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

Explanatory notes for SL 2025 No. 148

made under the

Medicines and Poisons Act 2019

General Outline

Short title

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

Authorising law

Sections 54 and 240 of the *Medicines and Poisons Act 2019*.

Policy objectives and the reasons for them

The *Medicines and Poisons Act 2019* (Act) establishes a framework to ensure particular substances are made, sold, used and disposed of in a manner that is safe, effective and appropriate. The Act also provides for the management of health risks associated with these substances.

The *Medicines and Poisons (Medicines) Regulation 2021* (Medicines Regulation) regulates medicines and complements the Act by:

- promoting the safe and effective use of regulated substances to minimise harm;
- prescribing the 'authorised way' for persons to undertake regulated activities involving medicines; and
- providing flexible requirements for authorised activities, which are proportionate to the qualifications and roles of approved persons, as well as the public health and safety risks associated with the medicines.

The Medicines Regulation is regularly reviewed and amended to reflect changes in Queensland Health policies and practices, and to address practical and operational issues. These amendments ensure the Medicines Regulation remains current and fit for purpose, maintains appropriate regulatory controls, enables health practitioners to practise to the full extent of their qualifications and training, and supports improved access to medicines and health services throughout Queensland.

The *Medicines and Poisons (Medicines) Amendment Regulation (No. 4) 2025* (Amendment Regulation) amends the Medicines Regulation to:

- authorise specialist general practitioners 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in adults aged 18 to 25 years to support continued treatment of young persons transitioning to adulthood, and update outdated language;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 to prescribe and administer additional medicines under the Physiotherapists Extended Practice Authority, when treating patients in public sector urgent care settings;
- authorise registered nurses employed by, or for, a Hospital and Health Service (HHS) to give a treatment dose of a Schedule 2(S2), Schedule 3(S3) or Schedule 4 (S4) medicine for preparation of the bowel for a procedure, where the medicine is given on a prescription or a standing order;
- remove hydroxychloroquine from the list of restricted medicines; and
- make other administrative amendments.

Psychostimulants

The objective of the psychostimulant prescribing amendments is to improve access to psychostimulant medicines for the treatment of ADHD in Queensland.

Psychostimulants such as dexamfetamine, lisdexamfetamine, and methylphenidate are classified as Schedule 8 (S8) medicines under the Commonwealth Poisons Standard due to their potential for misuse and dependence. 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.

Under the Medicines Regulation, prescribing authorisations for psychostimulants are limited to the following health practitioners and circumstances:

- Psychiatrists are authorised to prescribe psychostimulants for adults diagnosed with ADHD, provided the dosage does not exceed the maximum daily dosage limits. These limits are 40 mg for dexamfetamine, 70 mg for lisdexamfetamine, and 80 mg for methylphenidate. Psychiatrists may also prescribe psychostimulants for children up to 18 years of age with ADHD or brain injury, without dosage limits.
- Paediatricians may prescribe psychostimulants for children up to 18 years of age who have been diagnosed with ADHD or brain injury. There are no maximum dosage limits when prescribing under these circumstances.
- Medical practitioners may prescribe psychostimulants for children aged 4-17 years with ADHD or brain injury without maximum dosage limits. However, they are not authorised to prescribe psychostimulants for adults with ADHD or brain injury unless they obtain a prescribing approval. Medical practitioners may also prescribe psychostimulants for the treatment of narcolepsy in a patient of any age. In institutional settings such as hospitals or custodial facilities, they may continue treatment under supervision.
- Nurse practitioners are authorised to prescribe psychostimulants for continuing treatment in institutional settings, such as hospitals or custodial facilities, and must do so under supervision.

Prescribing approvals

Under section 75 of the Act, a medical practitioner can apply for a prescribing approval to prescribe a psychostimulant for a patient in circumstances outside their standard authorisation. Applications for prescribing approvals are considered and decided on a case-by-case basis by the chief executive of Queensland Health or their delegate. In recent years, there has been a significant increase in applications for psychostimulant prescribing approvals, primarily from medical practitioners working in general practice seeking to prescribe psychostimulants for adults for the treatment of ADHD. The application process can create delays in treatment and impose administrative burden on prescribers.

Improving access to psychostimulants.

To improve access to psychostimulants, the Amendment Regulation authorises specialist general practitioners (specialist GPs) to prescribe, give a treatment dose, dispense, administer, give a purchase order and possess psychostimulants for the treatment of adults with ADHD, within established maximum dosage limits. These amendments will enable specialist GPs to initiate, modify and continue psychostimulant treatment for adults with ADHD. This reform is expected to reduce the demand for appointments with other specialist medical practitioners, primarily psychiatrists, and increase access to treatment for Queenslanders with ADHD.

Specialist GPs undergo extensive training, 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. They then must pass an accredited examination to be registered by the Medical Board of Australia as a 'specialist general practitioner'.

The Amendment Regulation also expands paediatricians' prescribing authority to include patients with ADHD aged 18 to 25 years, within established maximum dosage limits. Authorising paediatricians to treat this cohort will support continuity of care during their transition from adolescence to adulthood. This period is particularly challenging for maintaining access to ADHD treatment.

The Amendment Regulation also makes related amendments to:

- update outdated terminology, for example replacing 'attention deficit disorder' with 'attention deficit hyperactivity disorder' and 'brain damage' with 'brain injury';
- standardise references to psychostimulants; and
- clarify prescription requirements under section 87 of the Medicines Regulation.

Senate inquiry

These reforms respond to the findings of the 2023 Senate inquiry titled *Assessment and support services for people with ADHD*, which was commissioned by the Commonwealth government to investigate the barriers to accessing psychostimulants for the management of ADHD. In November 2023, the Senate Community Affairs References Committee released its final report (Senate report), which identified that prescribing regulations, low availability of specialist healthcare professionals and high out of pocket costs were the primary barriers for patients to access psychostimulants. The inquiry also identified that the transition to adulthood is one of the most challenging periods to access psychostimulants.

In response to the Senate report, most jurisdictions have committed to expanding prescribing authorisations for GPs to improve access to psychostimulants for the treatment of patients with ADHD.

Queensland is leading this national reform, with the amendments to commence on 1 December 2025. Other jurisdictions are progressing similar changes, with most expected to commence by the end of 2026.

First contact emergency physiotherapist practitioners

The objective of the amendments relating to credentialed first contact emergency physiotherapist practitioners (credentialed EPPs) is to enhance the scope of practice for credentialed EPPs, enabling them to deliver timely, autonomous, and high-quality care for patients presenting with musculoskeletal conditions in public sector emergency departments and urgent care facilities.

Credentialed EPPs are highly trained professionals, who operate as first-contact practitioners. They are authorised to independently undertake a broad range of clinical functions, including:

- comprehensive assessment and diagnosis;
- requesting and interpreting pathology and imaging;
- initiating treatment and management; and
- referring patients onward as required.

These functions are delivered within a collaborative multi-disciplinary environment and support efficient patient flow of low-acuity, non-complex neuromusculoskeletal presentations. This includes:

- fracture management, for example, plastering, splinting, reduction;
- joint relocation;
- minor wound care;
- management of complex traumatic musculoskeletal injuries; and
- acute or chronic multifaceted pain presentations.

To be credentialed to deal with medicines, physiotherapists must complete a tertiary level program covering essential competencies in clinical therapeutics, safe prescribing practices and quality use of medicines and must have undertaken a period of supervised practice.

<u>Proposed changes to Physiotherapists Extended Practice Authority</u>

Credentialed EPPs are authorised to prescribe and administer the medicines specified in the Physiotherapists Extended Practice Authority (Physiotherapists EPA)[1]. These include:

- analgesics;
- local anaesthetics;
- antispasmodics;

[1] An extended practice authority (EPA) is an instrument made by the Director-General of Queensland Health under section 232 of the Act. EPAs provide additional authorisations beyond those listed in the Medicines Regulation and may impose specific conditions, qualifications and other requirements for dealing with a regulated substance. Schedule 1, part 1 of the Medicines Regulation lists the approved EPAs by name and version number. When a new version is made, the Medicines Regulation must be amended to reflect the update so it can take legal effect.

- medicines for the management of neuropathic pain; and
- medicines for the relief of nausea and gastro-oesophageal reflux associated with prescribed analgesics.

Currently, the Physiotherapists EPA does not enable credentialed EPPs to fully utilise their professional capabilities, limiting their autonomy and efficiency in public sector urgent care environments.

The Amendment Regulation updates the Physiotherapists EPA to enable credentialed EPPs to prescribe and administer additional medicines and amends the current conditions for certain medicines already within the Physiotherapists EPA. These changes will allow credentialed EPPs to practice to their full scope, enhancing patient care and service delivery in public sector urgent care settings.

Bowel preparation medicines

The Amendment Regulation aims to improve patient access to bowel preparation medicines required for gastrointestinal procedures conducted at HHSs. These medicines are essential for ensuring accurate diagnostic outcomes, particularly in procedures such as colonoscopies used to detect bowel cancer or investigate gastrointestinal concerns.

Bowel preparation medicines are supplied to, and taken by, patients undergoing specific clinical procedures or diagnostic assessments. Patients scheduled for a gastrointestinal procedure at a HHS typically meet with an RN for a pre-procedural consultation, which includes education on the bowel preparation process.

Under the Medicines Regulation, RNs are not authorised to give a treatment dose of bowel preparation medicines either on a prescription or a standing order[2]. This restriction means RNs cannot provide these medicines directly to patients to take home as part of in-person pre-procedural consultations, requiring patients to subsequently obtain them from a pharmacy.

Once prescribed, bowel preparation medicines are dispensed either at:

- the hospital-based pharmacy; or
- a community pharmacy (at cost to the patient).

As part of their dispensing protocol, the dispensing pharmacist will educate the patient about the medicines, which may result in duplication of education already provided by the RN as part of the pre-procedural consultation. This additional step creates an unnecessary burden for patients and can delay or complicate the pre-procedure process.

For many patients, particularly those in rural and remote areas, the hospital-based pharmacy is the only dispensing option, due to the prohibitive cost of having their prescription dispensed at a community pharmacy, or lack of access to a community pharmacy. These barriers can negatively impact on a patient's willingness to follow the required preparation process for planned diagnostic procedures. This may result in not taking any of the required bowel preparation medicine, or not taking it as directed. Inadequate preparation may lead to inaccurate diagnostic results, rescheduling of procedures or increased health risks due to delays.

[2] 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.

To address these issues, the Amendment Regulation authorises RNs employed by, or for, a HHS, to give a treatment dose of an S2, S3 or S4 medicine for the preparation of the bowel for a procedure, provided the medicine is given on a prescription or on a standing order. This amendment will:

- reduce duplication in patient education;
- remove unnecessary steps in the pre-procedural gastrointestinal process;
- improve access to essential medicines; and
- support timely and accurate diagnostic procedures.

The Amendment Regulation also makes related additional amendments to the Medicines Regulation to standardise references to persons employed to work at a HHS facility, or for a HHS service.

Hydroxychloroquine

Hydroxychloroquine is an S4 medicine under the Commonwealth Poisons Standard. It is primarily used for the treatment of autoimmune conditions such as rheumatoid arthritis and systemic lupus erythematosus, and for the prophylaxis and treatment of malaria.

During the COVID-19 pandemic, there was a significant increase in off-label prescribing of hydroxychloroquine as an unproven treatment and preventative measure for COVID-19. This raised concerns about potential shortages of the medicine in Australia, posing a serious health risk to individuals who relied on hydroxychloroquine for approved therapeutic indications.

In response, the Therapeutic Goods Administration (TGA) amended the Commonwealth Poisons Standard in March 2020 to restrict the prescribing of hydroxychloroquine for the initiation of treatment to certain medical specialists. These included practitioners with specialist registration in dermatology, intensive care medicine, paediatrics and child health, physician, and emergency medicine. This measure was intended to mitigate the risk of medicine shortages and ensure continued access for patients with a legitimate clinical need for the medicine.

Following the TGA's action, the Chief Health Officer issued a Public Health Direction in April 2020 to enforce these restrictions in Queensland. These restrictions were subsequently reflected in the list of restricted medicines in schedule 2, part 1 of the Medicines Regulation, when the regulation commenced in September 2021. Restricted medicines are limited to certain specialist practitioners due to the therapeutic risks associated with their use.

Under the Medicines Regulation, only certain specialist medical practitioners and specialist dentists are authorised to initiate treatment with hydroxychloroquine. However, all medical practitioners and nurse practitioners are authorised to deal with hydroxychloroquine for continuing treatment if the patient was previously prescribed hydroxychloroquine by an authorised prescriber.

Under section 75 of the Act, a medical practitioner or nurse practitioner can apply for a prescribing approval to prescribe hydroxychloroquine for initiation of treatment. Applications for prescribing approvals are considered and decided on a case-by-case basis by the chief executive of Queensland Health or delegate.

In February 2025, the TGA removed the Commonwealth restrictions on initiating the prescribing of hydroxychloroquine, citing that the public health risks of a potential shortage are now mitigated. The removal of these Commonwealth controls mean it is no longer necessary for hydroxychloroquine to be listed as a restricted medicine in the Medicines Regulation.

The Amendment Regulation will remove hydroxychloroquine from the list of restricted medicines and remove all references to hydroxychloroquine from the Medicines Regulation. This amendment aligns the Medicines Regulation with the removal of restrictions by the Commonwealth and ensures that health practitioners in Queensland can provide timely and clinically appropriate care to patients.

Administrative amendments

Therapeutic Goods Advertising Code

The Therapeutic Goods Advertising Code specifies a range of requirements to protect the Australian public from the personal and public health risks that may arise from unethical, inaccurate or misleading advertising of therapeutic goods. It establishes clear and enforceable standards to ensure that advertising promotes the safe and proper use of therapeutic goods, supports informed health care choices, and does not mislead consumers or create unrealistic expectations about product performance.

As part of ongoing regulatory improvements, the Medicines Regulation is being amended to remove reference to the outdated 'Price information code of practice' published by the TGA. This reference is being replaced with the 'Therapeutic Goods Advertising Code', which is now the relevant document.

Adrenaline devices

Anaphylaxis is the most severe form of allergic reaction, which can be life threatening and must always be treated as a medical emergency. Anaphylaxis requires immediate administration of adrenaline, which is usually administered as an intramuscular injection using an autoinjector device such as an Epipen®. Delayed administration of adrenaline during anaphylaxis significantly increases the risk of severe outcomes and may result in death.

Currently, adrenaline is only available in Australia in two forms: autoinjector device, which is preloaded to deliver a single fixed dose of adrenaline, and in ampoules/vials form where the correct dose requires the adrenaline to be drawn up manually prior to administration. While both forms are suitable for treating anaphylaxis, the use of autoinjectors is preferred in emergency settings due to the ease of use and rapid administration.

The Medicines Regulation authorises certain classes of persons, including trained staff in schools and childcare facilities, first aid providers and various allied health professions to administer an adrenaline (epinephrine) autoinjector, via the intramuscular route, for emergency management of anaphylaxis. These authorisations do not extend to other forms of adrenaline, such as ampoules or emerging-noninjectable devices.

To ensure the Medicines Regulation remains responsive to evolving clinical practice and device innovation, the Amendment Regulation proposes to replace references to 'adrenaline (epinephrine) autoinjector' with 'adrenaline (epinephrine) device'. This change will enable the use of new S3 non-injectable adrenaline devices, such as nasal sprays, for anaphylaxis management.

Further amendments are proposed to the EPAs for Aboriginal and Torres Strait Islander health practitioners, Aboriginal and Torres Strait Islander health workers, Indigenous health workers, pharmacists and Queensland Ambulance Service. These updates will reflect the changes to include alternative routes of administration of adrenaline for anaphylaxis.

Enabling the administration of non-injectable adrenaline devices will:

- improve timely administration of adrenaline in emergency situations, particularly where there may be apprehension around the use of needles and injections;
- provide greater flexibility and choice in anaphylaxis management; and
- ensure the Medicines Regulation remains fit for purpose if other types of S3 adrenaline devices become available for use in Australia.

Achievement of policy objectives

The Amendment Regulation commences on 1 December 2025.

Psychostimulants

The Amendment Regulation amends schedule 6, part 2 of the Medicines Regulation to create a new class of person—general practitioner—being a medical practitioner who is a specialist registrant[3] in general practice (specialist GP). This amendment authorises specialist GPs to deal with psychostimulants for an adult with ADHD, subject to the same maximum dose limits that apply to psychiatrists (see schedule 22 of the Medicines Regulation).

This amendment is intended to reduce demand for appointments with other specialist medical practitioners, primarily psychiatrists, which are often subject to long wait times and limited availability. By expanding the prescribing authority to specialist GPs, the amendment will improve timely access to treatment for adults with ADHD, which is expected to increase the availability of psychiatrists and enhance patient access for other services.

The Amendment Regulation also amends schedule 6, part 2, division 15 of the Medicines Regulation to extend the psychostimulant prescribing authority to paediatricians treating an adult with ADHD aged 18 to 25 years, within the same maximum dose limits as psychiatrists (see schedule 22 of the Medicines Regulation). This amendment will allow paediatricians to treat a young person transitioning to adulthood, improving continuity of care and ongoing access to psychostimulants for the treatment of ADHD.

Further, the Amendment Regulation will make related minor amendments to improve clarity and consistency across the Medicines Regulation to:

- replace outdated terminology: ‘attention deficit disorder’ with ‘attention deficit hyperactivity disorder’ and ‘brain damage’ with ‘brain injury’;
- standardise language by replacing all references to psychostimulants with the term ‘psychostimulant medicine’. Psychostimulant medicine is defined at schedule 22 of the Medicines Regulation as an S8 medicine that is dexamfetamine, lisdexamfetamine or another type of amfetamine; or methylphenidate; and

[3] A specialist registrant, in relation to a person for a field of practice, means the person is registered as a specialist in the field under the Health Practitioner Regulation National Law.

- amend section 87 to require prescribers of an S8 psychostimulant medicine to specify the condition being treated, or use the words ‘specified condition’ if the medicine is for the treatment of a specified condition. The Amendment Regulation also amends section 87 to define specified condition to mean ADHD, brain injury or narcolepsy.

First contact emergency physiotherapist practitioners

The Amendment Regulation amends schedule 1, part 1 of the Medicines Regulation to give effect to version 3 of the Physiotherapists EPA. This update expands the list of approved medicines that may be prescribed and administered by credentialed EPPs and amends the conditions for certain categories of medicines currently listed in the Physiotherapists EPA.

These changes will enable credentialed EPPs to practice to their full scope and deliver more comprehensive urgent care services in public sector urgent care settings.

Bowel preparation medicines

The Amendment Regulation amends schedule 7, part 3, division 2 of the Medicines Regulation to authorise RNs employed by, or for, a HHS to give a treatment dose of bowel preparation medicines to patients on a prescription or a standing order. This amendment enables the provision of necessary medicines to patients as part of the in-person pre-procedural consultations conducted by RNs.

This amendment is restricted to HHSs, acknowledging different clinical and administrative 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.

Additionally, the Amendment Regulation will make related minor amendments to improve clarity and consistency across the Medicines Regulation by replacing all references to a person employed ‘at a HHS’ with ‘for a HHS’. A HHS is an entity, not a location. The amendments ensure the policy intent is achieved, by capturing all persons working at a HHS facility, or as part of a HHS service.

Hydroxychloroquine

The Amendment Regulation amends schedule 2 of the Medicines Regulation by removing hydroxychloroquine from the list of restricted medicines. The Amendment Regulation also removes all other references to hydroxychloroquine throughout the Medicines Regulation.

Amending the Medicines Regulation to remove hydroxychloroquine from the list of restricted medicines enables any practitioner authorised to prescribe an S4 medicine, other than a restricted medicine, to prescribe hydroxychloroquine. This amendment aligns the Medicines Regulation with the removal of restrictions by the Commonwealth and ensures that health practitioners in Queensland can provide timely and clinically appropriate care to patients.

Administrative amendments

Therapeutic Goods Advertising Code

The Amendment Regulation amends section 234(2)(a)(ii) of the Medicines Regulation by removing the reference to the 'Price information code of practice' published by the TGA and replacing it with the reference to the 'Therapeutic Goods Advertising Code', which is now the current document.

This amendment ensures Queensland legislation accurately reflects the correct and current TGA code.

Adrenaline devices

The Amendment Regulation amends schedule 22 of the Medicines Regulation to replace the term 'adrenaline (epinephrine) autoinjector' with 'adrenaline (epinephrine) device' and define it as an S3 medicine that is adrenaline (epinephrine) in a device designed to administer a single dose of the medicine for the purpose of managing anaphylaxis or allergic reactions.

The Amendment Regulation also replaces all references to 'adrenaline (epinephrine) autoinjector' with 'adrenaline (epinephrine) device' throughout the Medicines Regulation.

The 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 amendments improve flexibility and responsiveness in anaphylaxis management and ensure the Medicines Regulation remains relevant and adaptable if other types of S3 adrenaline devices become available for use in Australia.

A further administrative amendment will amend schedule 1, part 1 of the Medicines Regulation, to update references to the following EPAs. These EPAs have been amended to allow for the administration of adrenaline via alternative 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.

Consistency with policy objectives of authorising law

The Amendment Regulation is consistent with the policy objectives of the authorising Act.

Inconsistency with policy objectives of other legislation

No inconsistencies with the policy objectives of other legislation have been identified.

Alternative ways of achieving policy objectives

Psychostimulants

Currently, the Medicines Regulation does not authorise medical practitioners, other than psychiatrists, to deal with psychostimulants for the treatment of adults with ADHD without first obtaining a prescribing approval. This approach is overly restrictive, since in many cases it is safe and appropriate for a paediatrician or specialist GP to initiate or continue treatment with psychostimulants without requiring them to apply for a case-by-case prescribing approval or to refer the patient to a psychiatrist. Given the significant increase in applications for prescribing approvals and associated administrative burden, it has become necessary to provide an alternative form of authorisation for medical practitioners that maintains regulatory safeguards while improving access to care.

Authorising specialist GPs to deal with psychostimulants for adults with ADHD will reduce the regulatory burden for prescribers and 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.

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 compared to non-specialist medical practitioners and are suitably qualified to initiate treatment and provide continuity of care for adult patients with ADHD. Specialist GPs are professionally accountable to know when to refer a patient to a medical practitioner in another specialty field when clinically required. For these reasons it is appropriate that the authorisation is limited to specialist GPs rather than all medical practitioners.

Currently the Medicines Regulation authorises paediatricians 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. Extending the authority for paediatricians to enable them to prescribe psychostimulants for an adult with ADHD aged 18 to 25 years, within the same maximum dose limits that apply to psychiatrists, promotes continuity of care and allows a paediatrician to treat a young person transitioning to adulthood.

First contact emergency physiotherapist practitioners

Under the current Physiotherapists EPA, credentialed EPPs are unable to work to the full extent of their professional capabilities. This limitation reduces their autonomy and efficiency, ultimately affecting the delivery of timely and comprehensive care. The amendments to the Physiotherapists EPA will enable credentialed EPPs to provide more comprehensive management within urgent care settings. To implement these changes, amendments to the Medicines Regulation are required to give effect to the updated EPA.

An alternative approach would require credentialed EPPs to individually apply for prescribing approvals under the Act. However, this would introduce an additional layer of administrative burden for EPPs, particularly given that the clinical settings and conditions in which these practitioners operate already incorporate robust risk management through established clinical governance, multidisciplinary teams, and credentialing processes. Therefore, authorising credentialed EPPs via an amendment to the Physiotherapists EPA is considered a simpler and more effective solution. This approach is both reasonable and appropriate, offering a streamlined pathway that aligns with existing safeguards.

Bowel preparation medicines

There are no reasonable alternatives to the proposed amendments as the current process for supplying bowel preparation medicines creates financial and practical barriers for patients. The amendments will remove these barriers by allowing RNs employed by, or for, a HHS to provide necessary medicines as part of the in-person pre-procedural consultation.

An alternative option would be to expand the Registered Nurses EPA to include the supply of bowel preparation medicines. However, this activity is already within the general scope of practice for RNs and does not require an extension of practice. Therefore, it is more appropriate for this authorisation to be provided under the Medicines Regulation as an 'as-of-right' authorisation, aligning with the existing regulatory framework and professional competencies of RNs.

Additionally, consideration was given to applying the authorisation more broadly across public and private health sectors. However, processes for pre-procedural care and medicine supply vary significantly in private settings. Limiting the amendments to HHSs allows for appropriate oversight and monitoring by Queensland Health during implementation of the amendments.

Given these considerations, the amendments to the Medicines Regulation represent the most effective and proportionate means of achieving the policy objectives while ensuring patient safety, regulatory clarity, and operational efficiency.

Hydroxychloroquine

There are no reasonable alternatives to the proposed amendments, given the current misalignment between the Medicines Regulation and the Commonwealth's removal of restrictions on hydroxychloroquine prescribing.

While maintaining prescribing approvals could theoretically continue to manage therapeutic risks, this approach is no longer proportionate given the Commonwealth's decision to remove restrictions on hydroxychloroquine prescribing.

Given these considerations, the removal of hydroxychloroquine from the list of restricted medicines is the most effective and proportionate approach to ensure regulatory consistency and support timely patient care.

Administrative amendments

Therapeutic Goods Advertising Code

There are no reasonable alternatives to achieving the policy objective. The administrative amendment is necessary to ensure regulatory clarity and consistency by removing outdated references to the 'Price information code of practice' published by the TGA. This document is no longer the relevant standard. Replacing it with reference to the 'Therapeutic Goods Advertising Code' aligns the legislation with contemporary regulatory practice. No other alternatives would achieve this objective without causing confusion or misalignment with existing advertising requirements.

Adrenaline devices

Currently, the Medicines Regulation restricts certain classes of persons to administering S3 adrenaline for anaphylaxis via the intramuscular route using devices such as an Epipen®. This does not accommodate emerging non-injectable delivery methods, such as intranasal sprays, which may offer practical advantages in accessibility and ease of use. As a result, the Medicines Regulation lacks the flexibility needed to support evolving clinical practice and innovation in emergency anaphylaxis treatment.

Amending the regulation to allow for the administration of non-injectable S3 adrenaline devices by appropriately trained persons is the most effective and proportionate way to ensure the regulation remains relevant, supports timely access to treatment, and upholds public safety.

Benefits and costs of implementation

There are no significant financial or resource implications associated with the proposed amendments. Any financial impacts for government will be managed within existing budget allocations.

Consistency with fundamental legislative principles

The Amendment Regulation is generally consistent with the fundamental legislative principles outlined in section 4 of the *Legislative Standards Act 1992*. However, it may potentially impact on the fundamental principle relating to sub delegation of power, as outlined below.

Institution of Parliament

Does the subordinate legislation allow for the sub delegation to appropriate persons or in appropriate cases?

Section 4(5)(e) of the Legislative Standards Act provides that legislation should have sufficient regard to the institution of Parliament. This includes ensuring that any delegation of legislative power occurs only in appropriate cases and to appropriate persons, and that the exercise of delegated legislative power is sufficiently subject to scrutiny by the Legislative Assembly.

EPAs are technical documents made under section 232 of the Act by the chief executive (or delegate) of Queensland Health. These documents authorise approved persons to deal with regulated substances and may specify conditions, qualifications, and the circumstances under which the substances may be dealt with.

EPAs are developed through consultation with relevant experts and stakeholders and are updated regularly to reflect clinical best practice and the healthcare needs of specific patient populations. They are published on the Queensland Health website and referenced in schedule 1, part 1 of the Medicines Regulation, which lists the name and version number of each EPA. A copy of the updated EPA is tabled as extrinsic material each time the Medicines Regulation is amended. This process provides transparency and operational flexibility, but referencing external documents such as EPAs may be seen to breach section 4(5)(e) of the Act, as it involves sub-delegation of legislative power without direct Parliamentary oversight.

Including a list of EPAs in the schedule of the Medicines Regulation creates certainty for the relevant professions and the public about the status of EPAs published on the Queensland Health website and the date when these took effect. The use of EPAs is considered justified due to the rigorous development process, the technical nature of the documents, and their role in ensuring Queenslanders receive healthcare based on best clinical practice.

Consultation

In August 2025, a consultation paper on the proposed amendments was published on the Queensland Health website and disseminated to key stakeholders across medical, nursing, pharmacy and physiotherapy peak bodies, ADHD consumer groups, Aboriginal and Torres Strait Islander health organisations, educational institutions, paediatricians and Queensland Health, including Queensland Ambulance and Hospital and Health Services.

Further consultation feedback on each of the proposals is outlined below.

Psychostimulants

The majority of stakeholders, including the Royal Australian College of General Practitioners, Queensland Branch (RACGP), Australian Medical Association of Queensland (AMAQ) and the Queensland ADHD General Practitioners Alliance, expressed support for the psychostimulant prescribing amendments.

RACGP welcomed the amendments, noting alignment with their recently released national position statement *ADHD: Initiation, modification and continuation of psychostimulants by specialist GPs.*[4] RACGP noted that specialist GPs are highly qualified medical practitioners with over a decade of training and are experts in managing uncertainty, complexity and prescribing.

AMAQ also supported the amendments, particularly the limitation to specialist GPs rather than all medical practitioners. They encouraged Queensland Health to provide associated support measures, such as training incentives and adequate telehealth funding, to support collaboration between health practitioners. However, AMAQ urged against mandatory training requirements, as this could deter specialist GP participation.

The Royal Australian and New Zealand College of Psychiatrists (RANZCP) agreed that specialist GPs are critical in assessing and treating ADHD in Queensland. However, they noted that blanket approval for all specialist GPs may carry risks. To mitigate these risks they

[4] RACGP Position Statement - ADHD: Initiation, modification and continuation of psychostimulants by specialist GPs. Accessed here: www.racgp.org.au/advocacy/position-statements/view-all-position-statements/health-systems-and-environmental/adhd-initiation-modification-continuation-by-gps.

suggested training be required to ensure specialist GPs are appropriately skilled to deal with psychostimulants.

The Australasian ADHD Professionals Association (AADPA) also supported the amendments, noting that these reforms will significantly improve access to care, address bottlenecks in the system, and help ensure smoother transitions from child to adult services. AADPA, similar to RANZCP, recommended ADHD-specific training for newly authorised prescribers to support collaborative care pathways and appropriate escalation of complex cases.

It is considered that specialist GPs already possess the requisite skills and training to undertake the proposed activities. As noted above, specialist GPs undergo significant training in medicine and are highly qualified. They are trained in diagnosis, treatment, prevention and management of both acute and chronic conditions and coordination and supervision of care arrangements. They also undertake ongoing professional development each year to maintain their registration, which includes opportunities for additional training in ADHD management. 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. They are also professionally accountable to know when to refer a patient to a medical practitioner in another specialty field when clinically required.

The Queensland Nurses and Midwives' Union (QNMU) and the Australian College of Nurse Practitioners (Queensland) were generally supportive of the amendments, however they raised concerns regarding the exclusion of nurse practitioners. Queensland Health acknowledges the valuable contribution of nurse practitioners as a highly skilled and valued workforce, and engagement with state-wide nurse practitioner groups will continue to explore opportunities that could be considered in the future for enabling nurse practitioners to support the treatment of patients with ADHD without requiring a prescribing approval.

First contact emergency physiotherapist practitioners

The majority of stakeholders, including the Pharmacy Guild, QNMU, Australian College of Nurse Practitioners (Queensland), and Advanced Pharmacy Australia expressed support for the amendments enabling credentialed EPPs to prescribe and administer additional medicines under the Physiotherapists EPA, when treating patients in public sector urgent care settings.

RACGP raised concerns surrounding the conflation of diagnosing and prescribing skills of credentialed EPPs, particularly in relation to wound care. Queensland Health considers that credentialed EPPs possess the necessary skills, training and expertise to safely undertake the activities provided for in the Physiotherapists EPA. Prescribing decisions made by credentialed EPPs are guided by clinical safety and appropriateness, taking into account the patient's presentation, the intended therapeutic outcome, and alignment with established clinical governance processes for antimicrobial stewardship and medicines safety. These processes must align with best practice and comply with the standards set by the Commission on Safety and Quality in Healthcare. The medicines added to the Physiotherapist EPA, and the restrictions for their use, were considered based on the presentations that may be independently managed by Credentialed EPPs, the Australian Immunisation Handbook and the Therapeutic Guidelines. Where there is uncertainty in diagnosis, complexity in management, or the presentation is out of scope, referral to a medical practitioner is required.

RACGP and Pharmaceutical Defence Limited also raised concerns regarding the list of approved medicines that may be prescribed and administered by credentialed EPPs. Queensland Health has reviewed and selected these medicines based on the types of presentations that credentialed EPPs are expected to manage independently within their scope of practice.

Bowel preparation medicines

The majority of stakeholders, including the Colorectal Surgical Society of Australia and New Zealand, expressed support for the amendment to authorise RNs employed by, or for, a HHS to give a treatment dose of S2, S3 and S4 medicines for bowel preparation, when the medicines are given on a prescription or on a standing order.

QNMU also supported this amendment, noting that it will alleviate the burden on patients to independently source the medicines.

Hydroxychloroquine

Stakeholders who provided feedback on the hydroxychloroquine amendments expressed support for the changes, including QNMU, the Australian College of Nurse Practitioners (Queensland) and Pharmaceutical Defence Limited.

The Australian College of Nurse Practitioners (Queensland) acknowledged the proposal represents a practical step towards reducing regulatory burdens, while maintaining safeguards for patient safety and supporting high-quality clinical care.

Administrative amendments

Therapeutic Goods Advertising Code

No feedback was received on this amendment.

Adrenaline devices

All stakeholders who provided feedback on the adrenaline devices amendments supported the proposal, including the Pharmacy Guild, QNMU and CSL Seqirus. The global biotechnology company CSL Seqirus welcomed this planned and proactive approach in supporting the quality use of medicines and their role in supporting positive patient outcomes in anaphylaxis management.