Queensland Health

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

February 2022

Information about this application form

This application form is to be used to apply for a general approval for an **immunisation program** under section 75 of the *Medicines and Poisons Act 2019* (**MPA**).

Persons who have previously held a certification under the *Health (Drugs and Poisons) Regulation 1996* (**HDPR**) for an 'immunisation program (immunisation program nurses)' should use this form.

Note – Immunisation programs are not for the provision of COVID-19 vaccines. For information about COVID-19 vaccines see www.qld.gov.au/health/conditions/health-alerts/coronavirus-covid-19/protect-yourself-others/covid-19-vaccine.

Immunisation programs – registered nurses

Under schedule 7, part 3, division 2 of the *Medicines and Poisons (Medicines) Regulation 2021* (**MPMR**), a registered nurse is authorised to buy, possess and administer an S4 medicine under the Extended practice authority for registered nurses (**RNEPA**).

Part D of the RNEPA (clause 5.3.1) provides that, to the extent necessary to provide immunisation program services, a registered nurse may administer a vaccine that contains an antigen listed in Appendix 4 of the RNEPA 'Queensland Immunisation Program medicines' under a general approval (immunisation program), subject to the requirements.

Applications for a general approval (immunisation program) are generally made by entities/organisations and not individual registered nurses. General approvals (immunisation programs) are typically granted to entities/organisations carrying out immunisation program services, which will cover suitably qualified individual registered nurses working for the entity/organisation.

Scope of a general approval for an immunisation program

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 a general approval for an immunisation program

A general approval for an immunisation program authorises the holder (including persons stated in the approval to be acting for the approval holder) to carry out the following regulated activities with the regulated substances (medicines) stated in the approval:

1. A senior person, being a person who is responsible for daily operations for the entity, to give a purchase order to buy stock of the medicines stated in the approval.
2. A registered nurse to possess and administer:
    a. a medicine that is a vaccine that contains any of the antigens listed in column 1 of Appendix 4 of the RNEPA 'Queensland Immunisation Program medicines'.
    b. a Japanese encephalitis vaccine only if working under a Japanese Encephalitis immunisation program approved by the chief executive of the Torres and Cape Hospital and Health Service (TCHHS) or the Public Health Medical Officer of the TCHHS and in accordance with local procedures for the Japanese Encephalitis Vaccine Program for Outer Islands of the Torres Strait.
    c. a Bacillus Calmette-Guerin (BCG) vaccine or tuberculin skin test only under a Tuberculosis immunisation program in accordance with the Health Services Directive – *Tuberculosis Control* [#QH-HSD-040:2018] and the Health Service Directive *Protocol for the Control of Tuberculosis* [Protocol QH-HSDOTL-040-1:2018].
    d. a tetanus immunoglobulin in accordance with the requirements for vaccine administration in the current online edition of the *Australian Immunisation Handbook*.

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 immunisation programs

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

- 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' and part 10 'Administering medicines'

- chapter 8 of the MPMR 'Offences' – part 2 'Secure storage systems', part 4 'Recording and keeping information', and part 5 'Reporting particular matters'
- the RNEPA.

1. A registered nurse may only administer the medicines under Part D of the RNEPA if the registered nurse has successfully completed any of the following (clause 5.1 of the RNEPA):
    a. an approved program of study for endorsement as an Immunisation Program Nurse with the former Queensland Nursing Council.
    b. a qualification in immunisation previously approved by the chief executive under the (repealed) *Health (Drugs and Poisons) Regulation 1996*.
    c. an accredited immunisation training course that contains learning objectives equivalent to the domains in the *National Immunisation Education Framework for Health Professionals*.
2. The registered nurse must act in accordance with a current health management protocol that applies to the dealings of the registered nurse and that complies with the requirements specified in Appendix 1 of the RNEPA (clause 1.2 of the RNEPA).
3. The registered nurse must ensure they have access to their applicable health management protocol, *Australian Immunisation Handbook* and current guidelines, manuals or protocols adopted or established by their employer when acting under the RNEPA (clause 1.1 of the RNEPA).
4. Before administering or giving a treatment dose of a medicine the registered nurse must be familiar with the contra-indication(s) and known side effects of the medicine and advise the patient accordingly (clause 1.4 of the RNEPA).
5. For the administration of vaccines, the registered nurse must act in accordance with (clause 1.5 of the RNEPA):
    a. the requirements for vaccine administration in the current online edition of the *Australian Immunisation Handbook* including for patient selection, patient consent, vaccine administration, documenting vaccination and follow up care; and
    b. the current online edition of the *Immunisation Schedule Queensland*.
6. Before vaccines are administered, the registered nurse must ensure the equipment and procedures detailed in the current online edition of the *Australian Immunisation Handbook* are in place (clause 1.6 of the RNEPA).
7. Prior to performing a Tuberculin Skin Test (TST) or administering a BCG vaccination for Tuberculosis (TB), registered nurses must demonstrate that they have completed the specified training and been assessed by a clinician as required by the Health Services Directive – *Tuberculosis Control* and the Health Service Directive *Protocol for the Control of Tuberculosis* (clause 1.7 of the RNEPA).
8. When vaccines are in the possession of the registered nurse, the registered nurse must ensure that the storage and transport of vaccines is in accordance with the *National vaccine storage guidelines: Strive for 5* (clause 1.8 of the RNEPA).
9. The registered nurse who administers a vaccine must ensure (clause 1.9 of the RNEPA):
    a. the vaccination is recorded on the Australian Immunisation Register (AIR) as soon as practicable and ideally at the time of vaccination

b. any adverse events occurring following immunisation must be notified using the adverse event following immunisation reporting form published on the Queensland Health website.

10. If Consumer Medicine Information (CMI) is available for a particular medicine, the registered nurse must, where reasonably practicable, offer the information to each person to whom the registered nurse administers or gives a treatment dose of the medicine (clause 1.10 of the RNEPA).
11. 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'.
12. For administering a medicine, the approval holder and persons acting under the general approval must comply with the requirements stated in chapter 4, part 10 of the MPMR 'Administering medicines'.
13. 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'.
14. The approval holder and persons acting under the general approval must establish and maintain a medicines register, to track all the regulated activities with medicines under the substance authority until medicines are completely used or destroyed, in accordance with chapter 8, part 2, division 3 of the MPMR 'Medicines registers'.
15. 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).
16. 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.
17. 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 the senior person responsible for daily operations); 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.
18. 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.

Common additional conditions

Under section 70 of the MPA, a substance authority is subject to a condition (a standard condition) prescribed by regulation to apply in relation to the substance authority and any additional or changed condition decided by the chief executive of Queensland Health (or delegate).

Commonly imposed additional conditions for general approvals (immunisation program) are for approval holders to:

- maintain a record of all places where immunisation programs are carried out under the approval, including the dates on which the services are provided; and
- prepare a substance management plan for locations where medicines are stored, or services are provided, under the approval.

Entities granted an approval should review their approval instrument carefully to ensure that any changed or additional conditions are met.

Health Management Protocols

Appendix 1 of the RNEPA specifies the requirements for a Health Management Protocol (under which a registered nurse must act):

1. A health management protocol is a document approved and dated by the chief executive of a Hospital and Health Service[1] or the Chief Executive Officer[2] of a non-Queensland Health employing organisation that details the clinical use of medicines for services provided by a registered nurse under the EPA for patients of the Hospital and Health Service or other employing organisations.
2. A health management protocol must have been reviewed and endorsed by an inter-disciplinary health team comprising, at a minimum, a medical practitioner, a registered nurse and a pharmacist, and may include other identified professional personnel (an inter-disciplinary team).
3. A health management protocol details the clinical use of medicines that may be administered or given as a treatment dose by a registered nurse under Appendix 2 or 3 of the RNEPA, and must include the following:
    a. The procedures for clinical assessment, management, and follow up of patients, including the recommended medicine for the relevant clinical problem.
    b. For each medicine in the health management protocol:
        i. a clinical indication or time when medical referral/consultation must occur for that condition;
        ii. the name, form and strength of the medicine and the condition/situation for which it is intended and any contraindications to the use of the medicine;

[1] refer to *Hospital and Health Services Boards Act 2011*

[2] Chief Executive Officer means the highest-ranking executive or administrator in charge of the management of an organisation

iii. the recommended dose of the medicine, the frequency of administration (including rate where applicable) and the route of administration of the medicine;

iv. for a medicine to be administered, the maximum dose of a medicine that may be administered or maximum duration of administration allowed without a prescription from an authorised prescriber;

v. for a medicine to be given as a treatment dose, the maximum quantity of or duration of treatment with a medicine that may be given without a prescription;

vi. the type of equipment and management procedures required for management of an emergency associated with the use of the medicine.

c. When to refer to a higher level of care for intervention or follow-up.

4. A health management protocol is either:
   a. developed for the Hospital and Health Service or for a non-Queensland Health employing organisation by an inter-disciplinary team for the Hospital and Health Service or another employing organisation (a local inter-disciplinary team); or
   b. a clinical guideline containing all the required content specified in paragraph 3 or a health management protocol developed by another entity's interdisciplinary team and endorsed as the health management protocol for the service by the local inter-disciplinary team.
5. A health management protocol is current when it has been approved the chief executive of a Hospital and Health Service or the Chief Executive Officer of a non-Queensland Health employing organisation within two (2) years of the day a registered nurse acts in accordance with the health management protocol unless the current on-line edition of the *Primary Clinical Care Manual* (PCCM)[3] has been endorsed and approved as the a health management protocol for the service.
6. If PCCM is adopted as the health management protocol, the health management protocol is current when it has been approved the chief executive of a Hospital and Health Service or the Chief Executive Officer of a non-Queensland Health employing organisation within three (3) years of the day a registered nurse acts in accordance with the health management protocol.

Information about general approvals for immunisation programs

Reporting of adverse events

An adverse event following immunisation (**AEFI**) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receiving a vaccine. An adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. Please see Queensland Health's website for more information.

[3] For the Primary Clinical Care Manual - 10th edition see www.health.qld.gov.au/rrcsu/clinicalmanuals/primary-clinical-care-manual-pccm.

Under the *Public Health Act 2005*, vaccine service providers are required to report any AEFI directly to Queensland Health. Reporting an AEFI is an important part of surveillance to monitor vaccine and immunisation program safety.

Substance management plans – chapter 4, part 2 of the MPA

A substance management plan (**SMP**) is a document setting out how known and foreseeable risks associated with any regulated activity with a regulated substance are to be managed at a regulated place (section 92 of the MPA). Holders of general approvals for immunisation programs may be required, as a condition on the approval, to have an SMP that meets the requirements specified in section 93 of the MPA and in the *Departmental standard: Substance management plans for medicines* under the MPMR, detailing what governance is in place to ensure that medicines will be managed effectively. A guideline for developing an SMP for medicines is available on the Queensland Health website.

To provide sufficient time for approval holders to comply with this new requirement, **an SMP is not required until 1 year after the commencement of the MPA**, i.e. 27 September 2022 (s280 MPA). Despite this, applicants should be able to demonstrate how they intend to manage and mitigate risks, by having in place appropriate procedures and protocols – as was required under the HDPR. Read more about SMPs for medicines.

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 immunisation programs 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-75GIP
Version 2:02/2022

INITIAL APPLICATION FOR 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 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 (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)

Section 2 – Relevant persons (s76 MPA)

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

1. (a) If the approval is to be issued to a sole trader, the **applicant** must complete the relevant person form; OR
   (b) If the approval is to be issued to a partnership, **each partner** must complete the relevant person form; OR
   (c) If the approval is to be issued to a body corporate, **each executive officer** (directors, company secretary, chief executive officer/general manager and chief financial officer) must complete the relevant person form.
2. A senior person (the person responsible for daily operations) must be nominated for each approval. **Each senior person** must complete the relevant person form.

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

Section 3 – Immunisation program setting

Provide details of the settings in which you propose to provide immunisation services.

☐ Organised groups of children	☐ Community outreach services
☐ Educational facilities	☐ Persons attending pharmacies
☐ Indigenous communities	☐ Workplaces
☐ Other, (please specify)	

General description of services to be provided

Section 4 – Details about proposed storage locations

Provide details of proposed locations where vaccines will be stored. If there are more than two locations, please provide an attachment. Please note, these locations may be subject to an inspection.

Location 1

Location Name					
Street Address		Town /Suburb		P/C	

Nature of storage (details of room, receptacle etc.)

Control of access (details of safe, keyholders etc.)

Location 2

Location Name					
Street Address		Town /Suburb		P/C	

Nature of storage (details of room, receptacle etc.)

Control of access (details of safe, keyholders etc.)

Section 5 – Medicines proposed to be used under this approval

The medicines that may be authorised for a general approval for an immunisation program are stated in Appendix 4 of the Extended Practice Authority – 'Registered Nurses' (**RNEPA**) *made under the MPMR.*

Select which medicines are sought for this approval:

☐ Diphtheria	☐ Haemophilus influenzae	☐ Hepatitis A
☐ Hepatitis B	☐ Human Papillomavirus	☐ Influenza
☐ Measles	☐ Mumps	☐ Meningococcal (ACWY)
☐ Meningococcal B	☐ Meningococcal C	☐ Pertussis
☐ Pneumococcal	☐ Poliomyelitis	☐ Rotavirus
☐ Rubella	☐ Tetanus	☐ Varicella (chickenpox)
☐ Zoster (herpes zoster)		

Section 6 – Health management protocol

A registered nurse is only authorised to administer vaccines under the RNEPA where the registered nurse is acting under a health management protocol (HMP) that meets the requirements of Appendix 1 of the RNEPA.

Have you prepared or have you adopted a health management protocol that meets the requirements specified in Appendix 1 of the RNEPA?	☐ Yes	☐ No

Section 7 – 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.

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

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

Section 8 – Duration of the substance authority (s69 MPA)

General approvals for immunisation programs may be granted 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 9 – 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)

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

☐ Other **relevant documents** (e.g. letter or contract confirming engagement of services, operational procedures) 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 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)