Medicines and Poisons (Medicines) Amendment Regulation (No. 4) 2025

Consultation Paper
August 2025

Contents

Purpose

The purpose of this consultation paper is to seek stakeholder feedback on proposed changes to the *Medicines and Poisons (Medicines) Regulation 2021* (Medicines Regulation).

Queensland Health acknowledges and thanks those stakeholders who have previously provided feedback on the proposed amendments. This feedback has been taken into consideration during the further development of the proposed amendments.

The consultation paper is for consultation purposes only and does not represent Queensland Government policy.

Your views are valuable and may be referred to in material provided to Government in considering this proposal. If legislative amendments are progressed, your feedback may be referred to in public documents, for example, as part of the Explanatory Notes.

Please provide any feedback on the proposed amendments by email to legislationconsultation@health.qld.gov.au by 5pm, **5 September 2025**.

If you have any questions or require further information about possible changes, please email your queries to the email address above before the closing date and an officer from Queensland Health will contact you.

Background

The main purposes of the *Medicines and Poisons Act 2019* (Act) include ensuring particular substances are made, sold, used and disposed of in an appropriate, effective and safe way and ensuring that health risks arising from the use of substances are appropriately managed.

Medicines Regulation

The Medicines Regulation regulates medicines and complements the Act by:

- ensuring regulated substances (medicines) are used safely and effectively to reduce public harm;
- setting out the 'authorised way' for a person to perform regulated activities with certain medicines; and
- providing flexible requirements for regulated activities, such as storage and disposal of medicines, that are commensurate with the approved person's qualifications and activities, and the public health and safety risk of the relevant medicines.

Section 30 of the Act specifies the following persons who are authorised to carry out regulated activities with a regulated substance, such as a medicine, poison or prohibited substance:

- an *approved person* who is a member of a 'class of persons', such as a doctor, nurse practitioner or another health practitioner;
- a *person acting under an emergency order*, issued to deal with an event such as a declared public health emergency or disaster;
- a *holder of a substance authority*, such as a company that holds a wholesale licence; or
- a *person acting under a substance authority*, such as a person employed by a company holding a wholesale licence.

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

The Medicines Regulation is amended from time to time to reflect changes to Queensland Health policies and practices and to address practical and operational issues. These periodic updates enable the Medicines Regulation to remain fit for purpose, ensuring that medicines continue to be subject to appropriate regulatory controls, that health practitioners are authorised to practice to the full extent of their professional qualifications and training, and that individuals have improved access to medicines and health services across all parts of Queensland.

Glossary

Term	Definition
Diversion-risk medicines	Diversion-risk medicines are those that pose a high risk of being misused or diverted for illicit purposes. They are listed in schedule 2, part 3 of the Medicines Regulation.
High-risk medicines	High risk medicines have an increased risk of causing significant harm or death if misused. High-risk medicines are listed in schedule 2, part 2 of the Medicines Regulation.
Monitored medicines	Monitored medicines are medicines identified by Queensland Health as potentially presenting a high risk of harm to patients and the community as a result of overdose, dependence, misuse and/or diversion. All schedule 8 medicines (and certain schedule 4 medicines) are monitored medicines. Monitored medicines are listed in schedule 2, part 4 of the Medicines Regulation.
Psychostimulants	Amfetamines and methylphenidate (collectively psychostimulants) are the first-line pharmacological treatment for adults and children with attention deficit hyperactivity disorder and are classed as schedule 8 medicines under the Commonwealth Poisons Standard. Under schedule 2 of the Medicines Regulation, psychostimulants are classed as restricted medicines, high-risk medicines, diversion-risk medicines and monitored medicines.
QScript	QScript is Queensland's online prescription monitoring system that collects real-time prescription information for monitored medicines from nationally conformant prescribing and dispensing software systems. QScript helps to inform prescribers and dispensers when a patient may be at risk of monitored medicine-related harm.
Restricted medicines	Restricted medicines are limited to certain specialist practitioners to deal with due to therapeutic risks associated with their use. Restricted medicines are listed in schedule 2, part 1 of the Medicines Regulation.
Standing order	A standing order is a document that authorises a medicine to be administered or given as a treatment dose to a person at a stated place, provided several conditions are met.
Urgent care settings	Urgent care settings means emergency service settings (that meet the descriptors outlined in the Clinical Services Capability Framework: Emergency Services for a Level 1 service or above), minor injury and illness clinics/centres, satellite health centres and urgent care clinics, virtual emergency care clinics, rapid access clinics and other equivalent services and facilities.

Overview of the Medicines and Poisons (Medicines) Amendment Regulation (No. 4) 2025

Proposed amendments

The proposed Medicines and Poisons (Medicines) Amendment Regulation (No. 4) 2025 will amend the Medicines Regulation to:

- authorise specialist general practitioners (specialist GPs) to deal with psychostimulants for the treatment of adults with attention deficit hyperactivity disorder (ADHD); authorise paediatricians to deal with psychostimulants for the treatment of ADHD in adults aged 18 to 25 years to support continued treatment of young persons transitioning to adulthood; and update outdated language;
- allow appropriately qualified and credentialed first contact emergency physiotherapist practitioners (credentialed EPPs) to prescribe and administer additional medicines under the Physiotherapists Extended Practice Authority, when treating patients in urgent care settings;
- authorise registered nurses (RNs) with an endorsement to prescribe schedule 2 (S2), schedule 3 (S3), schedule 4 (S4) and schedule 8 (S8) medicines (excluding monitored medicines, other than in QScript exempt circumstances, and restricted medicines) in partnership with an authorised health practitioner;
- authorise RNs at a Hospital and Health Service (HHS) to give a treatment dose of S2, S3 and S4 medicines, if the medicine is given for bowel preparation required for relevant procedures or diagnostics at an HHS, and the medicines are given on a prescription or on a standing order;
- remove hydroxychloroquine from the list of restricted medicines; and
- make minor administrative amendments.

Details about the proposed amendments are provided below.

Description of proposed amendments

Psychostimulant prescribing

It is proposed to amend the Medicines Regulation to:

- authorise specialist GPs to deal[1] with psychostimulants for the treatment of adults with ADHD, subject to maximum dosage limits;
- authorise paediatricians to deal with psychostimulants for the treatment of ADHD in adults aged 18 to 25 years, to support continued treatment of young people transitioning to adulthood, subject to maximum dosage limits; and
- update outdated language.

Background

Psychostimulants are the first-line pharmacological treatment for adults and children with ADHD. The use of psychostimulants for the treatment of ADHD is well established in clinical practice and there is substantial evidence of their safety and effectiveness.

Psychostimulants are classed as S8 medicines under the Commonwealth Poisons Standard and as restricted medicines, high-risk medicines, diversion-risk medicines and monitored medicines under schedule 2 of the Medicines Regulation.

Under the Medicines Regulation, medical practitioners are authorised to deal with psychostimulants for the treatment of ADHD in children aged 4 to 17 years. However, only psychiatrists are authorised to deal with psychostimulants for the treatment of ADHD in adults, subject to maximum dosage limits.

Health practitioners can apply for a prescribing approval under section 75 of the Act to prescribe a psychostimulant for a patient in circumstances beyond their current authorisation. A prescribing approval authorises a prescriber to prescribe restricted medicines in circumstances stated in the approval. Prescribing approvals typically relate to individual patients and are decided on a case-by-case basis by the chief executive of Queensland Health or their delegate. Prescribing approvals are typically granted for a period of two years.

Growth of psychostimulant prescriptions

In recent years there has been a rapid growth of psychostimulant prescriptions in Australia. In Queensland, this has led to a substantial increase in applications for prescribing approvals, primarily from medical practitioners working in general practice seeking to prescribe psychostimulants for adults for the treatment of ADHD.

The application process for prescribing approvals creates regulatory burden for prescribers and may lead to delays in clinical treatment. For a prescribing approval application to be granted to a medical practitioner for treating an adult with ADHD, the patient must have already been diagnosed with ADHD by a psychiatrist, and have commenced treatment with a psychostimulant or had it recommended by the psychiatrist. When a child transitions to adulthood they are required to be reviewed and seek a confirmation of diagnosis of ADHD from a psychiatrist, even if a paediatrician has made an initial diagnosis during childhood.

[1] For the psychostimulant prescribing amendments, *deal* means prescribe, give a treatment dose, dispense, administer, give a purchase order or possess.

Senate Inquiry

In 2023, the Commonwealth government commissioned a Senate inquiry – 'Assessment and support services for people with ADHD' – to investigate the barriers to accessibility of psychostimulants for the management of ADHD. The primary barriers identified were:

- prescribing regulations;
- low availability of specialist healthcare professionals; and
- high out of pocket costs.

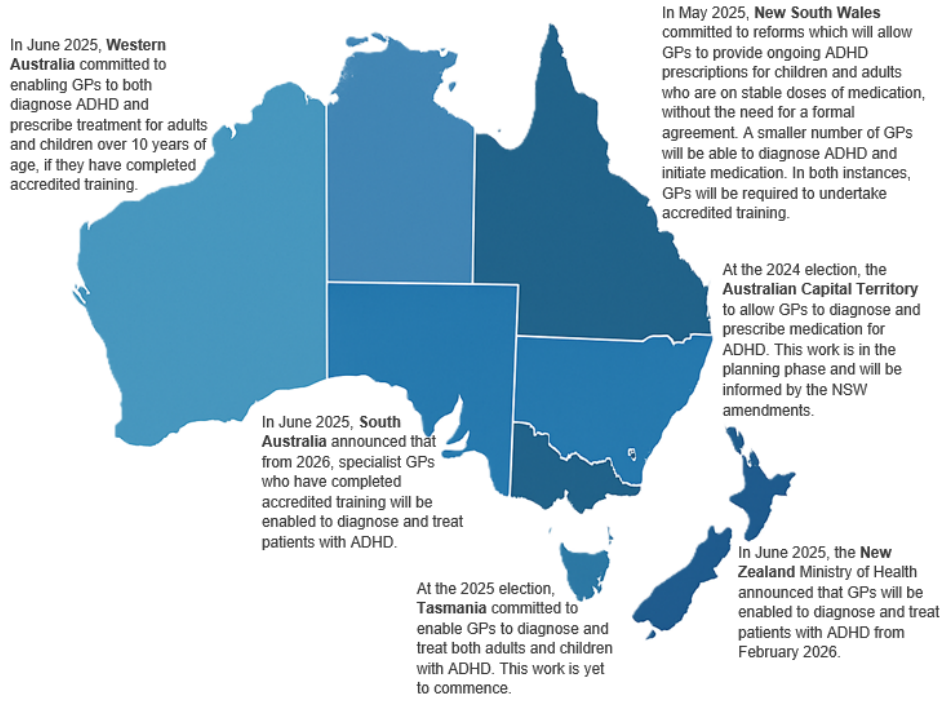
The report of the Senate Community Affairs References Committee (Senate report), released in November 2023, identified that prescribing regulations present significant challenges for patients to access psychostimulants, with the transition to adulthood identified as one of the most challenging periods.

A large number of submitters to the inquiry explained that low availability of specialist healthcare professionals (particularly publicly funded psychiatrists) meant that they and their families had to wait long periods for assessment and diagnosis of ADHD. Patient access is further impacted for those in rural, regional and remote areas where there is a lack of psychiatrists able to diagnose ADHD and initiate treatment.

The inquiry also found that high out of pocket expenses for ADHD support services present another barrier, as bulk billing by specialist medical practitioners is limited, with insufficient Medicare rebates payable—particularly on allied health services – and limited coverage by private health cover.

Jurisdictional comparison

In response to the Senate report, most jurisdictions are progressing amendments to expand psychostimulant prescribing authorisations for general practitioners with the aim of improving access to treatment for those with ADHD.



Previous proposal

In December 2024, in response to the Senate report, Queensland Health released a public consultation paper proposing amendments to the Medicines Regulation to improve access to psychostimulants by

allowing medical practitioners and nurse practitioners to deal with psychostimulants for the ongoing treatment of adults diagnosed with ADHD, if a psychiatrist or paediatrician had made the diagnosis and commenced treatment or recommended a treatment plan.

The feedback on the proposed amendments was largely supportive, with many stakeholders recommending the proposal go further, authorising medical practitioners to diagnose ADHD and initiate psychostimulants for adults in the same way they are currently authorised for children. The feedback in response to authorising prescribing by nurse practitioners was mixed, with some stakeholders expressing strong support, and others strong opposition.

Overall, it was identified there were practical challenges with the proposal, in particular with compliance monitoring and enforcement of the proposed amendments. Queensland Health determined it was premature to proceed until these issues could be considered further.

Further consultation

In March and April 2025, further consultation occurred with key stakeholders with a view to addressing the challenges identified during the previous public consultation. A number of options were considered, including enabling all medical practitioners to deal with psychostimulants for adults with ADHD in the same way that they are currently authorised for children with ADHD, or whether a phased approach, initially authorising a smaller cohort, would be preferred. Peak medical bodies expressed broad support for enhancing authorisations for medical practitioners to deal with psychostimulants, but preferred that a phased approach be taken, initially authorising certain specialist medical practitioners, rather than all medical practitioners.

Proposal

Adults with ADHD

It is proposed to initially authorise specialist GPs as a new class of person under the Medicines Regulation to deal with psychostimulants for the treatment of adults with ADHD, subject to the same maximum dosage limits that apply for psychiatrists. No prior diagnosis of ADHD by a paediatrician or psychiatrist will be required.

If a medical practitioner does not hold registration as a specialist GP, they will not be in-scope for the proposed amendments and will continue to require a prescribing approval to deal with psychostimulants for the treatment of adults with ADHD.

What is a specialist general practitioner?

Specialist GPs are medical practitioners, recognised under the *Health Practitioner Regulation National Law Act 2009* (National Law), with specialist registration in general practice listed on the Australian Health Practitioner Regulation Agency register. The term ‘specialist general practitioner’ is a protected title.

Specialist GPs undergo significant training in medicine, including the completion of a Bachelor of Medicine and Bachelor of Surgery, followed by two years of post-graduate hospital training and three years of supervised training in a general practice setting. Following this, prospective specialist GPs must pass examinations of an accredited general practice training program, such as Fellowship of the Royal Australian College of General Practitioners or Fellowship of the Australian College of Rural and Remote Medicine, before being able to be registered by the Medical Board of Australia as a ‘specialist general practitioner’. Specialist GPs undertake ongoing quality improvement and continuing professional development activities each year to maintain their registration.

Specialist GPs typically act as the first point of contact for patients within the healthcare system, providing ongoing care and establishing an ongoing therapeutic relationship with the patient. They are trained in diagnosis, treatment, prevention and management of both acute and chronic conditions and coordination

and supervision of care arrangements. It is considered that specialist GPs have an additional skillset and are suitably qualified to initiate treatment and provide continuity of care for adult patients with ADHD, and are professionally accountable to know when to refer a patient to a medical practitioner in another specialty field when clinically required.

Authorising specialist GPs to prescribe psychostimulants for adults with ADHD will reduce the demand for appointments with other specialist medical practitioners, primarily psychiatrists. Often psychiatrists have lengthy wait times and are unable to take on new patients. The amendments are expected to increase availability for psychiatrists and enhance patient access for other services.

Authorising specialist GPs to diagnose ADHD and commence treatment with psychostimulants will increase access to treatment for Queenslanders with ADHD. It is acknowledged that this increase in access will likely add to the growth in psychostimulant prescribing rates. As psychostimulants are diversion-risk medicines any increase in prescriptions may lead to an increased risk of misuse or diversion. These risks will be mitigated through appropriate safeguards such as only authorising specialist GPs to deal with psychostimulants and the mandatory requirements to check QScript before prescribing or dispensing a psychostimulant for a patient.

Despite being authorised to deal with psychostimulants for an adult with ADHD, there is the possibility that some specialist GPs may consider that it is not within their professional scope of practice and choose not to prescribe psychostimulants. It is expected that there will be sufficient specialist GPs to deal with psychostimulants under the proposed amendments to significantly enhance access for patients.

Transition to adulthood for children with ADHD

Paediatricians are already authorised under the Medicines Regulation to deal with psychostimulants for a child with ADHD until the age of 18. It has been identified that the transition to adulthood is a challenging period for continuity of care and ongoing access to psychostimulants. It is proposed to extend the authorisation for paediatricians under the Medicines Regulation, allowing them to deal with psychostimulants for adults with ADHD aged 18 to 25 years, subject to the same maximum dosage limits for adults that apply to psychiatrists. This will allow paediatricians to continue treatment of a young person transitioning to adulthood.

Nurse practitioners

In line with stakeholder feedback, any new as-of-right authorisations for nurse practitioners to deal with psychostimulants will be further considered at a later stage. Nurse practitioners working with patients with ADHD may continue to apply for prescribing approvals to deal with psychostimulants.

Minor amendments

It is also proposed to make related minor amendments to the Medicines Regulation to:

- Replace the outdated term ‘attention deficit disorder’ with ‘attention deficit hyperactivity disorder’.
- Replace the outdated term ‘brain damage’ with ‘brain injury’.
- Amend inconsistent language throughout the Medicines Regulation in reference to psychostimulants. In some sections of the Medicines Regulation, psychostimulants are referred to as ‘amfetamine or methylphenidate’, and in other sections the medicines are referred to in the plural form.
- Amend section 87 of the Medicines Regulation regarding required annotations by a prescriber on prescriptions for psychostimulants to reflect the proposed amendments. Prescribers are currently required under this section to write ‘specified condition’ or words to indicate the condition being treated on a prescription for a psychostimulant to indicate their authorisation to prescribe the medicine. Specified condition is not defined in the Medicines Regulation. Further clarity is required to ensure that the intent of this section is captured appropriately in line with the amendments. For example, specified condition could be defined to capture any as-of-right authorisations to prescribe psychostimulants, such as a paediatrician prescribing for ADHD for a child or a medical practitioner prescribing for brain injury for a child.

Credentialed first contact emergency physiotherapist practitioners

It is proposed to amend the Medicines Regulation to allow appropriately qualified and credentialed EPPs to prescribe and administer additional medicines (including additional S8 medicines) under the Physiotherapists Practice Authority (Physiotherapists EPA), when treating patients in public sector urgent care settings. It is also proposed to amend the current conditions for certain medicines already listed in the Physiotherapists EPA. This will enable credentialed EPPs to provide more comprehensive urgent care services.

Background

Credentialed EPP roles are a long-established model of care within HHSs. Credentialed EPPs autonomously manage patients presenting to public sector emergency departments and urgent care facilities with musculoskeletal conditions. First-contact patient management by credentialed EPPs includes independent assessment, requests for investigation, interpretation of pathology and imaging, diagnosis, treatment and onward referral. These functions are performed within a collaborative multi-disciplinary environment and support patient flow of low category, non-complex neuromusculoskeletal injuries including fracture management (plastering, splinting, reduction), joint relocation, management of minor wounds, complex traumatic musculoskeletal injuries, and acute or chronic multifaceted pain. presentations.

Credentialed EPPs working in a public sector urgent care setting are authorised to prescribe and administer the medicines specified in appendix 2 of the Physiotherapists EPA. This includes a subcutaneous local anaesthetic medicine (lidocaine), non-opioid analgesics and medicines for the relief of nausea and gastro-oesophageal reflex associated with prescribed analgesics.

To be credentialed to prescribe, physiotherapists are required to complete tertiary level study programs covering essential competencies in clinical therapeutics, safe prescribing and quality use of medicines, and must have undertaken a period of supervised practice and have been credentialed by their employing HHS. The use of medicines by credentialed EPPs is subject to local clinical governance, including credentialing, medicines safety and antimicrobial stewardship, which provides appropriate controls to manage the risks associated with the use of medicines by credentialed EPPs.

Issues

Since 2021, credentialed EPPs have been authorised under the Physiotherapists EPA to prescribe and administer specified medicines in certain circumstances. The medicines specified in the Physiotherapists EPA have not been reviewed since the commencement of the EPA in September 2021.

In its current state, the Physiotherapists EPA does not support credentialed EPPs to work to the full extent of their professional capabilities and impacts their efficiency and autonomy in public sector urgent care environments.

Extended practice authorities

An EPA states the places or circumstances in which an approved person may deal with a regulated substance. It may also impose conditions on the dealing with a regulated substance or require an approved person to hold particular qualifications or training to deal with a regulated substance.

Section 232 of the Act enables the chief executive of Queensland Health (or their delegate) to make an EPA. Schedules 3 to 15 of the Medicines Regulation provide ‘as-of-right’ authorisations for certain classes

of person to deal with certain medicines. EPAs provide additional authorisations beyond those stated in the Medicines Regulation.

As schedule 2, part 1 of the Medicines Regulation lists all approved EPAs, when a new version of an EPA is made by the chief executive or their delegate, the Medicines Regulation must be amended to allow the new version to take effect.

Proposal

The proposed amendments to the Medicines Regulation will give effect to a new version of the Physiotherapists EPA, which expands the list of approved medicines that may be used by credentialed EPPs and amends the conditions for certain categories of medicines currently listed in the Physiotherapists EPA. The amendments will allow credentialed EPPs to prescribe and administer additional local anaesthetics and non-opioid analgesics, and add new medicines for the management of minor wounds such as oral antibiotics and tetanus immunisations (including adrenaline for the management of immunisation induced anaphylaxis).

The proposed amendments to appendix 2 of the Physiotherapists EPA are summarised in the table below. Further details about the proposed changes are also provided below.

Additional medicines				**Revised restrictions**
Local anaesthetics	Non-steroidal anti-inflammatory drugs (NSAIDs)	Medicines for management of wounds associated with musculoskeletal or traumatic injury		Removal of single dose restrictions and indication restrictions
Amethocaine Lidocaine (topical) Prilocaine Anaesthetic formulations containing Adrenaline	Ketorolac Meloxicam	Amoxicillin + clavulanic acid Cefalexin Ciprofloxacin Clindamycin Dicloxacillin Doxycycline Flucloxacillin Metronidazole Trimethoprim + sulfamethoxazole	Tetanus immunisation (tetanus + diphtheria + pertussis) Adrenaline	Esomeprazole Metoclopramide Omeprazole Ondansetron Pantoprazole

Local anaesthetics

Credentialed EPPs may perform painful procedures such as fracture reductions and joint relocations and may manage the debridement of superficial and contaminated wounds. These procedures can be complex and take an extended amount of time.

Under the current Physiotherapists EPA, where local anaesthesia is required, credentialed EPPs are limited to the use of lidocaine via subcutaneous injection. It is proposed to add local anaesthetic preparations that have benefits in wound management (including formulations containing adrenaline, such as laceraine®) and authorise the topical route of administration for lidocaine that has benefits for use with paediatric or needle-phobic patients.

NSAIDs

Credentialed EPPs manage a broad range of musculoskeletal conditions which present with multisystem, complex pain behaviours that may be musculoskeletal, neuropathic, or behavioural in origin, and often occur in combination.

It is proposed to add ketorolac and meloxicam to the approved medicines to assist in pain management and reducing inflammation. These medicines complement the NSAIDs currently listed in the Physiotherapists EPA and have advantages over the current NSAIDs in certain patient groups. The inclusion of additional NSAIDs allows for a patient's individual circumstances to be considered when prescribing.

Medicines for minor wound management

Oral antibiotics

Credentialed EPPs may independently manage patients with minor wounds associated with musculoskeletal injuries that may be infected or at a high risk of infection, including superficial lacerations, abrasions, grazes, nailbed injuries and avulsed nails. Currently, if a wound is identified as infected, or at risk of infection, credentialed EPPs are required to refer the patient to an authorised prescriber for prescription of antibiotics. It is proposed to amend the Physiotherapists EPA to include oral antibiotics consistent with the antibiotics listed in the *Therapeutic Guidelines for Traumatic Wound Infections*.

The inclusion of oral antibiotics in the Physiotherapists EPA will remove the need for other authorised health practitioners to prescribe certain antibiotics, enabling credentialed EPPs to manage low-risk minor wounds more comprehensively within the primary contact model.

Tetanus immunisation

In accordance with the Australian Immunisation Handbook, when a patient presents with a traumatic wound the treating health professional must ensure that the patient's tetanus immunisations are up to date. Currently, where a credentialed EPP identifies the need for a tetanus booster they must refer the patient to another authorised practitioner within the urgent care setting to administer the tetanus immunisation. This delays patient treatment and contributes to ineffective workflow.

Credentialed EPPs are trained to perform intra-muscular injections and may safely administer immunisations. Credentialed EPPs demonstrated the ability to safely administer vaccines during the COVID vaccination rollout. Given this training and experience, it is proposed to authorise credentialed EPPs to administer tetanus immunisations, and in line with other EPAs, include adrenaline as an approved medicine for the management of anaphylaxis associated with immunisation.

Removal of single dose restrictions and indication restrictions

It is proposed to amend the Physiotherapists EPA to remove the single dose and indication restrictions for the prescription of medicines used to treat nausea and reflux.

Nausea treatment

Under the current Physiotherapist EPA, treatment with ondansetron is limited to a single dose to manage nausea caused by treatment with analgesic medicines. This limits credentialed EPPs' management of nausea where a patient may require repeat doses or have nausea from another identifiable cause.

Reflux treatment

Credentialed EPPs are limited to prescribing and administering a single dose of certain proton-pump inhibitor (PPI) medicines for the treatment of reflux associated with prescribed NSAIDs. This restriction conflicts with their authorisation to prescribe NSAIDs for longer treatment durations. Removal of the single dose restriction will allow the credentialed EPP to prescribe a duration of PPI treatment that aligns with the duration of NSAID therapy prescribed.

In addition, it is proposed to amend the title of the table '*Medicines for the relief of nausea and gastro-oesophageal reflux associated with prescribed analgesics*' to '*Medicines for the management of*

gastrointestinal side effects associated with prescribed analgesics' to accurately reflect the therapeutic uses of PPIs, including the prevention of NSAID-induced peptic ulcers and erosions.

Designated registered nurse prescribers

It is proposed to amend the Medicines Regulation to authorise RNs with an endorsement to prescribe S2, S3, S4 and S8 medicines (excluding monitored medicines, other than in QScript exempt circumstances, and restricted medicines) in partnership with an authorised health practitioner, such as a medical practitioner or nurse practitioner, under a prescribing agreement.

Background

Currently, the Medicines Regulation does not authorise RNs to prescribe medicines. RNs are comprehensively educated health professionals with a broad scope of practice and make up the largest proportion of health professionals in Australia.

Under section 94 of the National Law, a National Board may endorse the registration of a health practitioner registered by the Board as being qualified to administer, obtain, possess, prescribe, sell, supply, or use a scheduled medicine or class of scheduled medicines if an approved qualification is held.

In 2013, the Health Ministers granted approval to commence the Health Professionals Prescribing Pathway, a project exploring ways to provide a consistent, nationally recognised approach to prescribing by a diverse range of health professionals.

In 2016, the former Health Workforce Principal Committee requested the Nursing and Midwifery Board of Australia (NMBA) and the Australian and New Zealand Council of Chief Nursing and Midwifery Officers explore potential models of prescribing by RNs. The NMBA and Australian and New Zealand Council of Chief Nursing and Midwifery Officers conducted extensive research and consultation to develop the most effective model of prescribing by RNs. Following this extensive research and consultation, the NMBA prepared a proposal to be considered at the Health Ministers' Meeting (sitting as the Ministerial Council under part 2 of the National Law).

In December 2024, at the Health Ministers' Meeting, it was agreed to:

- endorse the NMBA's proposal for a scheduled medicines endorsement and the associated *Registration Standard: Endorsement for scheduled medicines – designated registered nurse prescriber* (Registration Standard), which outlines the role of a designated RN prescriber; and
- commence amendments to respective state, territory and Commonwealth policies and drugs and poisons legislation to enable operationalisation of the designated RN prescriber role.

The draft Registration Standard was approved by the Ministerial Council under section 12 of the National Law. The NMBA has published an advance copy of the Registration Standard and Guidelines to allow applicants time to familiarise themselves with the new standard.

Registration Standard

The Registration Standard will come into effect in September 2025. It describes how an RN can qualify for the endorsement for scheduled medicines and sets out the scope of the endorsement, and what the NMBA expects of RNs to attain and retain this endorsement.

An endorsement of registration will enable suitably educated and qualified RNs to prescribe S2, S3, S4 and S8 medicines in partnership with authorised health practitioners under a clinical governance framework and an active prescribing agreement (these underlined terms are defined below).

It is important to note that the endorsement to deal with scheduled medicines under the national registration scheme indicates the RN is qualified to administer, obtain, possess, prescribe, supply and/or use S2, 3, 4, and 8 medicines specified in the endorsement, **but it does not authorise them to do so**. This authorisation

is provided under each state or territory's relevant medicines legislation. Designated RN prescribers must deal with medicines in accordance with the relevant jurisdiction's legislation at all times.

Authorised health practitioner

For the purposes of prescribing as a designated RN prescriber, an authorised health practitioner is a registered health practitioner who is an authorised autonomous prescriber (for example, a medical practitioner or nurse practitioner). More than one authorised health practitioner may work with the designated RN prescriber under a prescribing agreement.

Clinical governance framework

The clinical governance framework is to be established by the relevant health organisation/service or employer, who are best placed to develop and approve clinical governance frameworks for this designated prescribing model.

It is the employer's responsibility together with the designated RN prescriber and authorised health practitioner to ensure there is an appropriate clinical governance framework in place to support the model of prescribing.

Prescribing agreement

The key document for the RN prescribing model is the prescribing agreement, which is a written agreement between the designated RN prescriber and the authorised health practitioner, approved by the relevant health organisation/service or employer.

This agreement will be retained by the health service, regularly reviewed, and may be subject to audit by the NMBA. Details of the prescribing agreement must clearly document the role of both the designated RN prescriber and the authorised health practitioner.

The scope of the prescribing authorisation may vary according to the health organisation or facility, prescribing agreement and the specific clinical context of its application. To reflect this, the prescribing agreement must include:

- roles and responsibilities of both the designated RN prescriber and authorised health practitioner;
- clients and/or conditions within the scope of prescribing practice of the designated RN prescriber;
- medical conditions for which the designated RN prescriber has authority to prescribe;
- medicines that the designated RN prescriber is authorised to prescribe;
- where S8 medicines are included, specific details including a risk analysis;
- responsibility for aspects of care regarding diagnosis and associated prescribing including use of the real time prescription monitoring system (QScript);
- clearly documented processes for consultation and referral including provisions where proximity and/or availability of the authorised health practitioner to the designated RN prescriber may need consideration;
- arrangements where the agreement is with multiple authorised health practitioners;
- a plan for regular review (at least annually);
- a process for monitoring and audit of designated RN prescribing; and
- processes for resolving or escalating differences of opinions.

Previous consultation

In March 2025, Queensland Health released a public consultation paper proposing amendments to the Medicines Regulation to authorise RNs with an endorsement to prescribe scheduled medicines in partnership with an authorised health practitioner.

Feedback on the proposed amendments was largely supportive, with many stakeholders commending the proposal. However, some key stakeholders expressed reservations due to a lack of information. A number of stakeholders raised that without reviewing the Registration Standard, it would be difficult to provide fulsome feedback. Feedback also noted that further information on prescribing agreements was required.

Queensland Health is again consulting on proposed amendments, now that an advance copy of the Registration Standard is available and more details about the requirements for prescribing agreements have been provided.

Proposal

It is proposed to amend schedule 7 of the Medicines Regulation to add 'designated RN prescribers' as a new class of person (being an endorsed RN under the National Law) to prescribe S2, S3, S4 and S8 medicines (excluding monitored medicines, other than in QScript exempt circumstances, and restricted medicines) in partnership with an authorised health practitioner. This proposal will support the delivery of high-quality healthcare to Queenslanders, enhancing their access to timely, essential care.

Introducing this authority has the potential to alleviate pressure points in the healthcare system by improving access to essential health care services for patients, particularly those who live in regional, rural, and remote areas who are often disadvantaged due to their location.

QScript look-up requirements and exemptions

Section 41 of the Act includes mandatory requirements for relevant practitioners to check the prescribing and dispensing history for a patient on QScript before prescribing or dispensing a monitored medicine for a person, unless they have a reasonable excuse or an exemption specified in the Medicines Regulation. QScript helps to inform prescribers and dispensers when a patient may be at risk of monitored medicine related harm. The exemptions from this requirement apply to specific circumstances, for example, prescribing monitored medicines for administration when a patient is an inpatient at a hospital. These exemptions are further detailed in schedule 18, part 1A of the Medicines Regulation.

Under the Medicines Regulation, RNs are not classified as relevant practitioners required to check QScript, so do not have access to QScript. This means if designated RN prescribers were authorised to prescribe monitored medicines in any circumstance, they would not have access to the same safety mechanisms as other health practitioners, such as medical practitioners and nurse practitioners. While the Registration Standard will allow prescribing of all S2, S3, S4 and S8 medicines, at this stage it is proposed to exclude monitored medicines, except in QScript exempt circumstances. In situations where there is an exemption from checking QScript, it is proposed to allow designated RN prescribers to prescribe monitored medicines if it is within the scope of their prescribing arrangement and the clinical governance framework of their employer.

Queensland—along with the other states and territories—is working with the Australian Digital Health Agency and the national real-time prescription monitoring system vendor to explore the possibility of making technical enhancements to facilitate access to jurisdictional real-time prescription monitoring systems to a broader range of health practitioners, including designated RN prescribers.

Further amendments authorising designated RN prescribers to prescribe monitored medicines will be considered should these technical enhancements be made.

Registered nurses giving a treatment dose of bowel preparation medicines

It is proposed to amend the Medicines Regulation to authorise RNs at a HHS, to give a treatment dose of a S2, S3 or S4 medicine, if the medicine is given for bowel preparation required for relevant procedures or diagnostics at a HHS, and the medicine is given on a prescription or on a standing order.

Background

Bowel preparation medicines are medicines supplied to, and taken by, patients undergoing specific clinical procedures or diagnostic assessments (for example, a colonoscopy), often for the purpose of detecting bowel cancer or investigating gastrointestinal concerns. These medicines can be unscheduled, S2, S3, or S4, with the majority classified as S3.

Patients who have been scheduled for a gastrointestinal procedure at a HHS will typically meet with an RN prior to their procedure for a pre-procedural consultation, which includes education on bowel preparation. As the Medicines Regulation does not authorise RNs to give a treatment dose of bowel preparation medicines either on a prescription or a standing order, RNs cannot provide patients with these medicines as part of in-person pre-procedural consultations.

Once prescribed, bowel preparation medicines are dispensed either at the hospital-based pharmacy (nil cost to patient) or at a community pharmacy (at cost to patient). The dispensing pharmacist will educate the patient about the medicines as part of their dispensing protocol.

Having to attend a pharmacy after the pre-procedural consultation with the RN creates duplication regarding patient education and an unnecessary additional step in the pre-procedure process for patients.

Issues

HHSs have reported issues surrounding the current process for the supply of bowel preparation medicines through hospital-based pharmacies. The need for patients to attend a pharmacy subsequent to the RN pre-procedural consultation is creating additional resource requirements for HHSs, particularly for hospital pharmacy teams.

For many patients the hospital-based pharmacy is the only dispensing option, due to the prohibitive cost of having their prescription dispensed at a community pharmacy. The current process places additional burden on hospital-based pharmacies, which can lead to delays for consumers waiting in pharmacy queues.

Redirecting consumers to community pharmacies creates additional barriers due to the cost of purchasing the medicines. Consumers living in rural or remote areas may also experience barriers in accessing community pharmacies, including lack of transport and health issues that impact the patient's ability to attend a community pharmacy.

Cost and practical barriers to accessing bowel preparation medicines can have an impact on a patient's willingness to follow the required preparation processes for planned diagnostic procedures. This may mean not taking any of the required bowel preparation medicine, or not taking it as directed. If bowel preparation is unsatisfactory, the procedure is unlikely to produce accurate results and may require rescheduling. This can result in increased health risks to patients due to delays in undertaking procedures and the potential for inaccurate diagnostic findings. It also impacts already constrained HHS resources if procedures must be repeated.

Proposal

The proposed amendments will enhance access to bowel preparation medicines by enabling RNs at HHSs to provide patients with their bowel preparation medicines on a standing order or prescription, at nil cost to the patient, as part of in-person pre-procedural consultations. This will reduce resourcing costs for hospital-based pharmacies, improve patient wait times, and remove unnecessary burden for patients requiring gastrointestinal procedures at a HHS.

The proposal is limited to HHSs as different processes may occur in private health settings. Further, limiting the authorisation to HHSs will allow for appropriate oversight and monitoring by Queensland Health during implementation of the amendments.

Hydroxychloroquine

It is proposed to amend the Medicines Regulation to remove hydroxychloroquine from the list of restricted medicines and remove all references to hydroxychloroquine from the Medicines Regulation.

Background

Hydroxychloroquine is an S4 medicine and is used to treat certain autoimmune conditions including rheumatoid arthritis and lupus and can also be used for the prevention and treatment of malaria.

Therapeutic Goods Administration restrictions

During the COVID-19 pandemic, there was a significant increase in off-label prescribing of hydroxychloroquine as an unproven preventative and treatment for COVID-19, which raised concerns that this would create a potential shortage of the medicine in Australia. This shortage posed a serious health risk to individuals who were already using hydroxychloroquine for approved indications.

In March 2020, the Therapeutic Goods Administration (TGA) announced amendments to the Commonwealth Poisons Standard to include an Appendix D listing for hydroxychloroquine. This placed restrictions on the medical specialists who could initiate prescribing of hydroxychloroquine to mitigate the health risks associated with the potential shortage.

These restrictions limited the ability to initiate prescribing of hydroxychloroquine to certain medical practitioners who held specialist registration with the Medical Board of Australia in certain fields of specialty practice including dermatology, intensive care medicine, paediatrics and child health, physician, and emergency medicine.

Public Health Direction

In April 2020, in response to the TGA restrictions, the Chief Health Officer issued a Public Health Direction to enforce the restrictions in Queensland. This was reflected in the list of restricted medicines in the Medicines Regulation when it commenced in September 2021, with the direction subsequently revoked in March 2022.

Under the Medicines Regulation, initiation of hydroxychloroquine is limited to specialist dentists and certain specialist medical practitioners. Medical practitioners and nurse practitioners are authorised to deal with hydroxychloroquine for the continuing treatment of a patient. That is, where an authorised specialist medical practitioner has already initiated treatment by prescribing hydroxychloroquine for the patient.

A medical practitioner or nurse practitioner can apply for a prescribing approval under section 75 of the Act to prescribe hydroxychloroquine for initiation of treatment.

Removal of restrictions

In February 2025, the TGA amended the Commonwealth Poisons Standard to remove the restrictions around initiating the prescribing of hydroxychloroquine. The TGA considered that the risks to public health of a potential shortage are now mitigated.

The removal of these Commonwealth controls means it is no longer necessary for hydroxychloroquine to be listed as a restricted medicine in the Medicines Regulation.

Proposal

It is proposed to amend the Medicines Regulation to remove hydroxychloroquine from the list of restricted medicines and remove all references to hydroxychloroquine. This will enable any practitioner who is authorised to prescribe an S4 medicine, other than a restricted medicine, to prescribe hydroxychloroquine, removing the need for practitioners to apply for prescribing approvals to prescribe hydroxychloroquine for initiation of treatment.

These amendments align with the removal of restrictions by the Commonwealth and will ensure that practitioners in Queensland are able to provide timely, clinically appropriate care to their patients.

Minor administrative amendments

Therapeutic Goods Advertising Code

It is proposed to make an administrative amendment to the Medicines Regulation to remove reference to the 'Price information code of practice' published by the TGA and replace it with the 'Therapeutic Goods Advertising Code', which is now the relevant document.

Adrenaline devices

It is proposed to make an additional administrative amendment to the Medicines Regulation to replace the definition and all references to adrenaline (epinephrine) autoinjector with adrenaline (epinephrine) device to enable the use of S3 non-injectable adrenaline devices for anaphylaxis management.

The proposed amendments will enable persons currently authorised to administer adrenaline via autoinjectors to also administer S3 adrenaline via other devices, such as an adrenaline nasal spray, for anaphylaxis management. The proposed amendments will provide flexibility to ensure the Medicines Regulation remains relevant if other types of S3 adrenaline devices are registered for use in Australia.

A further administrative amendment is proposed for the following EPAs, which currently refer to administration of adrenaline via the intramuscular route, to include administration of adrenaline via alternate routes for anaphylaxis:

- Aboriginal and Torres Strait Islander health practitioners;
- Aboriginal and Torres Strait Islander health workers;
- Indigenous health workers;
- Pharmacists; and
- Queensland Ambulance Service.