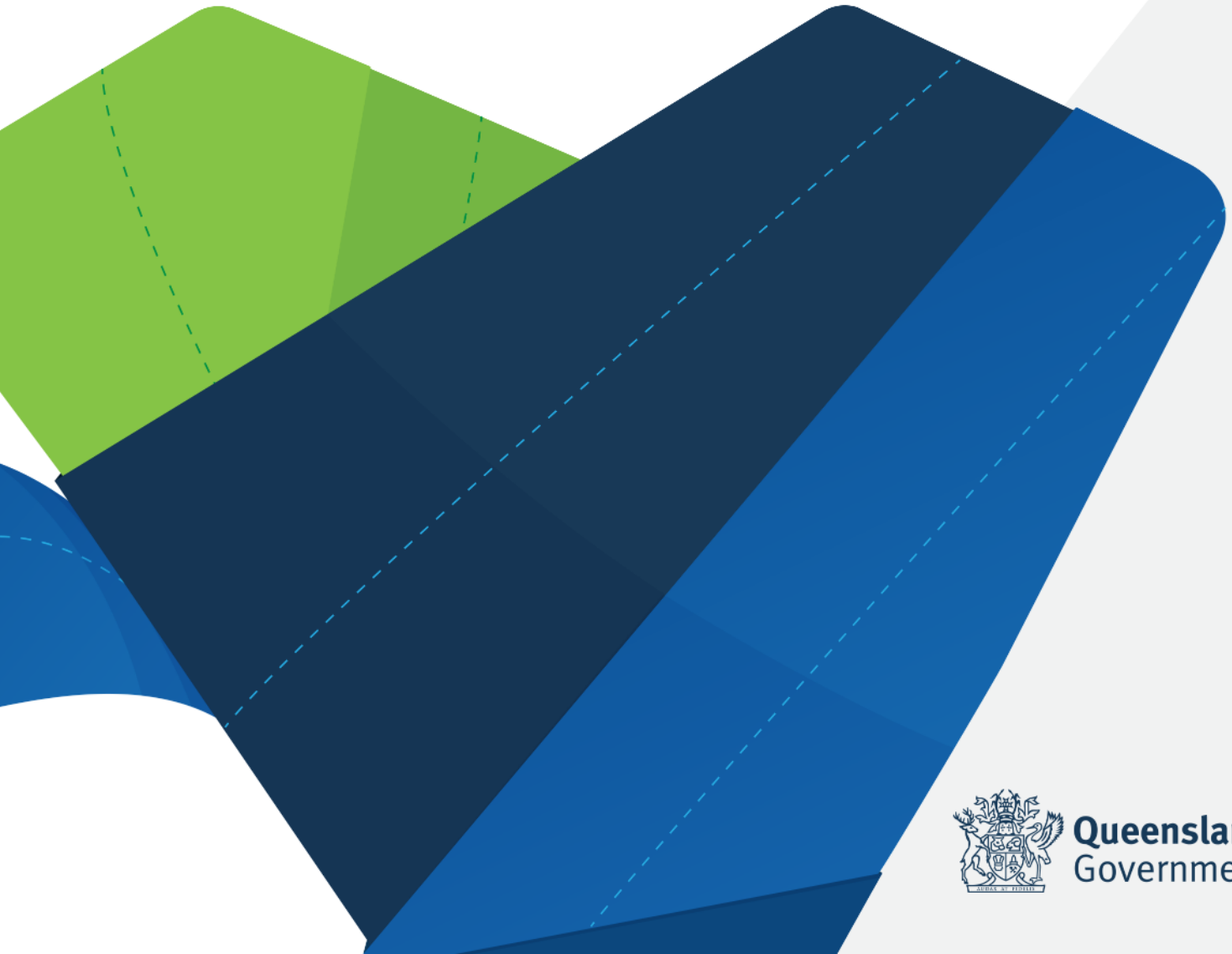
Queensland Health

Psychostimulant prescribing authorisations

Consultation Paper
December 2024



Queensland Government

Table of 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) in relation to psychostimulant prescribing authorisations for adults and children with attention deficit hyperactivity disorder (ADHD).

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 mlp.consultation@health.qld.gov.au by **5pm, Tuesday 17 December 2024**.

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

Background

Medicines and poisons legislative framework

The Medicines Regulation regulates medicines and complements the *Medicines and Poisons Act 2019* (Medicines and Poisons Act) by:

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

Section 30 of the Medicines and Poisons Act specifies how a person may be authorised to deal 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 pharmacist, dentist, doctor or nurse 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 manufacturing or wholesale licence; or
- a person specified within a substance authority, such as a prescribing or general approval.

The proposed changes to the Medicines Regulation aim to improve access to psychostimulants for adults and children with ADHD and reduce administrative burden on prescribers by authorising the prescribing of psychostimulants in a broader range of circumstances.

Psychostimulants and attention deficit hyperactivity disorder

ADHD, previously termed attention deficit disorder, is a neurodevelopmental disorder characterised by pervasive inattention and/or hyperactivity and impulsivity, which is more than what is typical for a person's developmental age[1]. In Australia, the prevalence of ADHD is estimated to be 6 to 10 per cent of children and adolescents, and 2 to 6 per cent of adults[2]. ADHD is the most common neurodevelopmental disorder diagnosed in children and adolescents; however, the condition can also be diagnosed for the first time in adulthood.

Psychostimulants, including an amfetamine (dexamfetamine or lisdexamfetamine) or methylphenidate, are the first-line pharmacological treatment for adults and children with ADHD and are classed as Schedule 8 medicines under the Commonwealth Poisons Standard (the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)). The use of psychostimulants for the treatment of ADHD is well established in clinical practice and there is substantial evidence for their safety and effectiveness.

[1] Royal Australian & New Zealand College of Psychiatrists. ADHD across the lifespan. 2023. Accessed from https://www.ranzcp.org/clinical-guidelines-publications/clinical-guidelines-publications-library/adhd-across-the-lifespan

[2] Senate Community Affairs References Committee. Assessment and support services for people with ADHD. November 2023. Accessed from https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/ADHD/Report

Access to psychostimulants and relevant specialists

Barriers to the accessibility of psychostimulants for the management of ADHD prompted a Senate inquiry in 2023. The report of the Senate Community Affairs References Committee '*Assessment and support services for people with ADHD*' (Senate report)[2] was released in November 2023. The inquiry identified that prescribing regulations present significant challenges for patients to access psychostimulants. The recommendations of the Senate report aim to increase accessibility for patients to all healthcare services for ADHD, including increasing access to psychostimulants.

Current prescribing authorisations for specialist medical practitioners

Under schedule 2, part 1 of the Medicines Regulation, psychostimulants are classed as **restricted medicines**. Restricted medicines are identified as having specific health risks that may be mitigated by restricting availability and can only be prescribed by a certain class of specialist medical practitioner, a class of persons with prescribing authorisations under the Medicines Regulation, or an individual who holds a prescribing approval.

Under the Medicines Regulation, the specialists authorised to prescribe psychostimulants are:

- **paediatricians**[3], for ADHD or brain damage for a child; and
- **psychiatrists**[4], for ADHD for an adult within prescribed maximum dosages, or for ADHD or brain damage for a child.

The maximum dosages that can be prescribed by a psychiatrist for an adult with ADHD are described in schedule 6, part 2, division 16 of the Medicines Regulation and are listed below:

- dexamfetamine – a dose of the medicine that does not exceed 40mg a day; or
- lisdexamfetamine – a dose of the medicine that does not exceed 70mg a day; or
- methylphenidate – a dose of the medicine that does not exceed 80mg a day.

The maximum dose limits do not apply to paediatricians or psychiatrists prescribing psychostimulants for ADHD for children.

Current prescribing authorisations for medical practitioners

Under schedule 6, part 1, division 5 of the Medicines Regulation, all medical practitioners (including general practitioners) are authorised to prescribe psychostimulants for a **relevant condition**. Relevant conditions include narcolepsy for a patient of any age, or brain damage or ADHD for a child aged 4 to 17 years. The patient is not required to have had a review or a formal diagnosis made by a relevant specialist in order for a medical practitioner to prescribe psychostimulants for a patient with a relevant condition. This is a historical authorisation from the now repealed *Health (Drugs and Poisons) Regulation 1996* (HDPR) that was carried over to the Medicines Regulation.

[3] Medicines Regulation Schedule 6, part 2, division 15.

[4] Medicines Regulation Schedule 6, part 2, division 16.

Medical practitioners working in a hospital, prison, watch-house, or detention centre are also authorised to prescribe psychostimulants in certain circumstances. The psychostimulant must be prescribed under the supervision of a registrar or specialist medical practitioner authorised to prescribe psychostimulants (i.e., a paediatrician or psychiatrist) for administration by a health practitioner for continuing institutional treatment.

Current prescribing authorisations for nurse practitioners

Nurse practitioners working in a hospital, prison, watch-house, or detention centre are also authorised to prescribe psychostimulants for continuing institutional treatment under the same conditions as those imposed on medical practitioners. Nurse practitioners are not otherwise authorised under the Medicines Regulation to prescribe psychostimulants.

Prescribing approvals

Any prescriber intending to prescribe psychostimulants for a patient, but not authorised under the Medicines Regulation as described above, must apply for a **prescribing approval** under section 75 of the Medicines and Poisons Act. Prescribing approvals for psychostimulants authorise the practitioner to prescribe a psychostimulant for the patient stated in the approval and may impose certain conditions or restrictions. Applications for prescribing approvals are considered on a case-by-case basis and can be granted by the chief executive of Queensland Health or their delegate and are typically granted for a period of 2 years.

When a medical practitioner or nurse practitioner is applying for or renewing a prescribing approval to prescribe psychostimulants for an adult with ADHD, the prescriber is required to have the ongoing support of a psychiatrist. The prescriber must name the supporting psychiatrist in their application and the date when the patient was last reviewed by them. In practical terms, the prescriber is applying to continue the treatment which has been initiated and endorsed by the supporting psychiatrist. When a child transitions to adulthood they are required to be reviewed and seek a confirmation of diagnosis from a psychiatrist for a medical or nurse practitioner to be granted a prescribing approval to continue treatment, even if a paediatrician has made an initial diagnosis during childhood.

In recent years, there has been a substantial increase in applications for psychostimulant prescribing approvals. The overwhelming majority of these applications are from general practitioners seeking to prescribe psychostimulants for adults for the treatment of ADHD. The requirement to obtain a prescribing approval creates regulatory burden on prescribers and may lead to delays in clinical treatment. There is also a significant administrative burden involved for Queensland Health to manage and assess the high volume of applications, and additional resources are being allocated to this undertaking due to the rapid increase in the number of psychostimulant prescribing approval applications.

Monitored medicines and QScript

Psychostimulants are classed as **monitored medicines** under schedule 2, part 4 of the Medicines Regulation, which are medicines identified as presenting a potentially high risk of harm to patients as a result of misuse, abuse, diversion, substance use disorder or overdose. Section 224 of the Medicines and Poisons Act requires the chief executive to keep an electronic monitored medicines database to record information about the prescription and supply of monitored medicines.

QScript, the monitored medicines database used in Queensland, collects monitored medicine prescription information from prescribing and dispensing software systems, which can be viewed by authorised prescribers and pharmacists to support clinical decision-making. Since September 2021, Queensland Health has utilised QScript to monitor compliance for activities with certain monitored medicines, including for psychostimulant prescribing. Under section 41 of the Medicines and Poisons Act, all prescribers, including paediatricians and psychiatrists, must check QScript before prescribing psychostimulants, and all pharmacists must check QScript before dispensing psychostimulants.

Psychostimulant prescribing trends in Queensland

The implementation of QScript in Queensland provides detailed data to enable monitoring of psychostimulant prescribing and dispensing trends in Queensland. Figure 1 shows the trend in the number of psychostimulant dispensings by medicine (dexamfetamine, lisdexamfetamine or methylphenidate) from September 2021 to July 2024 and shows an overall trend of increased number of dispensings per month over time for all medicines.

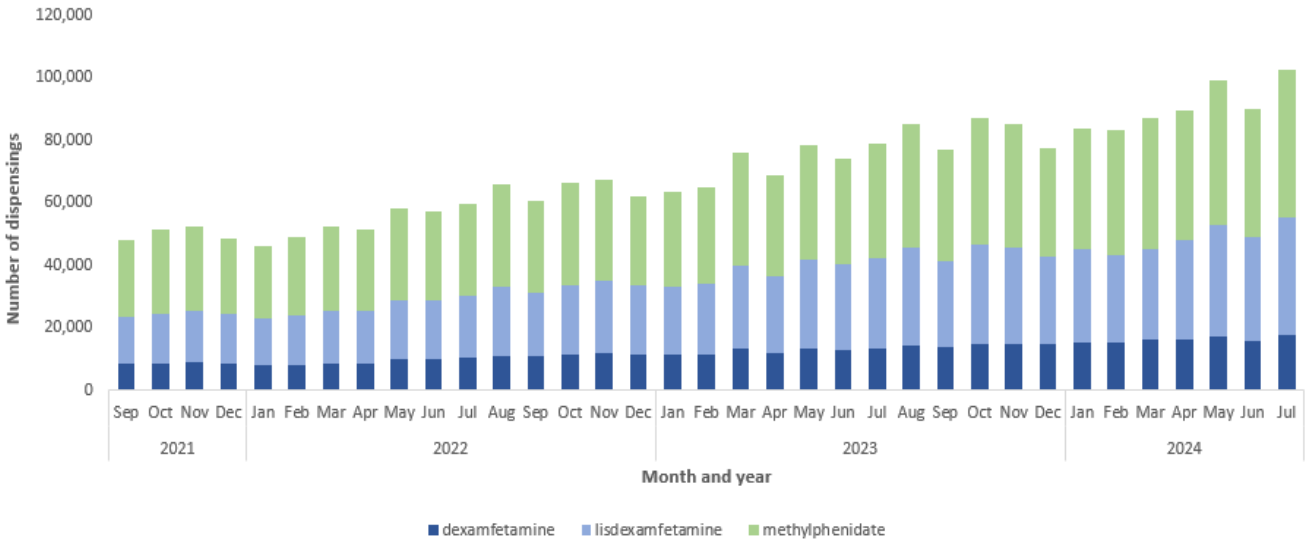


***Figure 1**. Number of QScript psychostimulant dispensings by medicine (September 2021 – July 2024)*

The breakdown of psychostimulant dispensing for adults (aged 18 and over) and children (aged 0-17 years) is shown below in figure 2. While a slightly higher percentage of psychostimulant dispensings for children was observed during 2022, this trend has since shifted to a slightly higher percentage of dispensings for adults. This data includes psychostimulants prescribed for all indications. While the data for 2022 and 2023 encompasses the entire year from January to December, the data for 2024 is only for the period from January until the end of July.

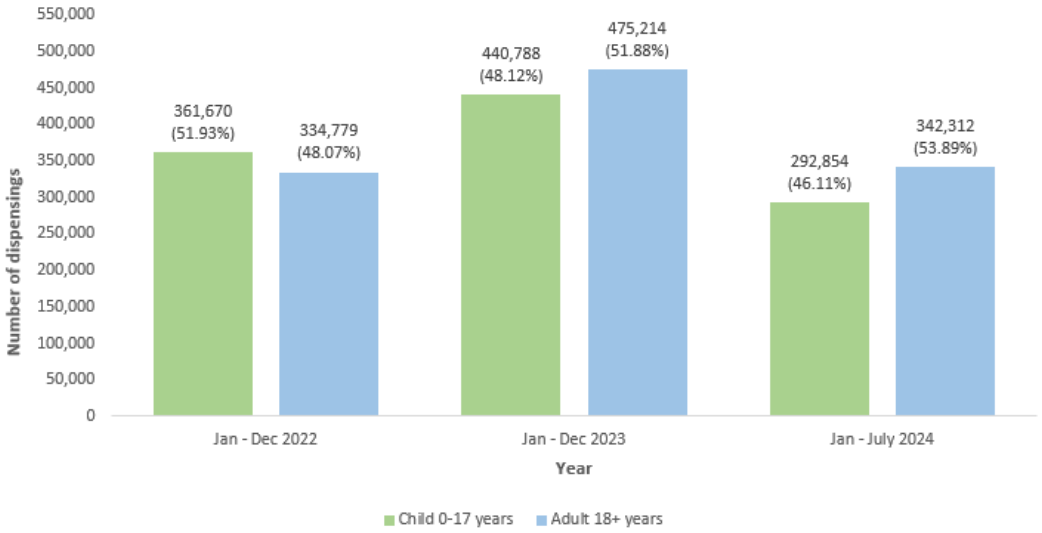


Figure 2. *Number of QScript psychostimulant dispensings by age group (January 2022 – July 2024)*

Psychostimulant dispensings by class of prescriber (classed either by profession or specialty) is shown below in figure 3. Across all observed years, psychostimulants prescribed by psychiatrists had the highest percentage of dispensings, followed by general practitioners then paediatricians. A minor percentage (less than 1 per cent of all dispensings) was attributed to psychostimulants prescribed by nurse practitioners or medical practitioners of a speciality other than psychiatry, paediatrics, or general practice. It was not possible to determine the class of prescriber for approximately 13 per cent of all dispensings, which may be explained by scenarios such as an incorrect link between the prescriber number in QScript to their details listed with the Australian Health Practitioner Regulation Agency (AHPRA) or linking the prescriber number to an AHPRA number that is no longer registered.

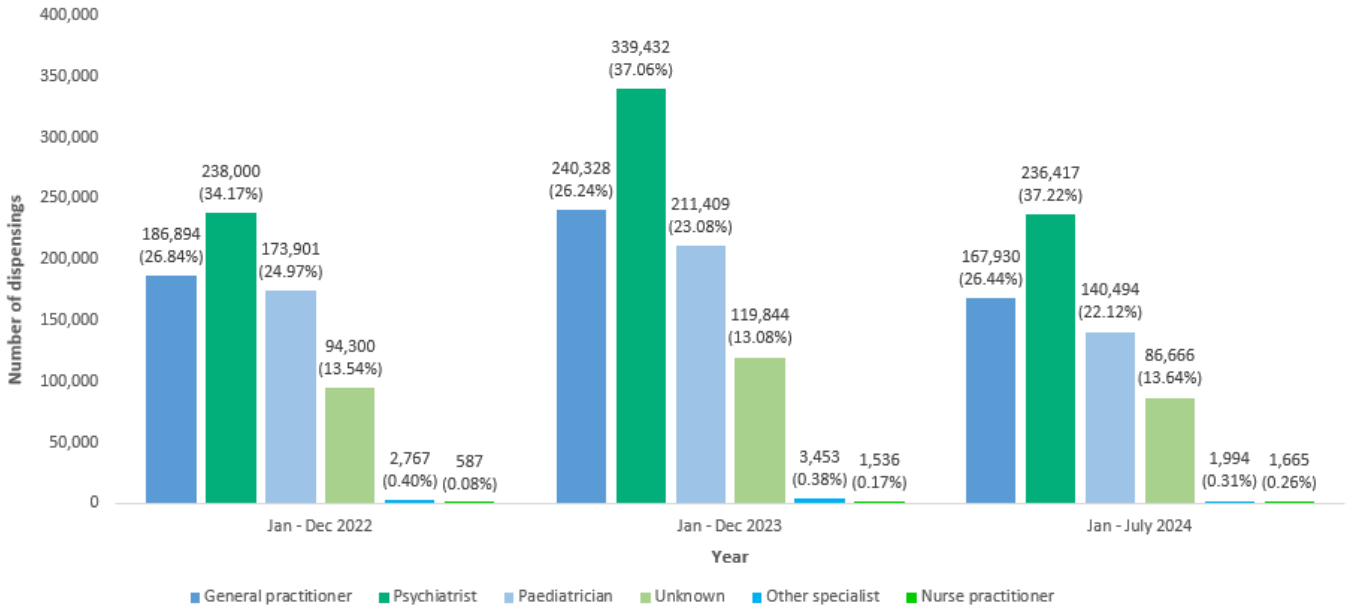


Figure 3. *Number of QScript psychostimulant dispensings by class of prescriber (January 2022 – July 2024)*

Description of proposed amendments

Amendments to the Medicines Regulation

It is proposed to make the following amendments to the Medicines Regulation:

- authorise medical practitioners to prescribe **continuing psychostimulant treatment** for an adult with ADHD; and
- authorise nurse practitioners to prescribe **continuing psychostimulant treatment** for an adult or a child with ADHD.

Continuing psychostimulant treatment by medical practitioners (including general practitioners) will require that the adult has been diagnosed with ADHD and commenced psychostimulant treatment, or had a treatment plan recommended, by a specialist medical practitioner authorised to prescribe psychostimulants (i.e., a paediatrician or psychiatrist).

Continuing psychostimulant treatment by nurse practitioners will require that the adult or child has been diagnosed with ADHD and commenced psychostimulant treatment, or had a treatment plan recommended, by a specialist medical practitioner authorised to prescribe psychostimulants (i.e., a paediatrician or psychiatrist).

Once the diagnosis of ADHD has been confirmed and treatment has been initiated by the relevant specialist, or a treatment plan has been recommended, the medical practitioner or nurse practitioner will be authorised to prescribe psychostimulants without delay and without the need for a prescribing approval.

The proposed amendments to authorise continuing psychostimulant treatment by medical practitioners and nurse practitioners will be in addition to the existing authorisations for psychostimulant prescribing under the Medicines Regulation for all professions. Expanding the authorisation scope for medical practitioners and nurse practitioners will improve access to psychostimulants for adults and children with ADHD.

It is intended these amendments will be the first step in a staged approach to improving access to psychostimulants in Queensland. If these amendments are progressed, the impacts will be monitored, and close consultation will continue with relevant stakeholders to consider further legislative amendments to authorisations to prescribe psychostimulants.

Maximum dose limits

The regulated maximum doses of psychostimulants that can currently be prescribed by a psychiatrist for an adult with ADHD under the Medicines Regulation will also be enforced for medical practitioners and nurse practitioners prescribing for adults with ADHD under the continuing treatment provisions.

It is not proposed to remove the requirement for prescribing approvals for psychiatrists intending to prescribe psychostimulants at doses above these regulatory limits.

Proposed consequential amendments

It is also proposed to make consequential amendments to update and ensure consistent references to psychostimulants, and update required annotations for psychostimulant prescriptions as outlined below:

- Replace the outdated term of attention deficit disorder with `attention deficit hyperactivity disorder';
- Amend inconsistent terminology in reference to psychostimulants. The terminology differs throughout the Medicines Regulation and should refer to 'an amfetamine or methylphenidate' in any section where these medicines are mentioned; and
- Update the terminology and requirements under section 87(2)(c) of the Medicines Regulation regarding required annotations by a prescriber on prescriptions for psychostimulants to reflect the proposed amendments. Currently, prescribers refer to their prescribing approval number on prescriptions to meet the requirements under section 86(1)(m)(i) of the Medicines Regulation for restricted medicines to indicate they have the relevant authorisation. Under the amendments, for most cases there will be no prescribing approval number to refer to, but a sufficient prescription annotation under section 87(2)(c) of the Medicines Regulation will still be required to indicate prescribers are continuing psychostimulant treatment. The current wording required on a prescription for psychostimulants under section 87(2)(c) is only relevant for prescribing for a relevant condition, not continuing treatment.

Key policy questions

What are the requirements for continuing psychostimulant treatment for a patient with ADHD?

The proposed amendments for continuing psychostimulant treatment require a relevant specialist to make the initial diagnosis of ADHD. The specialist may then either:

- commence treatment by writing the initial psychostimulant prescription; or
- choose not to write the initial prescription and instead develop a treatment plan to recommend a course of action for the general practitioner or nurse practitioner to commence psychostimulant treatment.

It is not intended for the legislation to stipulate the exact requirements of the detail that must be included in the treatment plan or the manner in which this should be communicated to the general practitioner or nurse practitioner. This will be considered a professional practice matter and will depend on a variety of factors. At a minimum, the treatment plan should identify the initial psychostimulant medicine and dose that should be prescribed for the patient.

Will the medical practitioner or nurse practitioner be authorised to amend the dose or switch to an alternative psychostimulant to treat ADHD under the continuing treatment provisions?

This will depend on whether the relevant specialist chooses to include this detail in their treatment plan. If the specialist's preference is that a general practitioner or nurse practitioner cannot adjust the dose or switch the patient to an alternative psychostimulant without specialist review, this should be specified in the treatment plan.

However, some specialists may prefer that the general practitioner or nurse practitioner manage ongoing medicine changes without review by the specialist. For example, a specialist may specify in their treatment plan that the general practitioner or nurse practitioner may commence the patient on an initial dose and titrate up to a set maximum dose of an immediate release formulation, then consider switching the patient to a slow-release formulation.

If the relevant specialist writes the initial psychostimulant prescription without also providing a treatment plan, it is expected that the general practitioner or nurse practitioner will only continue the same medicine and dose as prescribed, unless otherwise specified by the specialist.

As these requirements are not legislated and will be individualised to the patient, it will be a professional practice obligation for the general practitioner or nurse practitioner to comply with the treatment plan recommendations.

How will prescribers need to demonstrate that they have met the requirements of continuing psychostimulant treatment for ADHD?

The specialist may communicate the treatment plan to the general practitioner or nurse practitioner in any manner that they consider to be clinically appropriate.

The general practitioner or nurse practitioner must ensure that they keep sufficient documentation as evidence that they are meeting the requirements of continuing psychostimulant treatment for a particular patient with ADHD.

Prescribers will be required to annotate a prescription for a psychostimulant under the proposed amendments to section 87 of the Medicines Regulation with wording to confirm that they are prescribing for continuing treatment for ADHD. This annotation is essentially considered to be a declaration by the prescriber that they are compliant with the legislated requirements.

Is there a required review period where the patient must be referred back to a relevant specialist for continuing psychostimulant treatment for ADHD?

The amendments will not require a specified review period for a patient with ADHD to return to the relevant specialist who made the initial diagnosis or treatment plan, or another relevant specialist. However, the intent is that professional practice obligations are followed and, if at any stage a general practitioner or nurse practitioner does not feel confident managing the psychostimulant treatment for a patient with ADHD, or that it is within their scope of practice, that they refer the patient to the relevant specialist. The expectation is that this would be the same as a prescriber referring a patient to a relevant specialist when required for the management of any chronic condition.

What do these amendments mean for a child who has been diagnosed with ADHD by a paediatrician and is transitioning to adulthood?

It is intended that with these amendments, a child who has been diagnosed with ADHD by a paediatrician will not require confirmation of the diagnosis by a psychiatrist after they transition into adulthood. The policy intent is that once a person has been diagnosed with ADHD by a relevant specialist at any age, that diagnosis remains valid indefinitely.

What do these amendments mean for a child who has been diagnosed with ADHD by a general practitioner (but not by a paediatrician or psychiatrist) and is transitioning to adulthood?

It is intended that with these amendments, a child who has not been diagnosed with ADHD by a paediatrician or psychiatrist will require confirmation of the diagnosis by a psychiatrist after they transition into adulthood. The policy intent is that for treatment in adulthood a person must have been diagnosed with ADHD by a relevant specialist at some point.

What if a patient has a break in psychostimulant treatment?

Treatment breaks or medication holidays can be common in patients taking psychostimulants for ADHD. It is also possible that a patient, in a joint decision with their prescriber, may cease psychostimulant medication altogether but may choose to recommence treatment at a later period in life if their circumstances change or they experience a return of symptoms.

The proposed amendments are intended to acknowledge that breaks in psychostimulant treatment may occur for a variety of reasons and will not require that a person must be referred to a specialist or receive a confirmation of diagnosis with ADHD if they choose to recommence treatment at a later time. The duration of what is considered a treatment break is not defined to allow flexibility depending on the circumstances. However, the intent is that if at any stage a general practitioner or nurse practitioner does not feel it is within their scope of practice to recommence the patient on psychostimulant treatment for ADHD that professional practice obligations are followed, and they refer the patient to a relevant specialist.

When will a prescribing approval continue to be required?

The proposed amendments only apply for the treatment of ADHD and do not change the requirement to obtain a prescribing approval to treat other conditions, other than those already specified in the Medicines Regulation such as narcolepsy or brain damage, or to prescribe a psychostimulant at a dose higher than the maximum limits.

What is the responsibility of the pharmacist in determining if the prescriber has the required prescribing authorisations?

Pharmacists should not dispense a psychostimulant prescription without being satisfied that it is safe, appropriate, and lawful to supply the medicine.

Under sections 86 and 87 of the Medicines Regulation, prescribers are required to include detail on a prescription of their qualifications and authorisation to prescribe psychostimulants (such as a prescribing approval number or their specialist qualifications) and must also include words to indicate the condition being treated. A pharmacist cannot dispense a psychostimulant prescription that does not include this detail as it would not be compliant with the legislation.

It is intended that the proposed consequential amendments will amend the detail required in section 87(2)(c) of the Medicines Regulation to be included on a psychostimulant prescription to make it clear to the dispensing pharmacist that the prescriber has the required authorisation under the Medicines Regulation and does not require a prescribing approval. By annotating the prescription with this detail, the prescriber is essentially declaring that they have met the requirements of the Medicines Regulation for continuing psychostimulant treatment for a patient with ADHD.

Pharmacists will continue to be required to check QScript when dispensing psychostimulants. There will be occasional circumstances where a prescriber will still require a prescribing approval. If a pharmacist believes a prescribing approval is required but is not written on the prescription as required under section 86(1)(m)(i) of the Medicines Regulation, they can also view in QScript if the prescriber has an approval. If it remains unclear if there is a valid prescribing approval, the pharmacist may need to contact the prescriber. A pharmacist who contacts a prescriber and discovers that the prescriber does not hold a prescribing approval and has no awareness of prescribing approval requirements might question whether the noted prescribing is safe, appropriate, or lawful.

How will prescribing compliance for the proposed amendments be monitored?

Ongoing monitoring of psychostimulant prescribing activities will be undertaken by Queensland Health through QScript and other mechanisms. The regulation of psychostimulant prescribing will involve the development of strategies to identify and monitor any potential risks resulting from the removal of a requirement for a prescribing approval for continuing psychostimulant treatment for ADHD within the regulated dose limits. Similar strategies used to monitor prescribing compliance for other Schedule 8 monitored medicines using QScript will be utilised. The compliance monitoring approach will be similar to when the requirement for prescribing approvals for Schedule 8 opioids was removed when QScript was introduced, and alternative compliance monitoring strategies were implemented. This work can be leveraged to create consistency for compliance monitoring for psychostimulants.