

# Consultation paper

## Pharmacists' authorisation to administer vaccines and other scheduled medicines

### Purpose

The purpose of this consultation paper is to seek stakeholder views on proposed changes to the authorisations for pharmacists to deal with medicines under the *Medicines and Poisons (Medicines) Regulation 2021* (Medicines Regulation).

Queensland Health is considering the following changes to the authorisations for pharmacists –

1. Increasing the number of vaccines listed in the [Extended Practice Authority – Pharmacists](#) that pharmacists can administer.
2. Enabling pharmacists to administer vaccines at a wider range of locations and services.
3. Enabling pharmacists to administer scheduled medicines, other than vaccines, under [Schedule 9, part 1, division 1](#) of the Medicines Regulation.

The consultation paper sets out more information about the proposed changes. To remove any doubt, the changes proposed in this paper are not related to the proposed North Queensland Pharmacy Pilot.

This consultation paper is provided for consultation purposes only and does not represent government policy. All documents must be kept confidential and circulation must be limited to those who have a direct role in considering the proposed changes.

Your views are valuable and may be referred to in material provided to Government in considering the proposal and, if legislative amendments are progressed, may be referred to in the Explanatory Notes.

Your feedback on the proposed changes would be greatly appreciated. The closing date for feedback is **30 June 2023**.

Feedback can be provided via email to [HLIU.Consultation@health.qld.gov.au](mailto:HLIU.Consultation@health.qld.gov.au).

# Background

## Who can deal with medicines?

Section 30 of the *Medicines and Poisons Act 2019* specifies how a person may be authorised to deal with a regulated substance (a medicine, poison, prohibited substance, fumigant or pesticide):

- as an approved person who is a member of a 'class of persons', such as a dentist, optometrist or pharmacist;
- as a person acting under an emergency order, issued to deal with an event such as a declared public health emergency or disaster;
- as a holder of a substance authority, such as a licence; or
- as a person specified within a substance authority.

The Medicines Regulation supports the Medicines and Poisons Act to regulate activities with scheduled medicines (Schedules 2, 3, 4 and 8 of the Poisons Standard (Cth)) for therapeutic purposes in Queensland.

The 'classes of persons' and the associated prescribed authorisations for each class are specified within Schedules 3 to 15 of the Medicines Regulation.

## Extended practice authorities

Section 232(4) of the Medicines and Poisons Act enables the chief executive<sup>1</sup> to make extended practice authorities (EPA) that state the places or contexts an approved person may deal with a regulated substance, imposing conditions on dealings with the substance, or requiring a person to hold particular qualifications or training.

The following EPAs have been made under schedule 1, part 1 of the Medicines Regulation:

- Aboriginal and Torres Strait Islander health practitioners;
- Aboriginal and Torres Strait Islander health workers;
- Indigenous health workers;
- Queensland Ambulance Service;
- Midwives;
- Registered nurses;
- Pharmacists; and

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<sup>1</sup> The Director General, as chief executive of Queensland Health (section 16, *Public Sector Act 2022*), is the 'responsible head' to administer the legislation portfolio set out under the latest [Administrative Arrangements Order](#).

- Physiotherapists.

The [Extended Practice Authority – Pharmacists](#) sets out which vaccines a pharmacist may administer (Appendix 2) and the locations in which vaccines may be administered, which are limited to community pharmacies and public sector hospitals.

## Emergency Order

During the COVID-19 public health emergency, emergency orders authorised a wide range of health and community workforce to give COVID-19 and influenza vaccines to Queenslanders.

Under the [Emergency order – COVID-19 Vaccination Service Providers – COVID-19 vaccine and influenza vaccine](#) (Emergency Order), which is in force from 30 April 2023 to 29 July 2023, a range of health professionals, including pharmacists, are authorised to administer COVID-19 and influenza vaccines at Australian Government-controlled and Queensland Government-controlled COVID-19 vaccination locations (which includes locations such as vaccination clinics, General Practices and Aboriginal and Torres Strait Islander community-controlled health services).

## Pharmacists

Pharmacists are a nationally regulated profession under the Health Practitioner Regulation National Law. A pharmacist must be registered with the Pharmacy Board of Australia and meet the Board's Registration Standards to practise in Australia.

Pharmacists work in both public and private health settings across Queensland where they provide medication management services that may include clinical services related to quality use of medicines or functions related to dispensing and supply of medicines.

Internationally, the scope of pharmacists is expanding, and many countries allow pharmacists to administer medicines including Canada, United States and the United Kingdom. Pharmacists are taking on an increasingly important role within primary healthcare, where pharmacists are contributing to the safe and effective care of patients including by providing administration of medicines. Health systems have enabled pharmacists to administer a broad range of medicines with improved access to healthcare services, reduced wait times for medicine administration services, improved medicine adherence and cost savings.

Best practice for dispensing requires pharmacists to provide advice or education to patients, carers and other health professionals regarding administration to ensure medicines are used safely and effectively. For example, a pharmacist may review and correct inhaler technique to ensure appropriate patient administration of an inhaled bronchodilator or corticosteroid thus ensuring effective treatment is occurring.

Current entry level education and training for pharmacists includes principles of pharmacology, including the pharmacokinetics and pharmacodynamics of medicines, as well as their safe and effective use in patient care, appropriate administration of medicines, including the different routes of administration, principles of dosing and drug interactions.

# Pharmacists and vaccine administration

Childhood vaccination coverage rates have been declining over the past two years, and there has been reduced uptake of adolescent vaccination through school immunisation programs. While vaccine hesitancy is thought to be a contributing factor to this trend, access to timely and convenient immunisation services has also been identified as an issue.

Pharmacists have been authorised to administer vaccines in Queensland since 2014. Pharmacists are trained to administer vaccinations as part of their clinical training and required to maintain competency as part of their ongoing registration.

Pharmacists have provided an important service to the Queensland population, administering a large proportion of vaccines and easing the demand on general practice to provide this service. Community pharmacies played a pivotal role in Queensland's COVID-19 vaccine roll-out, administering approximately 15 per cent of all COVID-19 vaccines to people aged 5 years and older.

In 2023, eligible Queensland pharmacies gained access to the National Immunisation Program (NIP) funded influenza vaccines through the Queensland Health Immunisation Program (QHIP). This enables QHIP registered pharmacies to access Commonwealth-funded influenza vaccines for administration to eligible cohorts.

## Issue 1: Pharmacists and vaccinations

### Current restrictions

Schedule 9 of the Medicine Regulation provides that pharmacists may administer a medicine mentioned in the EPA-Pharmacists.

Under the EPA-Pharmacists, a pharmacist in Queensland may administer the following vaccines:

- Influenza vaccine (as per the recommended doses by age group detailed in the Australian Immunisation Handbook or as determined by the Therapeutic Goods Administration);
- Diphtheria-tetanus-acellular pertussis vaccine (to persons aged 16 or over);
- Diphtheria-tetanus-acellular pertussis-inactivated poliovirus vaccine (to persons aged 16 or over);
- Measles-mumps-rubella vaccine (to persons aged 16 or over);
- Cholera vaccine (to persons aged 16 or over);
- Haemophilus influenzae type B vaccine (to persons aged 16 or over);
- Hepatitis A vaccine (to persons aged 16 or over);
- Meningococcal ACWY vaccine (to persons aged 10 or over);
- Poliomyelitis vaccine (to persons aged 16 or over);

- Pneumococcal vaccine (to persons aged 16 or over); and
- COVID-19 vaccine (must comply with any limitations in the product information or as determined by the Therapeutic Goods Administration).

Under the EPA-Pharmacists, pharmacists may only provide vaccinations at the following locations:

- a community pharmacy
- a public sector hospital.

However, the current Emergency Order, which expires on 29 July 2023, allows pharmacists to administer the Influenza vaccine and COVID-19 vaccine at a broader range of approved vaccination service locations.

## Policy rationale for expanding EPA-Pharmacists

Queensland pharmacists have a demonstrated track record of providing safe and effective vaccination services in a variety of settings. Some of the vaccines pharmacists are already authorised to administer have historically been considered to be “higher risk” vaccines (e.g. live vaccines, or vaccines with more complex clinical considerations). As such, there is little justification for continuing to restrict the list of vaccines pharmacists are authorised to administer. This is with the exception of specialised vaccines that require detailed clinical consultation and intervention prior to administering the vaccine.

The list of proposed vaccines (see below) provides consistency with the vaccines pharmacists are authorised to administer in other jurisdictions. Further, the list reflects vaccines for which there is an identified public health benefit in making them more accessible for consumers. It is anticipated improving access to routine vaccination services through pharmacies will assist in increasing childhood and adolescent vaccination coverage rates.

Limiting the locations in which pharmacists may administer vaccines restricts the ability of this key immunisation workforce to provide vaccine services offered by Hospital and Health Services outside of the hospital, as well as aged care, general practice, and Aboriginal and Torres Strait Islander health services.

By increasing the locations that pharmacists can vaccinate through the EPA-Pharmacists, the changes will ensure not only COVID-19 and influenza vaccines can be administered in a safe and controlled setting, an increased range of vaccines can also be administered.

## Other jurisdictions

All jurisdictions enable pharmacists that have completed a recognised vaccination training course to be authorised to administer vaccines under their relevant state or territory legislation. The types of vaccines that can be administered and conditions of administration vary between each state and territory.

A jurisdictional comparison of the vaccines and associated age-groups, pharmacists are authorised to administer is detailed in [Appendix 1](#).

# Proposed changes

## 1. Expanding the list of vaccines that can be administered by pharmacists

It is proposed to amend the EPA to expand the list of vaccines Queensland pharmacists may administer, to include –

- Hepatitis B vaccine
- Varicella vaccine
- Meningococcal B vaccine
- Human papillomavirus (HPV) vaccine
- Typhoid vaccine
- Zoster vaccine
- Japanese encephalitis vaccine
- Rotavirus vaccine.

The EPA will impose restrictions and conditions for vaccines that are consistent with the recommended doses by age group detailed in the *Australian Immunisation Handbook*.

## 2. Expanding the locations in which a pharmacist may administer a vaccination

On expiration of the Emergency Order, two possible options are:

Option 1: Return to status quo – pharmacists will revert to only being able to administer vaccines specified under the EPA in a community pharmacy or public hospital setting; or

Option 2: Introduce broader locations for pharmacists to administer vaccines under the EPA, in line with the services they have provided under the Emergency Order by amending the EPA to provide that in addition to a community pharmacy or public sector hospital, pharmacists may administer vaccines in:

- a service provided by a Hospital and Health Service;
- a general practice;
- an Aboriginal or Torres Strait Islander health service;
- an aged care facility; or
- an outreach clinic under the auspices of the organisations listed above (including community pharmacies or public sector hospitals).

This will ensure that after the Emergency Order ceases to operate, pharmacists can continue to administer vaccines at the above locations, as well as community pharmacies and public sector hospitals.

## Benefit of proposed changes

Pharmacists have vaccinated in a range of settings throughout the COVID-19 vaccine roll-out, as authorised under the Emergency Order for COVID-19 vaccination, which has been important in addressing access and workforce issues for the emergency response.

Pharmacists have continued to demonstrate a track record of providing safe and effective vaccination services in Queensland in a variety of settings. The proposed changes will facilitate broader access to vaccination services in primary healthcare settings by expanding the vaccination workforce and making it easier, and often more cost effective, for people to access timely services close to where they live, work, and play.

On the 28 April 2023, the Federal Health Minister, Mr Mark Butler MP, announced a range of reforms to Medicare to deliver on the recommendations of the Strengthening Medicare Taskforce Report. This includes support for workforces to work at the top of their scope of practice and reduce pressure on health systems.

From 1 January 2024, the Commonwealth Government has committed to expand the NIP to pharmacies across Australia. Expanding the list of vaccines, as proposed, ensures Queensland pharmacists have the authority to administer all the vaccines included under the NIP Schedule. Without these proposed changes, the Commonwealth Government commitment will not be able to be fully met in Queensland.

## Issue 2 – Authority for pharmacists to administer scheduled medicines, other than vaccines

### Current restrictions

In Queensland, pharmacists have several authorised dealings under the Medicines Regulation that include supply, dispense, sell without a prescription, give a treatment dose, repackage, compound, give a purchase order, possess and dispose.

However, pharmacists are not authorised within the Medicines Regulation to administer S2, S3, S4 and S8 medicines, except for a narrow scope of dealing for approved opioids and certain vaccines under the EPA-Pharmacists.

### Policy rationale for expanding EPA-Pharmacists

Pharmacists work in both public and private health settings across Queensland where they provide medication management services that may include clinical services related to quality use of medicines or functions related to dispensing and supply of medicines. Best practice for dispensing requires pharmacists to provide advice or education to patients, carers and other health professionals regarding administration to ensure medicines are used safely and effectively. For example, a pharmacist may review and correct inhaler technique

to ensure appropriate patient administration of an inhaled bronchodilator or corticosteroid thus ensuring effective treatment is occurring.

The current limitations imposed by the legislation may adversely impact timely access to care, a pharmacist's ability to provide opportunistic and comprehensive care and may be contributing to a higher workload on other professionals that administer medications (e.g., medical officers and nursing professionals).

Pharmacists are often the first point of contact for patients seeking medical advice. Authorising pharmacists to administer medications would provide an opportunity for pharmacists to provide timely treatment that may improve patient outcomes. This may be of considerable importance for patients living in rural or remote areas where there are established shortages of healthcare professionals. Authorising pharmacists to administer medications may provide an alternative health professional accessible for consumers seeking this service and health organisations that employ staff to administer medications. Regulated places that administer medications are required to have a Substance Management Plan (SMP) that describes the processes to ensure medicines are administered by persons with appropriate training and competency.

Current entry level education and training for pharmacists includes principles of pharmacology, including the pharmacokinetics and pharmacodynamics of medicines, as well as their safe and effective use in patient care, appropriate administration of medicines, including the different routes of administration, principles of dosing and drug interactions.

## Other jurisdictions

Queensland and the Northern Territory are the only jurisdictions to define *administer* within their respective medicines' regulations. The Northern Territory defines *administer* as to apply or introduce the substance to the body of a person or animal. This is consistent with the Queensland definition in section 26 of the Medicines and Poisons Act, that defines *administer* as to introduce a dose of the medicine into the body of a person or animal by any means, or to give a dose of the medicine to a person to be taken immediately.

Pharmacists' authority to administer medicine within Australia is subject to their respective authorities under the legislation:

- Western Australia - under part 7, division 10 of the *Medicines and Poisons Regulation 2016* (WA), pharmacists acting in the lawful practice of their profession, in accordance with specified *Structured Administration and Supply Arrangements*, may administer a S4 or S8 medicine.
- Northern Territory - under the *Medicines, Poisons and Therapeutic Goods Act 2012* (NT) a pharmacist is authorised to administer a S4 or S8 substance to another person under an administration order from an authorised prescriber.
- Victoria – Regulations 99, 100 and 101 of the *Victorian Drugs Poisons and Controlled Substances Regulation 2017* authorise a pharmacist to administer any Schedule 4, 8 or 9 poisons on the valid instruction from an authorised prescriber.
- Australian Capital Territory - under the *Medicines, Poisons and Therapeutic Goods Regulation 2008* (ACT), pharmacists are authorised to administer medicines to the extent necessary to practise pharmacy and, if employed, within the scope of employment.



- New South Wales – under the *Poisons and Therapeutics Goods Regulation 2008* (NSW) authorised pharmacists may supply and administer vaccines to a person without a prescription. Pharmacists in NSW are allowed to administer dispensed S4 and S8 medicines.
- Tasmania – Pharmacists can supply schedule 4 medicines in accordance with a valid prescription in accordance with the *Poisons Act 1971*. Under this act, the term supply includes administration. Additional legislative requirements apply for pharmacists administering vaccines.
- South Australia - under the *Controlled Substances (Poisons) Regulation 2011* (SA), the Minister may determine a class of registered health practitioner to administer a prescription drug as part of an immunisation program.

Within comparable Organisation for Economic Co-operation and Development (OECD) nations including Canada, New Zealand and the United Kingdom, pharmacists are authorised to administer injectable medications within their approved scope of practice. For example:

- Pharmacists practising in Canada (British Columbia) are allowed to administer most medications including controlled drugs and injectable medicines by intramuscular and subcutaneous injections (other than the deltoid and triceps area). The pharmacist is responsible for ensuring they have the required knowledge skills and abilities to safely administer these medicines.
- The scope of practice for pharmacists in New Zealand includes the administration of medicines, including injectable medicines.
- Some pharmacists in the United Kingdom are allowed to administer a range of medicines under the *Human Medicines Regulation 2012*. These regulations describe specific requirements for each type of medicine able to be administered, including the necessary training and qualifications.

## Proposed changes

It is proposed to amend the Medicines Regulation to enable pharmacists to *administer* scheduled medicines other than vaccines, including:

- schedule 2 (S2) and schedule 3 (S3) medicines,
- any medicine on a standing order,
- a schedule 4 (S4) or schedule 8 (S8) medicine on a prescription, and
- an S4 or S8 medicine in accordance with the medicine's approved label.

Under the proposed changes, pharmacists would be authorised to administer medicines in a variety of health contexts. Some examples are provided below:

1. S2 and S3 medicines – A pharmacist may administer a nicotine patch in a general practice to a patient for the purposes of demonstration.
2. Any medicine on a standing order – A pharmacist may administer salbutamol, naloxone or glyceryl trinitrate under a standing order at an Aboriginal and Torres Strait Islander Health Service for emergency management.

3. An S4 medicine in accordance with its approved label – A pharmacist may administer by subcutaneous injection a dose of dulaglutide in accordance with its dispensed label for the purposes of education or to facilitate compliance where a patient may be unable to store this medicine appropriately, in a community pharmacy
4. S8 medicine on a prescription - A pharmacist may administer a dose of oral oxycodone on the valid prescription of an authorised prescriber in a relevant institution (e.g., hospital) where they have observed a requirement for pain relief in a patient.

## Benefits of proposed changes

Pharmacists are well-placed to administer medicines within the health system. Enabling pharmacists to administer any scheduled medicine that has been prescribed in the authorised way, has the potential to build service capacity in enabling another professional to perform a core function related to medicine management. Extending the authorised scope of practice for pharmacists may improve access and timeliness of healthcare delivery, aid with medication adherence, improve patient safety and result in cost savings for the health system.

There is an established health workforce shortage particularly within underserved rural and regional areas of Queensland, where enabling health practitioners to work may build capacity within the system. The *Unleashing the potential: an open and equitable health system* report identifies an innovative system and empowered workforce as a key priority area for reform within the health system. The proposed policy matter aligns with *My health, Queensland's future: Advancing Health 2026* focus area 4.2 putting research and new ideas into practice and the Queensland Health *Advancing health service delivery through workforce: A strategy for Queensland 2017 - 2026* focus area 2 enabling the workforce by supporting innovative and streamlined work practices through effective legislation policy.

## Appendix 1

Jurisdictional comparison of vaccines authorised to be administered by pharmacists, including age restrictions for each state and territory (28 April 2023)

Vaccine	ACT	NSW	NT	Qld current	Qld proposed	SA	Tas	Vic	WA
Influenza	5+	5+	10+	All <sup>6</sup>	All <sup>6</sup>	5+	10+	5+	5+
dTpa	12+	12+ <sup>1a</sup>	16+	16+	All <sup>6</sup>	10+	16+	12+	11+ <sup>2</sup>
MMR	12+	12+	16+	16+	All <sup>6</sup>	10+	16+	15+	11+
COVID-19	5+	5+	All	All <sup>6</sup>	All <sup>6</sup>	5+	5+	All	All
Cholera	-	-	-	16+	All <sup>6</sup>	-	-	-	-
<i>Haemophilus influenzae</i> type B	-	-	-	16+	All <sup>6</sup>	10+	-	-	-
Hepatitis A	5+	5+	-	16+	All <sup>6</sup>	10+	-	-	-
Hepatitis B	5+	5+	-	-	All <sup>6</sup>	10+	-	-	-
Meningococcal ACWY	14+	14+ <sup>1b</sup>	-	10+	All <sup>6</sup>	10+	-	15+	11+ <sup>2</sup>
Meningococcal B	-	-	-	-	All <sup>6</sup>	10+	-	-	-
Pneumococcal	-	-	-	16+	All <sup>6</sup>	-	-	50+	-
Herpes zoster / varicella	50+ <sup>3</sup>	50+ <sup>3</sup>	-	-	All <sup>6</sup>	50+/10+ <sup>5</sup>	-	50+	-
Poliomyelitis	5+	5+ <sup>1c</sup>	-	16+	All <sup>6</sup>	10+	-	-	-
Human Papillomavirus	12+	12+ <sup>1d</sup>	-	-	All <sup>6</sup>	10+	-	12+	11+ <sup>2</sup>
Japanese Encephalitis	-	5+	-	-	All <sup>6</sup>	5+	-	5+	-
Typhoid	5+ <sup>4</sup>	5+ <sup>4</sup>	-	-	All <sup>6</sup>	-	-	-	-
Rotavirus	-	-	-	-	All <sup>6</sup>	-	-	-	-

Note: In NSW, Vic, Tas and ACT, pharmacists are authorised to administer any vaccination on prescription.

1. NSW: (1a) 12-19 years only, (1b) 12-19 years only, (1c) 5-19 years (1d) 14-19 years only
2. Persons aged 11-15 years can only be vaccinated by a pharmacist in accordance with the current Western Australian Immunisation Schedule
3. Shingrix brand only
4. Intramuscular injection only
5. Varicella only (chickenpox) vaccine to persons aged 10+, and herpes zoster (Shingrix) vaccine to persons aged 50+
6. Under the current EPA, pharmacists can administer influenza vaccine 'as per the recommended doses by age group detailed in the Australian Immunisation Handbook (AIH) or as determined by the Therapeutic Goods Administration (TGA)', and COVID vaccine as per 'any limitations in the product information or as determined by the TGA.' It is proposed to expand these conditions to all vaccines, rather than specify age limitations.