Queensland Health

Application form – General approval - Immunisation program (pharmacist) – Initial application

February 2024

Information about this application form

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

Immunisation programs – pharmacists

Under schedule 9, part 1, division 1 of the *Medicines and Poisons (Medicines) Regulation 2021* (**MPMR**), a pharmacist is authorised to buy, possess and administer an S4 medicine under the Extended Practice Authority - Pharmacists (**EPAP**).

Part 1 of the EPAP provides that, a pharmacist may administer a medicine listed in Appendix 2 of the EPAP 'Medicines for vaccinations', but only in certain settings.

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 substance authority that may be granted under the MPA (ss61 and 68 of the MPA). Failure to comply with these requirements may result in regulatory action being taken, including prosecution, which may attract a significant penalty.

A suitably qualified pharmacist may administer a vaccine listed in the EPAP in the following settings **without an approval**:

- at an aged care facility; or
- at a community pharmacy; or
- at a general practice; or
- at a private health facility; or
- at a facility operated by a relevant health service.

NO APPROVAL IS REQUIRED FOR A PHARMACIST TO ADMINISTER VACCINES IN THESE SETTINGS. AN APPROVAL IS ONLY REQUIRED FOR PHARMACISTS TO ADMINISTER VACCINES **OUTSIDE** THESE SETTINGS.

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

Purpose of a general approval for an immunisation program

A general approval for an immunisation program allows pharmacists of an approved entity/organisation to possess and administer a medicine that is a vaccine that contains any of the antigens listed in column 1 of Appendix 2 of the EPAP 'Medicines for vaccinations', outside of one of the settings listed in the EPAP.

Requirements and conditions

Requirements and standard conditions for general approvals for immunisation programs

Unless stated otherwise in the approval, the following requirements, standard conditions (sections 70 and 91 of the MPA) and 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 **EPAP**.

1. A pharmacist may only administer medicines under Part 1 of the **EPAP** if the pharmacist has successfully completed the following qualifications:
    a) Either:
        i) the training program for the Queensland Pharmacist Immunisation Pilot I and II (QPIP I & II); or
        ii) a training program accredited to meet the standards set by the Australian Pharmacy Council's 'Standards for the accreditation of programs to support Pharmacist Administration of vaccines'.
    b) A current Australian recognised qualification:
        i) in first aid, which includes cardiopulmonary resuscitation and anaphylaxis management; or
        ii) a current first aid certificate and a current certificate in anaphylaxis management.
2. A pharmacist who has successfully completed vaccination training requirements may administer a medicine listed in Appendix 2, Column 1:
    a) by a route of administration for the medicine as stated in the current online edition of the Australian Immunisation Handbook, or as stated in the product information approved by the Therapeutic Goods Administration (TGA), or as per current recommendations issued by the Australian Technical Advisory Group on Immunisation (ATAGI); and
    b) subject to the restrictions, if any, for a medicine listed in Appendix 2, Column 2.
3. Prior to administering a vaccine, the pharmacist must ensure the amenities and resources in Appendix 3 and the equipment and procedures detailed in the current online edition of the Australian Immunisation Handbook are in place.
4. The pharmacist must act in accordance with the requirements for vaccine administration in the current online edition of the Australian Immunisation Handbook including patient selection, patient consent, vaccine administration, documenting vaccination and follow up care.

5. When vaccines are in the possession of the pharmacist, the pharmacist must ensure that the storage and transport of vaccines is in accordance with the National vaccine storage guidelines: Strive for 5.
6. Before administering a vaccine, the pharmacist must be familiar with the precautions, contra-indication(s) and known side effect(s) of the medicine and advise the patient accordingly.
7. The pharmacist must advise a patient if a vaccine they propose to administer is listed in the National Immunisation Program (NIP) Schedule and of the cost to the patient for the vaccine (if any).
8. The pharmacist administering a vaccine must ensure that:
    a) all vaccinations are recorded on the Australian Immunisation Register in accordance with the requirements under the *Australian Immunisation Register Act 2015* (Cth) as soon as practicable and ideally at the time of vaccination; and
    b) any adverse events occurring following immunisation must be notified using the Adverse Event Following Immunisation (AEFI) reporting form available on the Queensland Health website.
9. 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'.
10. 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'.
11. 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.

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, including immunisation activities.

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

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.

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 are 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, including how cold-chain and patient privacy will be maintained. A guideline for developing an SMP for medicines is available on the Queensland Health website. 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 Medicines Approvals and Regulation Unit (MARU)
medicines.applications@health.qld.gov.au

Queensland Government

Queensland Health

Medicines and Poisons Act 2019

MPA-75GIP
Version 1:01/2024

INITIAL APPLICATION FOR A GENERAL APPROVAL — IMMUNISATION PROGRAM (Pharmacists)

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 seeking the approval

Type of entity seeking the approval	Select from list	Specify type (if another entity)	
Name of entity (e.g., 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)

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 approval is to be issued to a partnership, **each partner** must complete the relevant person form; OR
(b) If the approval is to be issued to a body corporate, an **executive officer** (one of 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 – Immunisation program setting

*Under the Extended Practice Authority – Pharmacists (**EPAP**), pharmacists **are authorised** to provide immunisation services in the following settings:*

- *aged care facilities*
- *community pharmacies*
- *general practices*
- *private health facilities*
- *at a facility operated by a relevant health service*

Provide details of the settings/locations that you propose to provide immunisation services (**other than those authorised in the EPAP**):

INITIAL APPLICATION FOR A GENERAL APPROVAL — IMMUNISATION PROGRAM (Pharmacists)

Section 4 – Details about proposed storage location

Provide details of proposed location where vaccines will be stored. Please note, this location may be subject to an inspection.

Storage location

Location Name					
Street Address		Town /Suburb		P/C	

Nature of storage (demonstrate compliance with Strive for 5 storage and cold chain requirements)

Control of access (if not stored in the pharmacy - details of lockable storage, keyholders etc.)

Section 5 – Medicines authorised for use under this approval

The medicines that may be authorised for a general approval for an immunisation program are stated in Appendix 2 of the Extended Practice Authority – 'Pharmacists' (**EPAP**) *made under the MPMR.*

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

The holder of a general approval for an immunisation program is required, as a condition on the approval, to make a substance management plan that covers each location where immunisation services are provided under this approval. Please note, immunisation activities can be included in the SMP for a pharmacy.

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 7 – 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.

☐ 1 year	☐ 2 years	☐ Another (shorter) term, please specify

Section 8 – 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) – if applicable

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

☐ Other **relevant documents** (e.g. notifications made to pharmacy business ownership)

Section 9 – 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)

Clear form