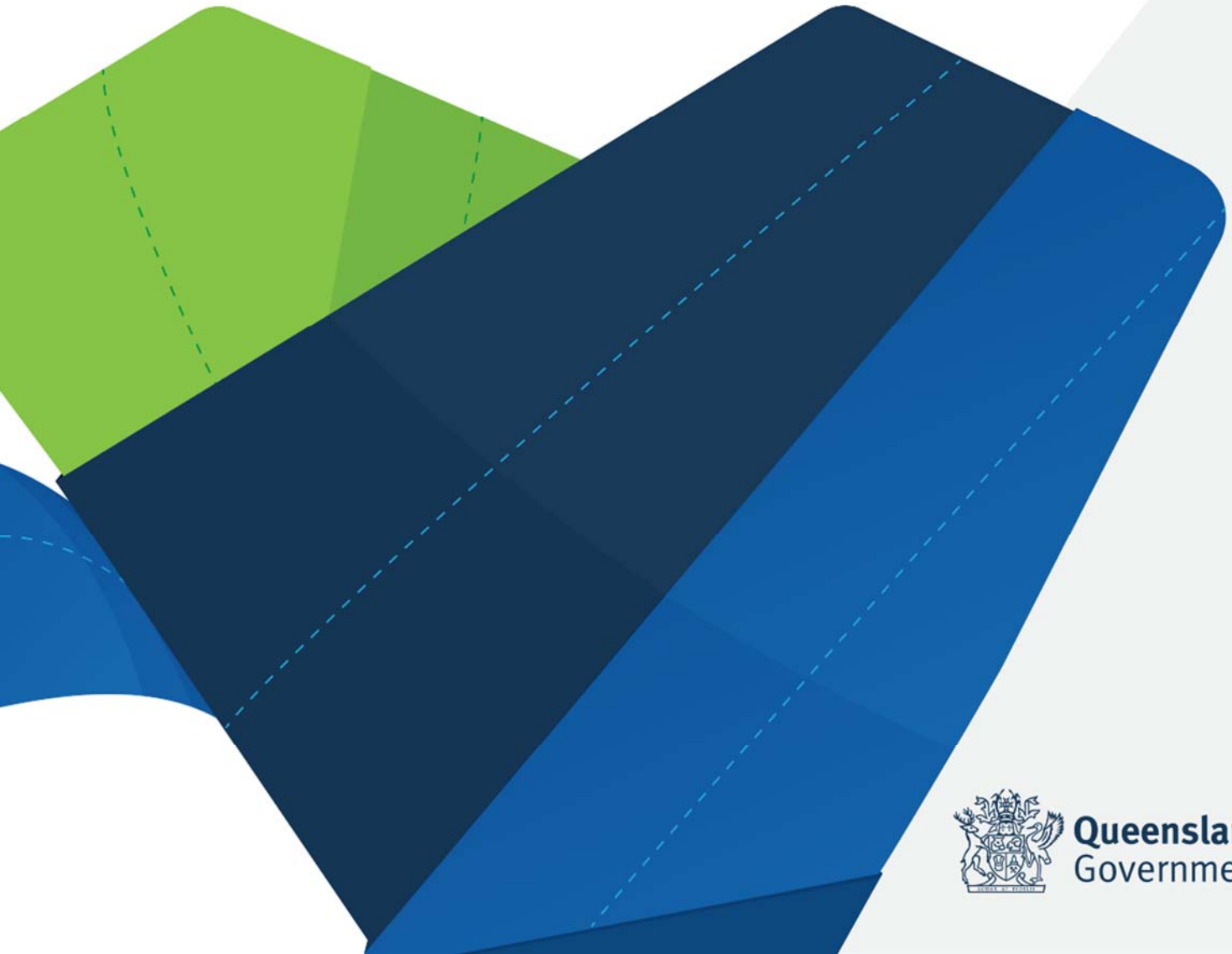
Queensland Health

Nurse Practitioner Prescribing – Unapproved Medicines

Consultation Paper

April 2024



Queensland Government

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Purpose

The purpose of this consultation paper is to seek stakeholder feedback on proposed changes to the authorisations for nurse practitioners to deal with medicines under the *Medicines and Poisons (Medicines) Regulation 2021* (Medicines Regulation). Queensland Health is considering amendments to authorise nurse practitioners to prescribe and give a treatment dose of unapproved medicines.

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

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, 24 April 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* (Act) by:

- ensuring regulated substances 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 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 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 'classes of persons' and the associated authorisations for each class are specified within schedules 3 to 15 of the Medicines Regulation.

The Medicines Regulation regularly requires updating to keep up with changes to Queensland Health policies and practices and the evolving needs of health care in Queensland.

The proposed changes to the Medicines Regulation aim to address practical and operational issues that have been identified by stakeholders and operational areas within Queensland Health. The changes will ensure the Medicines Regulation remains fit for purpose and allows health practitioners to practice to their full scope to help and support health consumers.

Nurse practitioners

A nurse practitioner is a registered nurse, working at an advanced practice level in a clinical specialty, who has undertaken a Master of Nurse Practitioner program (Australian Qualifications Framework [AQF] level 9) and is endorsed as a nurse practitioner by the Nursing and Midwifery Board of Australia (NMBA). A nurse practitioner practices under the legislatively protected title 'nurse practitioner' under the National Law.

Nurse practitioners are educated and authorised to independently diagnose and prescribe scheduled medicines and order diagnostic imaging in accordance with their scope of practice. Nurse practitioners take responsibility for care provided, following up on any components of care initiated and, like other treating clinicians, refer on when aspects of care fall outside of their individual scope of practice.

The nurse practitioner scope of practice is built on the platform of the registered nurse scope of practice and must meet the regulatory and professional requirements for Australia, including the NMBA Nurse Practitioner Standards for Practice, Safety and Quality Guidelines for nurse practitioners, code of conduct for nurses and International Council of Nurses' Code of Ethics for nurses.

Nurse practitioners have been providing care to all sectors of the Australian community for more than 20 years. Nurse practitioners provide high levels of clinically focused, autonomous healthcare for both acute and chronic conditions, in a variety of contexts. This includes across all geographic locations in Australia and within all settings including aged care, primary care, mental health, private practice, and public and private hospital care.

Description of proposed amendments

Nurse practitioners prescribing and giving a treatment dose of an unapproved medicine

The objective of this proposal is to support continuity of care and improve consumer access to timely treatment of health conditions with prescription medicines, by amending the Medicines Regulation to remove the restriction that only allows nurse practitioners to prescribe and give a treatment dose of registered S4 and S8 medicines. It is proposed to amend schedule 7, part 1 of the Medicines Regulation to enable nurse practitioners to:

- prescribe unapproved medicines; and
- give a treatment dose of unapproved medicines.

Schedule 7, part 1 of the Medicines Regulation provides authorisations for nurse practitioners to deal with medicines and includes an authorisation to prescribe Schedule 4 (S4) and Schedule 8 (s8) medicines.

What are unapproved medicines?

Unapproved medicines are medicines that are not included in the Australian Register of Therapeutic Goods (ARTG) but can be prescribed if certain conditions imposed by the Therapeutic Goods Administration (TGA) are met. These medicines have not been assessed by the TGA for safety, quality or effectiveness.

Unapproved medicines also include medicines that are extemporaneously compounded. The Commonwealth *Therapeutic Goods Act 1989* (Cth) and *Therapeutic Goods Regulations 1990* (Cth) include provisions for medicines to be compounded in limited circumstances, subject to minimum safety and quality standards.

Unapproved medicines may be prescribed for a number of reasons, including when:

- a medicine has an identified public health benefit but is not yet approved by the TGA;
- a patient is experiencing unwanted side effects from the registered product and there is no suitable product listed on the ARTG that is a recommended treatment for the condition; or
- there is a medicine shortage.

Unapproved medicines can be prescribed by a range of independent prescribing healthcare professionals including medical practitioners, dentists and endorsed midwives. Nurse practitioners in Queensland are not authorised to prescribe or give a treatment dose of unapproved medicines and are only authorised to administer them.

Benefits of proposed amendments

The proposed amendments will:

- optimise nurse practitioner scope of practice to enable intervention that increases continuity and improves consumer and provider experience of care in all locations of Queensland, which aligns with the Queensland Government Health Workforce Strategy Queensland to 2032, to modernise roles, service delivery and technology; maximise full scope of practice; and unlock new pipelines of talent that keep up with industry demand.[1] Continuity of care is shown to improve the quality of care, enhance health outcomes and contribute to improved health system performance;
- align nurse practitioner prescribing practices in Queensland with other professions, including endorsed midwives, and with most other jurisdictions in Australia;
- enhance efficiency within the system by enabling nurse practitioners to provide comprehensive treatment to patients under their care, having lesser reliance on other prescribers, and in doing so, minimise out of pocket expenses for consumers; and
- improve consumer access to individually suitable or best practice medicines, particularly for Queenslanders who live in rural, regional, and remote communities, including First Nations people who have a higher distribution in remote and very remote locations for cultural and social reasons.

Policy rationale

When nurse practitioners were first employed in Queensland, their prescribing practices were authorised under the repealed *Health Drugs and Poisons Regulation 1996*, Drug Therapy Protocol: Nurse Practitioner, which identified the condition that: A nurse practitioner acting under this Drug Therapy Protocol must not prescribe, give a written or oral instruction, supply or administer scheduled medicines that have not been approved by the Therapeutic Goods Administration. This condition has been carried over into the current Medicines Regulation, however, does not apply to other prescribers including, medical practitioners, dentists, physician's assistants and endorsed midwives.

Issue 1 – inequity of prescribing authority of independent prescribers

Prescribing authorities under the Medicines Regulation is inequitable across independent prescribing disciplines. Nurse practitioners are authorised to prescribe a registered medicine, other than a restricted medicine,[2] whereas this condition is not imposed on medical practitioners, dentists and endorsed midwives, who are authorised to prescribe both registered and unapproved medicines.

[1] Queensland Government (2023). Health Workforce Strategy for Queensland to 2023, Consultation Paper. Retrieved from: https://www.health.qld.gov.au/__data/assets/pdf_file/0033/1277628/health-workforce-strategy-queensland-2032.pdf

[2] Restricted medicines are listed in Schedule 2, Part 1 of the Medicines Regulation. They have common therapeutic uses, but are also liable to abuse, misuse and diversion, warranting more stringent controls on possession and supply. They include approved opioids for the Queensland Opioid Treatment Program (QOTP), amphetamines and methylphenidate (psychostimulants), other restricted medicines also listed in Appendix D of the Poisons Standard.

This inequitable prescribing authority is disparate to educational preparation. For example, to be eligible for endorsement as a nurse practitioner by the NMBA, a registered nurse must undertake a Master of Nurse Practitioner program (AQF level 9)[3], designed to prepare experienced registered nurses to function autonomously and collaboratively in advanced and expanded clinical roles. The course includes education to develop an individual's comprehensive knowledge and understanding of the quality use of medicines and pharmacology, pharmacokinetics and pharmacodynamics. A focus is on equitable, effective, safe, judicious, and appropriate medicines usage. Whereas to be eligible for endorsement as an endorsed midwife by the NMBA, which authorises a midwife to prescribe, one must complete at minimum a Prescribing for Midwives (or however named) course (AQF level 8), which provides the midwife with the knowledge and skills to order and interpret clinical investigations, create medication plans, and write prescriptions relevant to midwifery practice.[4]

Another example of inequitable prescribing authority that is disparate to educational preparation, relates to the physician assistant. To qualify as a physician assistant, an individual must complete a Bachelor of Health Science (Physician Assistant) (AQF level 7). They are authorised under the Medicines Regulation to prescribe a non-restricted medicine, under the supervision of a medical officer and in accordance with a practice plan.

Issue 2 – Disruption to continuity of care

Consumers are experiencing disruption to continuity of care when they must seek out alternative prescribers to their primary treating nurse practitioner clinician, if they require access to unapproved medicines to treat their health condition. Without good continuity of care, people can experience poorer health outcomes. Fragmented, poorly integrated care from multiple providers, often with suboptimal outcomes increases the risk of harm due to failures of communication, inadequate sharing of clinical information, poor reconciliation of medicines, duplication of investigations and avoidable hospital admissions or readmissions.

Issue 3 – System inefficiencies and increased cost for consumers and Medicare

Nurse practitioners in Queensland are reliant on other practitioners to prescribe unapproved medicines on their behalf in order to provide treatment of health conditions to patients under their specialist care. This is a resource imposition that results in system pressure and inefficiency. Consumers who are forced to seek a prescription from their general practitioner, are reporting up to several weeks wait and are experiencing unplanned out of pocket expenses. According to the Productivity Commission's Report on Government Services 2024, 29.6 per cent of people who saw a general practitioner for their own health waited longer than they felt was acceptable to get an appointment, an increase on 2021-22 (23.4 per cent).[5] Additional pressure is also placed on the Medicare system.

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[3] Australian Health Practitioner Regulation Agency - Approved Programs of Study (ahpra.gov.au). Retrieved from: https://www.ahpra.gov.au/Accreditation/Approved-Programs-of-Study.aspx?ref=Midwife&Type=Endorsement&_gl=1*1tqvsyk*_ga*MTcyMjk3NjU0NC4xNjg0Mjg3Nzc5*_ga_F1G6LRCHZB*MTcwNjA1OTcxMi43LjEuMTcwNjA2MTIzMS4wLjAuMA.

[4] Continuity and coordination of care: a practice brief to support implementation of the WHO Framework on integrated people-centred health services. Geneva: World Health Organization; 2018. Licence: CC BY-NC-SA 3.0 IGO. Retrieved from: https://iris.who.int/bitstream/handle/10665/274628/9789241514033-eng.pdf?sequence=1

[5] Australian Government (Productivity Commission). Report on Government Services 2024. Released on 31 January 2024. Retrieved from: https://www.pc.gov.au/ongoing/report-on-government-services/2024/health/primary-and-community-health

Issue 4 – Inequalities across healthcare in rural, regional, and remote communities

Geographical location should not be a barrier to achieving timely access to healthcare, including access to unapproved medicines if required. Queensland has large geographical distances and dispersed populations. Australians living in rural communities are having to spend considerable time and effort to access health services, and are experiencing poorer health outcomes, higher levels of disease, and lower life expectancy than those living in metropolitan areas. The Stronger Rural Health Strategy identifies that Australia continues to face a significant maldistribution of the medical workforce with regional, rural, and remote areas receiving far less access to medical services than the major cities.[6] Nurse practitioners may be the only prescribing clinician directly available to Queenslanders who live in rural and remote areas, for example at primary health care centres. Access to alternative prescribers to promote patient access to unapproved medicines that are considered best treatment for their condition, prove even more challenging for patients in rural and remote locations when compared to those in metropolitan areas. Nurse practitioners inability to prescribe unapproved medicines may magnify the inequality that people living in rural and remote locations experience in accessing healthcare.

Issue 5 – Cultural and social inequities in healthcare

Cultural and social backgrounds should not be a barrier to achieving timely access to healthcare, including access to unapproved medicines if required. For First Nations people, factors such as cultural identity, family and kinship, country and caring for country, knowledge and beliefs, language and participation in cultural activities and access to traditional lands are key determinants of health and wellbeing.[7] The proportion of the total First Nations population increases with remoteness from 1.8 per cent in Major cities, to 32 per cent in remote and very remote areas based on estimated Indigenous population projections for 2021.[8] With the significant maldistribution of the medical workforce with regional, rural, and remote areas nurse practitioners may be the only prescribing clinician directly available to First Nations people living in rural, remote, or very remote locations.

Barriers and limitations faced by nurse practitioners

Nurse practitioners have communicated that by not authorising their workforce to prescribe and give a treatment dose of unapproved medicines it limits their scope of practice and impacts on the timeliness and continuity of care, and lost time for patients, nurse practitioners and other medical professionals. Please refer to Appendix A for some examples of instances where nurse practitioners were unable to prescribe unapproved medicines.

[6] Australian Institute of Health and Welfare. Rural and remote health. Retrieved from: https://www.aihw.gov.au/reports/rural-remote-australians/rural-and-remote-health

[7] Commonwealth of Australia. A Stronger Rural Health Strategy. Retrieved from: https://www.aph.gov.au/About_Parliament/Parliamentary_departments/Parliamentary_Library/pubs/rp/BudgetReview201819/RuralHealthWorkforce

[8] Australian Institute of Health and Wellbeing. (2022) Determinants of health for Indigenous Australians. Retrieved from: https://www.aihw.gov.au/reports/australias-health/social-determinants-and-indigenous-health

Jurisdictional comparison

A jurisdictional comparison of authorisations for nurse practitioners to prescribe unapproved medicines shows that four of seven states and territories (Australian Capital Territory, Northern Territory, South Australia, and Victoria) do not impose restrictions. Two jurisdictions (New South Wales and Western Australia) allow nurse practitioners to prescribe unapproved medicines with some limitations. Tasmania and Queensland do not currently authorise this practice, which is out of step with the Australian Government's goal of health professionals being able to work to their full scope of practice, and the *Health Q32: A vision for Queensland's health system*.

Jurisdiction	Prescribe unapproved medicines	Prescribe unapproved medicines with restrictions	Can not prescribe unapproved medicines
Queensland			•
NSW		•	
ACT	•		
Victoria	•		
SA	•		
NT	•		
WA		•	
Tasmania			•

Appendix A

Individuals affected by the issue of nurse practitioners not being able to prescribe unapproved medicines

The following stories have been provided by nurse practitioners working in public and/or private health services in Queensland. These stories represent a small selection of those that were provided. The affected nurse practitioners communicated limitations to the current scope of practice and expressed frustration that these limitations impacted on the timeliness and continuity of care, caused out of pocket expenses and lost time for patients. Further, the nurse practitioner community expressed concern that in a time of chronic healthcare shortages, this prescribing restriction is limiting their invaluable contribution to the health care sector, and results in unnecessary health system inefficiencies.

Jo's story – Missed opportunity for Monkey Pox vaccine due to vaccine being unapproved by the TGA

Jo is a 29-year-old person who has Human Immunodeficiency Virus (HIV) and is under the care of a nurse practitioner, in a Queensland Health nurse practitioner run sexual health clinic. Jo dropped into the clinic to receive treatment for sexual health concerns and while they were there, the nurse practitioner identified that Jo meets the eligibility criteria for the Monkey Pox vaccine and had not yet been vaccinated. A Monkey Pox preventative program is recommended by the Australian Technical Advisory Group on Immunisation in high-risk populations, using JYNNEOS vaccine, however JYNNEOS is not registered with the TGA. Given Jo's irregular attendance at the clinic, Jo would benefit from opportunistic vaccination at the time of having their other sexual health care needs managed. However, as the nurse practitioner is unable to prescribe the unapproved JYNNEOS vaccine, the opportunity for Jo to receive the vaccine during this episode of care was missed. By authorising nurse practitioners to prescribe unapproved medicines in Queensland, Jo and people in similar circumstances, would be able to receive opportunistic vaccine for Monkey Pox, increasing public safety.

Max's story – Compounded medicine preference over registered product to decrease unwanted side effects

Max is a 55-year-old male with erectile dysfunction following a low anterior resection for colorectal cancer. He is under the care of a nurse practitioner, specialised in urology, who leads a state funded service for men who experience sexual function changes post complex surgical treatment for cancer.

The nurse practitioner trialled Max on tadalafil (Cilalis), with good effect but he experienced side effects of back pain and headaches which were impacting his quality of life. Max was then trialled on sildenafil (Viagra), which was also associated with unwanted side effects. The nurse practitioner is aware that both medicines can be compounded, and wished to trial these options in Max to see whether a clinical effect could be achieved with less side effects. Given the nurse practitioner is not authorised to prescribe unapproved medicines, alternative options to obtain the prescription were discussed with Max, including returning to his general practitioner, or booking Max into a urology medical consultant clinic for review and management. Both options would cause a delay in providing Max with optimal treatment. If the nurse practitioner could have prescribed this medicine, Max could have maintained continuity of care and experience no disruption to the provision of treatment.

Mohammad's story – TGA registered product discontinued due to reasons of commercial viability, not replaced

Mohammad, a 72-year-old man attends a long-standing nurse practitioner run wound clinic for bilateral lower leg wounds due to wet venous stasis eczema. The product that was used as an adjunct to treat Mohammad's lower leg wounds was discontinued by the pharmaceutical company, due to reasons of commercial viability. Mohammad's nurse practitioner was aware that the same medication of betamethasone and clioquinol can be safely compounded when required, normally for a 2-week treatment period. As the nurse practitioner is not authorised to prescribe compounded medications the practice within the facility is to request a medical officer, who is unfamiliar with the patient, their condition or wound plan, to prescribe the medicine. Were the nurse practitioner able to prescribe the unapproved medicine, then the time spent by the nurse practitioner and the medical officer to coordinate a prescription could be redirected.

Mùchén's story – Innovative formulation of medicine that improves healing and decreases risk of treatment

Mùchén, a 21-year-old male was admitted to a tertiary hospital in Queensland, with moderate to severe burns to his left leg. Pain management, including pharmacologic and nonpharmacologic approaches, is a central component of treating patients with burns. To manage his pain, Mùchén was under the care of a nurse practitioner who has specialised in Pain Management, who independently consults on, and treats, both acute and persistent pain conditions, and attends the Acute Pain Service round once a week.

Complex burns dressings changes can cause significant pain to the patient and if severe may require systemic anaesthesia every 1-3 days for dressing changes. A complex combination of medicines is used to minimise pain when performing dressing changes on the ward. Ketamine delivered by buccal lozenge, has been implemented at this tertiary hospital, providing effective analgesia for burns dressing changes, reducing the need for, and repetitive risk of, anaesthetics, and reduced duration of sedation. Patients can be discharged to local hospitals and to the community on these lozenges unlike other methods of analgesia for dressing changes.

The nurse practitioner assessed Mùchén to be a suitable candidate for buccal ketamine lozenges, however as the nurse practitioner is unable to prescribe the compounded formulation, they requested the admitting team's medical resident or registrar to prescribe the ketamine lozenges. The treating team's unfamiliarity with the ketamine lozenges has resulted in the incorrect prescription of the medication, and the prescription not being transcribed when the medication chart was rewritten, resulting in the patient returning to theatre for dressing changes for a four-day period, when the nurse practitioner was on leave. By authorising nurse practitioners to prescribe unapproved medicines, patient harm could have been avoided, continuity of care could be maintained, efficiencies gained through minimising duplication of effort and earlier patient discharge facilitated.

Jim's story – Shortage of recommended TGA approved medicine

Jim, a 56-year-old man with alcohol dependence, is under the care of a nurse practitioner who specialises in Alcohol and Other Drugs (AOD), and who runs a state-funded clinic for people experiencing AOD dependence. To support alcohol cravings, Jim had tried both Naltrexone and Acamprosate previously with limited effect, so Jim's nurse practitioner commenced him on Disulfiram. Part way through Jim's treatment, the TGA advised of a national shortage of Disulfiram. The medicine could be substituted with a compounded formulation however, as the nurse practitioner could not prescribe the compounded medicine, the interim alternatives that were discussed with Jim was to cease the medicine, refer Jim to his general practitioner to request a prescription of the compounded form of the medicine, or book Jim into a medical specialist outpatient clinic. Jim had significant reservation about disclosing his alcoholism to his general practitioner and chose to wait for a medical specialist outpatient appointment, which delayed his recovery. Were the nurse practitioner able to prescribe the unapproved medicine, Jim would have maintained continuity of care and continued the recovery trajectory that he was on.