Medicines and Poisons Act 2019

Extended Practice Authority 'Pharmacists'



## Queensland Government

#### **Version control**

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## **Extended Practice Authority - 'Pharmacists'**

This extended practice authority (EPA) has been made by the Director-General, Queensland Health, as the chief executive under section 232 of the *Medicines and Poisons Act 2019* (Qld). It states the scope of the regulated activities with the regulated substances which a pharmacist is authorised to carry out for the purposes described in the table under Schedule 9, Part 1, Division 1 of the Medicines and Poisons (Medicines) Regulation 2021 (Qld).

A term used in this EPA that is defined in the *Medicines and Poisons Act 2019* or the Medicines and Poisons (Medicines) Regulation 2021, has the meaning stated in the *Medicines and Poisons Act 2019* or Medicines and Poisons (Medicines) Regulation 2021.

## Part 1 - Immunisations

- 1.1 A pharmacist who has successfully completed *immunisation training* requirements as detailed in Appendix 1 of this EPA, may administer an immunisation medicine listed in Appendix 3, 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), or as per current recommendations provided on the *Immunisation Schedule Queensland*; and
  - b. subject to the restrictions, if any, for a medicine listed in Appendix 3, Column 2.
- 1.2 The pharmacist may administer an immunisation medicine listed in this EPA:
  - a. at an aged care facility; or
  - b. at a community pharmacy; or
  - c. at a general practice<sup>1</sup>; or
  - d. at a private health facility; or
  - e. at a facility operated by a relevant health service; or
  - f. at a facility where a general approval has been granted under the *Medicines and Poisons Act 2019* to deal with an immunisation medicine.
- 1.3 Prior to administering an immunisation medicine, the pharmacist must ensure the amenities and resources in Appendix 2 are in place and must take all reasonable steps to ensure the equipment and procedures detailed in the current online edition of the *Australian Immunisation Handbook* are in place.
- 1.4 For the requirements for administration of immunisation medicines, including for patient selection, patient consent, administration, documenting immunisation and follow up care, the pharmacist must act in accordance with:
  - a. the current online edition of the Australian Immunisation Handbook; or
  - b. the current recommendations issued by ATAGI; or
  - c. the product information approved by the TGA; or

<sup>&</sup>lt;sup>1</sup> Means an accredited practice which holds a current and valid accreditation through the National General Practice Accreditation Scheme or a non-accredited medical practice administering vaccines under the National Immunisation Program

- d. the current recommendations provided on the *Immunisation Schedule Queensland*.
- 1.5 When immunisation medicines are in the possession of the pharmacist, the pharmacist must take all reasonable steps to ensure that the storage and transport of the medicines is in accordance with the *National vaccine storage guidelines: Strive for 5*.
- 1.6 Before administering an immunisation medicine, the pharmacist must be familiar with the precautions, contra-indication(s) and known side effect(s) of the medicine and advise the patient accordingly.
- 1.7 The pharmacist must advise a patient if an immunisation medicine they propose to administer is listed in the National Immunisation Program (NIP) Schedule and of the cost to the patient for the medicine (if any).
- 1.8 The pharmacist administering an immunisation medicine must ensure that:
  - a. all immunisations 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 immunisation; 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.
- 1.9 The pharmacist to whom Part 1 of this EPA applies is authorised to administer adrenaline in a strength of 0.1% or less in a preloaded device such as an autoinjector, or in an ampoule, for the treatment of anaphylaxis.

## Part 2 - Urinary Tract Infection Community Pharmacy Service

- 2.1 A pharmacist who is working in a community pharmacy and has successfully completed the *Urinary tract infection training* in accordance with Appendix 1 may sell a medicine listed in Appendix 4, Column 1 of this EPA to a female patient aged between 18 and 65 years for the treatment of acute uncomplicated cystitis, without the requirement for a prescription:
  - a. subject to the restrictions for the medicine stated opposite in Appendix 4, Column 2 (if any); and
  - b. the pharmacist must take all reasonable steps to supply the medicine in accordance with the current online version of the section of the Therapeutic Guidelines titled '*Antibiotic: Urinary tract infections in adults: Acute cystitis in adults*'.
- 2.2 The pharmacist may sell the medicines only at a community pharmacy that includes the relevant amenities and resources in Appendix 2.
- 2.3 The pharmacist must not sell a medicine specified in Appendix 4, Column 1 of this EPA in a quantity that exceeds the smallest available size of the manufacturer's pack of the medicine.
- 2.4 The pharmacist must, when selling a medicine under Appendix 4, Column 1 of this EPA, keep a record of the sold S4 medicine in accordance with section 160 of the Medicines and Poisons (Medicines) Regulation 2021; in addition to keeping a clinical record. This clinical record must include relevant patient health history, problems

identified, actions taken, details of contact with other healthcare professionals, and the outcomes of any actions taken.

2.5 The pharmacist must make available a copy of the clinical record of the service to the patient.

## Part 3 - Hormonal Contraception Community Pharmacy Service

- 3.1 A pharmacist who is working in a community pharmacy and has successfully completed the *Hormonal contraception training* in accordance with Appendix 1 may prescribe a medicine listed in Appendix 5, Column 1 of this EPA to a female patient aged 16 years or older:
  - a. subject to the restrictions for the medicine stated opposite in Appendix 5, Column 2 (if any); and
  - b. the pharmacist must take all reasonable steps to prescribe the medicine in accordance with the current online version of the section of the Therapeutic Guidelines titled 'Sexual and Reproductive Health: Contraception'.
- 3.2 The pharmacist's name must appear on the prescriber register maintained by the Department for the hormonal contraception community pharmacy service.
- 3.3 The pharmacist may prescribe a medicine only at a community pharmacy that includes the relevant amenities and resources in Appendix 2.
- 3.4 When prescribing a medicine, the pharmacist must make a written prescription that is compliant with Chapter 4, Part 6, Division 3 of the Medicines and Poisons (Medicines) Regulation 2021.
- 3.5 The pharmacist must, when prescribing the medicine, make an individualised clinical assessment of the patient's contraceptive and sexual health needs and suitability for hormonal contraception and management; and keep a clinical record of the consultation with the patient, that includes:
  - a. Relevant patient history; and
  - b. An assessment of the requirement for the prescribed medicine; and
  - c. The management plan for treating the patient's condition including:
    - i. The name of the medicine prescribed; and
    - ii. The strength of the medicine prescribed; and
    - iii. The formulation of the medicine prescribed; and
    - iv. The instructions for use of the medicine prescribed; and
    - v. The amount of the medicine prescribed.
- 3.6 The pharmacist must not prescribe, in one prescription, greater than 12 months' supply of a medicine listed in Appendix 5 of this EPA.

## Part 4 - Fluoride Community Pharmacy Service

## **Circumstances and conditions**

4.1 A pharmacist who is working in a community pharmacy and has successfully completed training in the application of topical fluoride varnish (*Fluoride training*) in accordance with Appendix 1 may administer a schedule 4 medicine that is fluoride in a topical preparation for human use.

## Part 5 - General Health Community Pharmacy Services

- 5.1 A pharmacist who is working in a community pharmacy and has successfully completed the *General health services training* in accordance with Appendix 1 may prescribe a medicine listed in Appendix 6, Column 1 of this EPA:
  - a. for the indication listed in Appendix 6, Column 2; and
  - b. subject to the restrictions stated opposite in Appendix 6, Column 3; and
  - c. the pharmacist must take all reasonable steps to prescribe the medicine in accordance with the current online version of the section/s of the Therapeutic Guidelines specified within Appendix 6, Column 1.
- 5.2 The pharmacist's name must appear on the prescriber register maintained by the Department for general health community pharmacy services.
- 5.3 The pharmacist may prescribe a medicine only at a community pharmacy that includes the relevant amenities and resources in Appendix 2.
- 5.4 When prescribing a medicine, the pharmacist must make a written prescription that is compliant with Chapter 4, Part 6, Division 3 of the Medicines and Poisons (Medicines) Regulation 2021.
- 5.5 The pharmacist must, when prescribing the medicine, make an individualised clinical assessment of the patient's health needs and suitability for the prescribed treatment; and keep a clinical record of the consultation with the patient, that includes:
  - a. Relevant patient history; and
  - b. An assessment of the condition that requires the prescribed medicine; and
  - c. The management plan for treating the patient's condition including:
    - i. The name of the medicine prescribed; and
    - ii. The strength of the medicine prescribed; and
    - iii. The formulation of the medicine prescribed; and
    - iv. The instructions for use of the medicine prescribed; and
    - v. The amount of the medicine prescribed.
- 5.6 The pharmacist must not prescribe, in one prescription, greater than 12 months' supply of a medicine listed in Appendix 6 of this EPA.

## Appendix 1

### Immunisation training requirements

Pharmacists must meet BOTH requirements specified in 1 and 2 below.

- 1. Successful completion of either of the following qualifications:
  - a. the training program for the Queensland Pharmacist Immunisation Pilot I and II (QPIP I & II); or
  - b. 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*'.
- 2. A current Australian recognised qualification:
  - a. in first aid, which includes cardiopulmonary resuscitation and anaphylaxis management; or
  - b. a current first aid certificate, in addition to a current certificate in anaphylaxis management.

#### Urinary tract infection training requirements

Pharmacists must successfully complete one (or more) of the following training programs that must include learning objectives on classification and epidemiology of urinary tract infections, anatomy, pathogenesis, assessment and differential diagnosis, treatment and the urinary tract infection community pharmacy service:

- a. The training program developed for the Urinary Tract Infection Pharmacy Pilot Queensland; or
- b. Training delivered through a higher accreditation institution accredited by the Tertiary Education Quality and Standards Agency; or
- c. An accredited continuing professional development program, delivered by a training provider that meets the Australian Pharmacy Council's '*Standards for Continuing Professional Development Activities*'.

### Hormonal contraception training requirements

Pharmacists must successfully complete a training program that includes and assesses the requirements specified in 1 and 2 below.

- Learning objectives on anatomy and physiology as relevant to the provision of a hormonal contraception service, the physiology of reproductive hormones and contraception methods, the mechanisms of action, efficacy, and suitability of various contraceptive methods, contraceptive counselling and decision-making, patient assessment and formulation of treatment plans that are aligned with individual patient needs, preferences, medical history and cultural considerations, and the pharmacist's scope of practice for the Hormonal Contraception Community Pharmacy Service as described in Part 3 of this EPA; and
- 2. Prescribing competencies from the current version of the National Prescribing Service *Prescribing Competencies Framework*' relevant to providing a comprehensive hormonal contraception service including communication, history-taking, assessment, the prescribing process, and development of a treatment and sexual health plan.

A training program comprising of both training requirements specified in 1 and 2 above must be:

- a. a training program developed for the Queensland Community Pharmacy Hormonal Contraception Pilot; or
- b. a training program delivered by a higher accreditation institution accredited by the Tertiary Education Quality and Standards Agency; or
- c. a training program delivered by a training provider that meets the Australian Pharmacy Council's '*Standards for Continuing Professional Development Activities*'.

## Fluoride training requirements

Pharmacists must have completed training in the application of topical fluoride varnish that includes:

- a. assessing patient suitability for topical fluoride varnish application, including identification of clinical indicators, risk factors, and contraindications; and
- b. understanding the mechanism of action of topical fluoride in caries prevention; and
- c. recognising and managing potential safety risks associated with topical fluoride use; and
- d. providing patient advice on oral hygiene practices and preventive dental care.

## General health services training requirements

Pharmacists must successfully complete a training program comprising both training requirements specified in 1 and 2 below, or a training program developed for the Queensland Community Pharmacy Scope of Practice Pilot.

- 1. A prescribing training program accredited to meet the standards set by the Australian Pharmacy Council's 'Accreditation Standards for Pharmacist Prescriber Education Programs'; and
- 2. A clinical skills training program that includes and assesses:
  - a. learning objectives on the knowledge, skills and behaviours required to provide a comprehensive health service including ethical considerations, professional responsibilities, clinical documentation and professional communication; and
  - b. learning objectives on epidemiology, anatomy, physiology and pathophysiology as relevant to the provision of <u>all health services</u> listed in Appendix 6, Column 2, including the clinical assessment, diagnosis, therapeutic and non-therapeutic management and formulation of treatment plans that align with individual patient needs, preferences, medical history, and cultural considerations.

A training program comprising of both training requirements specified in 1 and 2 above must be a tertiary-level study program equivalent to Australian Qualifications Framework Level 8, and must be delivered through either:

- a. a higher education institution that is accredited by the Tertiary Education Quality Standards Agency; or
- b. an institution that is accredited by the Australian Skills Quality Authority.

## Appendix 2 - Amenities and resource requirements for services under this EPA

A pharmacist undertaking regulated activities with medicines must only act under the authority of this EPA when a screened or private consulting area is used that:

- 1. ensures patients' privacy and confidentiality; and
- 2. has sufficient space to allow the presence of the following: the patient; a carer if necessary; the pharmacist undertaking the consultation; consumables; equipment; and documentation; and
- 3. has seating for the patient and their carer during the consultation; and
- 4. has hand washing facilities/hand sanitising products available to allow for the performance of appropriate hand hygiene before and after immunisation or examination of a patient.

In addition, a pharmacist providing immunisation services under Part 1 of this EPA must ensure the following amenities and resources are in place:

- a. Sufficient space and appropriate surfaces for the patient to lie down in the event of an adverse reaction; and for staff to safely perform resuscitation procedures.
- b. An area with seating that provides for direct visual observation where patients can wait for at least 15 minutes following the immunisation.
- c. Enough appropriately trained staff, in addition to the pharmacist, who have current training in first aid (including cardiopulmonary resuscitation and management of anaphylaxis), available when administering immunisation medicines to ensure patient safety during post-immunisation monitoring and any adverse event management.
- d. For a community pharmacy, if operationally possible, two pharmacists should be available at any one time one to act as the dedicated immuniser and the other to manage the general business of the dispensary.
- e. A community pharmacy with only one pharmacist on duty must assess their workflows to ensure they are able to provide uninterrupted care to an individual patient when providing immunisation.

## Appendix 3 – Immunisation medicines

Immunisation medicines		
Column 1 – Regulated substance/antigen	Column 2 - Restrictions/Conditions	
Cholera	For persons aged 2 years or over	
COVID-19		
Diphtheria	For persons aged 2 years or over	
Haemophilus influenzae type b	For persons aged 2 years or over	
Hepatitis A	For persons aged 2 years or over	
Hepatitis B	For persons aged 2 years or over	
Human Papillomavirus	For persons aged 2 years or over	
Influenza		
Japanese encephalitis	For persons aged 2 years or over	
Measles	For persons aged 2 years or over	
Meningococcal	For persons aged 2 years or over	
Мрох	For persons aged 2 years or over	
Mumps	For persons aged 2 years or over	
Pertussis	For persons aged 2 years or over	
Pneumococcal	For persons aged 2 years or over	
Poliovirus	For persons aged 2 years or over	
Rabies	For persons aged 2 years or over for pre- exposure prophylaxis only	
Respiratory syncytial virus (RSV)	For persons aged 2 years or over	
Rubella	For persons aged 2 years or over	
Tetanus	For persons aged 2 years or over	
Typhoid	For persons aged 2 years or over	
Varicella (chickenpox)	For persons aged 2 years or over	
Zoster (herpes zoster)	For persons aged 2 years or over	

# Appendix 4 – Medicines for the Urinary Tract Infection Community Pharmacy Service

Medicines for the Urinary Tract Infection Community Pharmacy Service		
Column 1 - Regulated substance	Column 2 - Restrictions/Conditions	
Cefalexin		
Fosfomycin		
Nitrofurantoin		
Trimethoprim		

## Appendix 5 – Medicines for the Hormonal Contraception Community Pharmacy Service

Medicines for the Hormonal Contraception Community Pharmacy Service		
Column 1 - Regulated substance	Column 2 - Restrictions/Conditions	
Combined hormonal contraception - combined oral contraceptives (COCs) and the contraceptive vaginal ring.		
Excluding preparations containing 50 micrograms or more of ethinylestradiol, or preparations containing mestranol.		
Progesterone-only contraceptive pill		
Depot medroxyprogesterone (injection)		

## Appendix 6 - Medicines for the General Health Community Pharmacy Services

Medicines for the General Health Community Pharmacy Services		
Column 1 – Regulated substance	Column 2 – Indication	Column 3 – Restrictions/Conditions
A <u>topical</u> medicine mentioned in the current online version of the section of the Therapeutic Guidelines titled ' <i>Dermatology: Psoriasis</i> '.	Acute exacerbations of mild plaque psoriasis	For persons aged 16 years or over.
An <u>oral</u> medicine mentioned in the current online version of the section of the Therapeutic Guidelines titled <i>'Gastrointestinal: Nausea and vomitting: Antiemetic drugs in adults'.</i>	Acute nausea and vomiting associated with gastroenteritis	For persons aged 18 years or over.
An <u>oral</u> medicine mentioned in the current online version of the sections of the Therapeutic Guidelines titled:	Acute minor wound management	For persons aged 5 years or over.
<ul> <li>'Antibiotic: Traumatic wound infections: Bite wound infections, including clench-first injury infections; or</li> </ul>		
'Antibiotic: Traumatic wound infections: Post-traumatic wound infections; or		
'Antibiotic: Traumatic wound infections: Water-immersed wound infections'.		
Lidocaine preparations of 1% or less in accordance with the current online version of the section of the Therapeutic Guidelines titled 'Pain and analgesia: Drugs used for pain: Local anaesthetics for acute pain management'.		
An <u>oral or otic</u> medicine mentioned in the current online version of the sections of the Therapeutic Guidelines titled:	Acute otitis externa – treatment and/or management of associated pain	For persons aged 2 years or over.
<ul> <li>'Pain and Analgesia: Pharmacological management of acute pain: Mild, acute nociceptive pain'; or</li> </ul>		
• 'Antibiotic: Ear, nose and throat infections: Otitis externa'.		

Medicines for the General Health Community Pharmacy Services		
Column 1 – Regulated substance	Column 2 – Indication	Column 3 – Restrictions/Conditions
An <u>oral</u> medicine mentioned in the current online version of the sections of the Therapeutic Guidelines titled:	Acute otitis media – treatment and/or management of associated pain	For persons aged 2 years or over.
<ul> <li>'Pain and Analgesia: Pharmacological management of acute pain: Mild, acute nociceptive pain'; or</li> </ul>		
• 'Antibiotic: Ear, nose and thoat infections: Otitis media'.		
A medicine mentioned in the current online version of the sections of the Therapeutic Guidelines titled:	Allergic and nonallergic rhinitis	
• <i>'Respiratory: Rhinitis and rhinosinusitis: Allergic rhinitis</i> ; or		
<ul> <li>'Respiratory: Rhinitis and rhinosinusitis: Nonallergic rhinitis'.</li> </ul>		
Excluding ocular medicines containing ketorolac or corticosteroids.		
A medicine mentioned in the current online version of the section of the Therapeutic Guidelines titled 'Gastrointestinal: Oesophageal disorders: Gastro-oesophageal reflux in adults'.	Gastro-oesophageal reflux and gastro-oesophageal reflux disease	For persons aged 18 years to 55 years.
A <u>topical or oral</u> medicine mentioned in the current online version of the section of the Therapeutic Guidelines titled 'Antibiotic: Skin and soft tissue infections: Impetigo'.	Impetigo	For persons aged 1 year or over.
A medicine mentioned in the current online version of the section of the Therapeutic Guidelines titled 'Cardiovascular: Modifiable lifestyle risk factors for atherosclerotic cardiovascular disease: Excess body weight, obesity and atherosclerotic cardiovascular disease risk'. <u>Excluding</u> liraglutide, semaglutide and naltrexone + bupropion.	Management for overweight and obesity	For persons aged 18 years or over.

Medicines for the General Health Community Pharmacy Services		
Column 1 – Regulated substance	Column 2 – Indication	Column 3 – Restrictions/Conditions
A medicine mentioned in the current online version of the section of the Therapeutic Guidelines titled <i>'Dermatology: Acne'</i> .	Mild to moderate acne	For persons aged 12 years or over.
A <u>topical</u> medicine mentioned in the current online version of the section of the Therapeutic Guidelines titled 'Dermatology: Dermatitis: Atopic dermatitis'.	Mild to moderate atopic dermatitis	For persons aged 6 months or over.
An <u>oral</u> medicine mentioned in the current online version of the sections of the Therapeutic Guidelines titled:	Mild, acute, musculoskeletal pain	For persons aged 18 years or over.
<ul> <li>'Pain and Analgesia: Pharmacological management of acute pain: Mild, acute nociceptive pain'; or</li> </ul>		
<ul> <li>'Rheumatology: Overview of limb conditions: Analgesia for acute soft-tissue limb conditions'.</li> </ul>		
An <u>oral</u> medicine mentioned in the current online version of the sections of the Therapeutic Guidelines titled:	Shingles – treatment and/or management of associated pain	For persons aged 18 years or over.
<ul> <li>'Pain and analgesia: Pharmacological management of acute pain: Mild, acute nociceptive pain'; or</li> </ul>		
<ul> <li>'Pain and Analgesia: Managing specific pain syndromes: Pain associated with shingles (herpes zoster): Acute pain associated with shingles (herpes zoster)'; or</li> </ul>		
<ul> <li>'Antibiotic: Skin and soft tissue infections: Shingles (herpes zoster)'.</li> </ul>		
A medicine mentioned in the current online version of the section of the Therapeutic Guidelines titled: 'Addiction: Tobacco smoking and nicotine dependence'.	Treatment of nicotine dependence	For persons aged 18 years or over.
Excluding nortriptyline and nicotine vaping products.		

Medicines for the General Health Community Pharmacy Services		
Column 1 – Regulated substance	Column 2 – Indication	Column 3 – Restrictions/Conditions
An <u>oral</u> medicine mentioned in the current online version of the sections of the Therapeutic Guidelines titled:	Travel health – Acute mountain sickness - standby treatment and/or standby management of associated symptoms	For persons aged 8 years or over.
'Wilderness medicine: Altitude     illness'; or		
<ul> <li>'Gastrointestinal: Nausea and vomiting'.</li> </ul>		
A medicine mentioned in the current online version of the sections of the Therapeutic Guidelines titled:	Travel health - Travellers' diarhoea - standby emergency treatment and/or standby management of	For persons aged 2 years or over.
• 'Antibiotic: Infectious diarrhoea: Travellers' diarrhoea'; or	associated symptoms	
• 'Gastrointestinal: Acute gastroenteritis: Other supportive therapy and considerations for acute gastroenteritis: Antidiarroheal drugs for acute gastroenteritis'.		
A medicine mentioned in the current online version of the section of the Therapeutic Guidelines titled 'Antibiotic: Parasitic infections: Malaria'.	Travel health - Malaria - prophylaxis or standby emergency treatment of uncomplicated malaria	For persons aged 8 years or over.