so in the authorised way and a person to whom a substance authority applies must comply with the conditions of the authority. Failure to comply with these requirements may result in regulatory action being taken, including prosecution, which may attract a significant penalty.

Requirements and standard conditions for general approvals for naloxone supply

Unless stated otherwise in the approval, the following requirements and standard conditions described in sections 70 and 91 of the MPA and specified in the following chapters of the MPMR, apply to general approvals:

- chapter 3 of the MPMR 'Standard conditions for substance authorities' – part 6 'All substance authorities'
- chapter 4 of the MPMR 'General requirements for dealings' – part 3 'Buying by giving purchase orders', part 5 'Possessing stock for delivery', and part 9 'Giving treatment doses of medicines' and
- chapter 8 of the MPMR 'Offences' – part 2 'Secure storage systems', part 4 'Recording and keeping information'.

1. For buying stock of a medicine, the general approval holder and persons acting under the approval must comply with the requirements stated in chapter 4, part 3 of the MPMR 'Buying by giving purchase orders'.
2. For giving treatment doses of a medicine, the approval holder and persons acting under the general approval must comply with the requirements stated in chapter 4, part 9 of the MPMR 'Giving treatment doses of medicines'.
3. The approval holder and persons acting under the general approval must securely store medicines in accordance with the requirements stated in chapter 8, part 2 of the MPMR 'Secure storage systems'.
4. The approval holder must ensure any records required to be kept under the MPA in relation to an authorised place stated in the authority are available for inspection from

the place, and if the records are kept electronically, the approval holder must ensure the records for each authorised place stated in the substance authority are available for inspection from the primary place of business of the approval holder (s41 of the MPMR).

5. Where a record must be made or kept, approval holders must take all reasonable steps to ensure (s224 of the MPMR):
   a. the record is kept in a retrievable form, and is kept securely to ensure it cannot be altered, obscured, deleted or removed without detection; and
   b. the record is kept for a period of two years after it is made, or for a medicine register, for two years after the last entry in the register is made.
6. The approval holder must give notice to the chief executive of Queensland Health (or delegate) in the approved form if any of the following changes are proposed by the approval holder (s42 of the MPMR):
   a. a change to an authorised place stated in the substance authority;
   b. a change to a relevant person stated in the substance authority (such as a medical practitioner, nurse practitioner or senior person responsible for daily operations at a site); and
   c. another change to the approval holder's circumstances that substantially affects the holder's ability to comply with a condition of the substance authority.
7. Where the approval holder proposes to stop carrying out a dealing with a medicine under a substance authority, the holder must give the chief executive of Queensland Health (or delegate) a notice in the approved form stating the following information (s43 of the MPMR):
   a. the day the dealing is proposed to stop;
   b. the amount of medicines that are likely to be unused on that day, if any; and
   c. how the approval holder proposes to deal with any unused medicines.

Information about general approvals

Duration of approvals

Section 69 of the MPA provides that the chief executive of Queensland Health (or delegate) determines the duration of a granted substance authority. General approvals for therapeutic use will usually be granted for two years, but a shorter term may be granted if requested or if the chief executive of Queensland Health (or delegate) determines that a shorter period is appropriate.

Change of name, location or circumstances

Substance authorities are not transferable across different entities. Accordingly, substance authority holders must notify Queensland Health if the authorised entity intends to change their name or ACN/ABN; change premises; or has another change in circumstances during the term of the substance authority, because this may mean that the authority is no longer valid. If the change is due to a change in ownership of the entity, or the chief executive of Queensland Health (or delegate) otherwise considers the change to be substantial, a new application will likely be required; in other circumstances, an amendment application may be required.

Applying for a general approval

In determining the application, the matters described in section 76 of the MPA may be taken into consideration.

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.

An inspection of the premises may also be undertaken.

All applications are assessed individually, and there is no guarantee that a substance authority will be granted to any applicant.

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).

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-75GNX
Version 1:10/2022
APPLICATION FOR A GENERAL APPROVAL – NALOXONE

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 details of the legal entity (individual/organisation) seeking the approval

Type of entity seeking the approval		Specify type (if another entity)	
Name of entity (e.g. individual (surname, given names), partnership, company, incorporated association)			
Trading name (if applicable)		ACN or ACNC (if applicable)	
Entity phone		Entity email	
Postal address		Town/ Suburb	P/C
Contact person		Phone	Email

☐ Attach a current **company extract** from the Australian Securities and Investments Commission (ASIC) (if applicable)

☐ Attach a copy of **current registration** with the Australian Charities and Not-for-profits Commission (ACNC) (if applicable)

Section 2 – Relevant persons (s76 MPA)

All applications must include completed Details of relevant person forms (MPA-76) for each of the following:

A. If the applicant is an individual, the **applicant** must complete the relevant person form.

B. If the approval is for an entity:

(a) If the approval is to be issued to a sole trader, the **applicant** must complete the relevant person form.

(b) If the approval is to be issued to a partnership, **each partner** must complete the relevant person form.

(c) If the approval is to be issued to a body corporate, an **executive officer** (directors, company secretary, chief executive officer/general manager and chief financial officer) must complete the relevant person form.

☐ Attach completed **details of relevant person** forms for each person relevant to this application

Section 3 – Locations where naloxone is to be stored and given out

Provide details of the physical address where medicines are to be held and given out to at-risk persons. If more space is required, please attach further details.

Location 1

Name of location/ service etc.		Service type	
Street Address		Town /Suburb	P/C
Contact person		Phone	Email

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Location 2					
Name of location/ service etc.		Service type			
Street Address		Town /Suburb		P/C	
Contact person		Phone		Email	

Section 4 – Naloxone proposed to be given out under this approval

Specify the type of naloxone intended to be given out under the approval and expected volumes.
Note: any general approval granted will authorise all forms of naloxone, this question is for information purposes only.

☐ Prenoxad® pre-filled syringes (Phebra)	☐ Nyxoid® intranasal spray (Mundipharma)
☐ DBL naloxone hydrochloride ampoules (Pfizer)	☐ Naloxone hydrochloride ampoules (Juno)

Estimated volumes of naloxone to be given out e.g. per month, per quarter, and explanation

Section 5 – Training for persons providing interventions

Provide details of the naloxone training that persons will undertake to provide a brief intervention to at-risk persons when giving out naloxone.

- ☐ Insight (Queensland Health)
- ☐ QuIHN (Queensland Injectors Health Network)
- ☐ Other State/Territory Government training
- ☐ Other, provide name of program and attach details

Section 6 – 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 copy of **current registration** with the Australian Charities and Not-for-profits Commission (ACNC)
- ☐ Details of **relevant person forms** for each person relevant to the application (directors, partners etc.)
- ☐ Other **documents** (e.g. additional locations, details of training program) please specify

Section 7 – 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 consent to Queensland Health disclosing information submitted with this application to the Commonwealth Department of Health and Aged Care and the Pharmacy Programs Administrator for the purpose of registering with, and carrying out activities under, the Take Home Naloxone program.
- ☐ 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