Medicines and Poisons Act 2019

Factsheet – current as at October 2021

Naloxone

What is naloxone?

Naloxone hydrochloride (commonly known as naloxone, with brand names such as Narcan, Nyxoid, Prenoxad), is a medicine that may be used to temporarily reverse opioid overdose.

When used for the treatment of opioid overdose, naloxone is a Schedule 3 (Pharmacist Only Medicine) (**S3**) in the Commonwealth Poisons Standard (**Poisons Standard**).

When used otherwise, it is a Schedule 4 (Prescription Only) medicine in the Poisons Standard.

This fact sheet is focussed on **S3 naloxone for the treatment of opioid overdose**.

How is naloxone administered?

Naloxone may be injected into a muscle (intramuscularly) or sprayed into the nose (intranasally).

Who may administer naloxone for the treatment of opioid overdose?

As mentioned, when used for the treatment of opioid overdose, naloxone is an **S3 medicine**.

The *Medicines and Poisons (Medicines) Regulation 2021* (**MPMR**) authorises certain persons (i.e. 'approved persons' under the *Medicines and Poisons Act 2019* (**MPA**)) to administer naloxone (**either expressly or as an S3 medicine**) subject to requirements and for some persons, only in certain circumstances.

The following approved persons are authorised to administer naloxone:

- Aboriginal and Torres Strait Islander health practitioners (under their Extended Practice Authority (**EPA**));
- Indigenous health workers (under their EPA);
- Queensland Ambulance Service officers (under their EPA);
- Royal Flying Doctor Service workers (in certain circumstances – see Schedule 5, Part 3 of the MPMR);
- medical practitioners;
- nurse practitioners;

- midwives and endorsed midwives;
- registered nurses;
- enrolled nurses, restricted enrolled nurses and trainee enrolled nurses in certain circumstances;
- dentists;
- physiotherapists (under their EPA).

In addition to these approved persons, a **first aid provider,** being a person who has a current certificate granted by a registered training organisation for the provision of first aid, is authorised to administer naloxone, provided the first aid provider has completed *naloxone training* (see definition below).

Paramedics may administer naloxone (as an emergency medicine), in certain circumstances, under a general approval (emergency first aid).

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.

How may naloxone be bought?

Individual consumers – buying naloxone for treatment of opioid overdose as S3 medicine

Schedule 3 (Pharmacist Only Medicines) may be purchased from a pharmacy by a consumer without a prescription. However, S3 medicines may only be supplied from a pharmacy by or under the direction of a pharmacist.

A pharmacist must not sell an S3 medicine for a patient unless the pharmacist reasonably believes the patient has a therapeutic need for the medicine.

First aid providers and other approved persons

The MPMR permits S3 medicines, including naloxone, to be purchased from a supplier, such as a licensed wholesaler or community pharmacy, on a valid purchase order.

A supplier must not supply S3 medicines unless the supplier believes the buyer is authorised to buy the medicine.

General approvals to possess, supply and administer naloxone

Overview

A **general approval** is a type of *substance authority* under the MPA that authorises a person to carry out a *regulated activity* with a *regulated substance* stated in the approval. Applications for general approvals are considered carefully, individually, on their merits, and having regard to specific criteria.

An identified class of general approval is for certain entities to deal with naloxone **(general approval (naloxone))**. These types of programs are commonly known as Take Home Naloxone (**THN**) programs. This type of general approval is intended to enable staff (e.g. nurses, administrative or operational staff and volunteers) to possess, supply and in an emergency, administer naloxone. For example, trained staff of:

- Hospital and Health Services;
- State funded non-government mental health alcohol and other drug services;
- Aboriginal community controlled health organisations;
- Fixed or outreach needle and syringe programs (**NSPs**);
- Dosing centres (for the provision of opioid pharmacotherapy as part of the Queensland Opioid Treatment Program);
- Private health services that engage with people at risk of an opioid overdose or who are likely to witness an opioid overdose;
- other organisations that regularly engage with people at risk of opiate overdose.

General approvals (naloxone) may be granted to an organisation or entity that provides services to those at risk of opioid overdose or otherwise supports people who may provide a first line response to a person at risk of opioid overdose. In other circumstances, it is more appropriate for an entity to either apply for either a general approval (emergency first aid) to possess and administer naloxone, or for a wholesale licence to possess and supply naloxone.

A general approval (naloxone) enables a senior person nominated by the organisation, to purchase naloxone and issue it to staff and volunteers who have completed naloxone training (as defined in the MPMR) and undertaken brief intervention training for those they supply naloxone to. These staff or volunteers may then possess, supply, and administer naloxone in accordance with the entity's procedures and protocols.

Responsibilities of approval holders

A general approval (naloxone) is limited to staff members employed, contracted or volunteering for the entity holding the approval and who have completed naloxone training (as defined in the MPMR) and undertaken brief intervention training for those they supply naloxone to.

Entities who are granted a general approval (naloxone) must have sufficient governance and control over the purchase, storage and use of scheduled medicines to minimise the risk of harm to the public, by ensuring that medicines are only accessed and used by authorised persons and are used safely and effectively.

The MPMR prescribes how scheduled medicines must be purchased, stored and used, as well as requirements for documents that must be kept and for how long. In addition to these requirements, a decision-maker may impose additional conditions on a general approval (naloxone) that must be followed. These conditions are imposed to manage risks associated with the possession and use of scheduled medicines and are decided on a case-by-case basis after a careful assessment of the circumstances of an applicant.

How do I apply for a general approval (naloxone)?

An application to conduct a THN program must be made to the chief executive using the approved form '*Initial application for a general approval – therapeutic*' application form. Applications should be made by entities/organisations and not individual people. General approvals (naloxone) are granted to entities/organisations carrying out outreach services, which cover the individuals and volunteers working for the entity/organisation.

Associated guidance documents

- Extended practice authorities - factsheet
- Emergency first aid – factsheet
- General approval (therapeutic) initial application form

Further information

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