Medicines and Poisons (Medicines) Amendment Regulation (No. 2) 2022

Explanatory notes for SL 2022 No. 129

made under the

Medicines and Poisons Act 2019

General Outline

Short title

Medicines and Poisons (Medicines) Amendment Regulation (No. 2) 2022

Authorising law

Section 240 of the *Medicines and Poisons Act 2019*.

Policy objectives and the reasons for them

The *Medicines and Poisons Act 2019* (Act) was enacted in September 2019 and introduced a new regulatory framework for medicines and poisons in Queensland. The Act outlines who can deal with medicines and what dealings they can undertake.

The *Medicines and Poisons (Medicines) Regulation 2021* (Medicines Regulation) supports the Act by setting the scope of lawful practice for dealings with medicines, as well as stipulating how dealings with medicines must be done, including compliance with departmental standards and substance management plans.

The *Medicines and Poisons (Medicines) Amendment Regulation (No. 2) 2022* (Amendment Regulation) amends the Medicines Regulation to update a reference to a new version of the extended practice authority for Pharmacists to transition the model of care for the treatment of uncomplicated urinary tract infections (UTIs) by community pharmacists to usual practice. The extended practice authority allows any community pharmacist who has completed the required training, to supply specified medicines without a prescription for the treatment of women aged between 18 and 65 years.

Section 232 of the Act enables the chief executive or their delegate to make an extended practice authority and states that the extended practice authority must be approved by regulation (section 232(4)).

Schedule 1, part 1 of the Medicines Regulation lists the approved extended practice authorities (name and version number). When new versions of an extended practice authority are made by

the chief executive or their delegate, the Medicines Regulation requires an amendment to reflect the new version so it can take effect.

On 16 October 2018, the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee tabled Report No. 12, 56th Parliament, *Inquiry into the establishment of a pharmacy council and transfer of pharmacy ownership in Queensland*. In the report, the Committee recommended Queensland Health develop options to provide low-risk emergency and repeat prescriptions through pharmacies subject to a risk-minimisation framework.

To address this recommendation, Queensland Health developed and implemented a statewide trial of the management of UTIs by community pharmacists. In November 2019, a consortium led by the Queensland University of Technology (QUT) was engaged by Queensland Health to develop, implement and evaluate the Urinary Tract Infection Pharmacy Pilot – Queensland (UTI Pilot).

The endorsed model of care for the pilot enabled Queensland pharmacists, who had undertaken required education and training, to provide optimal, guideline-based treatment to women aged between 18 and 65 years of age, presenting with symptoms of an uncomplicated UTI, who met strict inclusion criteria, and consented to participate in the pilot.

The UTI Pilot commenced on 19 June 2020 and concluded on 31 December 2021. The pilot was extended for six months to 30 June 2022 to enable continuation of the service while consideration was given to whether to transition the model of care to usual practice for community pharmacists. The UTI Pilot was further extended to 31 October 2022, to ensure consultation was undertaken on the proposed amendments to the Pharmacists extended practice authority and for the Outcomes Report prepared by QUT to be released and published.

On 7 July 2022, the Minister for Health and Ambulance Services announced that Queensland Health would transition the community pharmacy UTI service to usual practice. This will ensure that Queensland women aged between 18 and 65 can continue to receive immediate advice and treatment for uncomplicated UTIs through their local participating pharmacy.

The legislative approval for the UTI Trial was initially provided by a Drug Therapy Protocol under the now repealed *Health (Drugs and Poisons) Regulation 1996*. The current authorisation for the trial is provided under the Medicines Regulation through the Pharmacists extended practice authority, which was approved by the chief executive on 12 August 2021 and took effect on 27 September 2021, on commencement of the Medicines Regulation.

Achievement of policy objectives

The Amendment Regulation amends schedule 1, part 1 of the Medicines Regulation to reflect the new version 2 of the Pharmacists extended practice authority.

Version 2 of the Pharmacists extended practice authority removes the requirement for the model of care to be undertaken as part of the UTI Trial and enables the model of care to continue as part of usual practice for community pharmacists in Queensland. Version 2 of the extended practice authority enables community pharmacists, who have completed the required training, to supply specified medicines without a prescription for the treatment of an uncomplicated UTI for women aged between 18 and 65 years.

The additional training which must be completed by pharmacists before providing the UTI service includes classification and epidemiology of UTIs, anatomy, pathogenesis, assessment and differential diagnosis, treatment and procedures for the UTI pharmacy service.

The updated version of the extended practice authority also requires pharmacists to keep appropriate clinical records and to make these records available to patients to enable them to notify their general practitioner or other healthcare professional.

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

The Amendment Regulation is the only effective means of achieving the policy objectives.

Benefits and costs of implementation

The cost of implementing the amendments to the Medicines Regulation will be met within existing budget allocations, and the resources to manage and administer the existing regulation framework will continue to be used.

Over the course of the UTI Pilot, a total of 6,531 Queensland women received 6,751 treatments for an uncomplicated UTI in a Queensland community pharmacy. A further 461 patients were ineligible for the service, of which 163 (35 per cent) were outside the eligible age range, 146 (32 per cent) had symptoms indicating other potential diagnosis and 76 (17 per cent) had frequent or recurrent UTIs. These services were distributed across Queensland.

Almost all (97 per cent) of eligible patients presented for a single episode of care. The primary presenting symptoms were consistent with an uncomplicated UTI and included urinary frequency (90 per cent), dysuria (74 per cent), urinary urgency (70 per cent) and a smaller number with suprapubic pain (37 per cent).

A total of 2,409 (36 per cent) of patients participated in follow up at seven-days following receipt of the UTI service. Of the patients who participated in this follow up, 87 per cent of patients reported that their symptoms had resolved. Consumers who reported persistent symptoms, were all referred for further medical review and management.

A small number of patients who participated in the follow up (3 per cent) reported experiencing adverse effects from the antibiotic treatment including nausea, vaginal candidiasis, gastrointestinal upset and headache/migraine. These events are generally consistent with those expected for the antibiotics prescribed and align with the consumer medicines information.

During follow up, four patients reported having visited an emergency department. All four had been supplied with trimethoprim by the treating pharmacist. One patient reported having an allergic reaction to trimethoprim and was prescribed steroids and antihistamines at the

emergency department. Two patients reported attending emergency department with unresolved symptoms; one of these patients was diagnosed with another infection and the second given intravenous nitrofurantoin. The fourth patient was admitted to hospital with appendicitis four days after the initial consultation with the pharmacist. The fourth patient, a 34-year-old female, initially presented to the pharmacy with dysuria, urinary frequency and urinary urgency (no suprapubic pain, vaginal or systemic symptoms were reported). Clinical review of the case by medical representatives on the Steering Reference Group for the UTI Pilot indicated the pharmacist management was consistent with the clinical protocol.

Overall consumer and pharmacist satisfaction with the service was positive.

Consistency with fundamental legislative principles

The Amendment Regulation is generally consistent with fundamental legislative principles in section 4 of the *Legislative Standards Act 1992*.

Institution of Parliament

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

Section 232 (Making extended practice authorities) of the Act empowers the chief executive or delegate to make an extended practice authority, authorising an approved person to deal with a regulated substance. The extended practice authority may state the places or circumstances in which the approved person may deal with the regulated substance, impose conditions on dealing with the regulated substance or require the approved person to hold particular qualifications or training to deal with the registered substances.

Prescribing requirements by reference to an external document may be seen to breach section 4(5)(e) of the Legislative Standards Act. An extended practice authority is a document certified by the chief executive of Queensland Health (or delegate) that sets out matters of technical detail for how an approved person can carry out a regulated activity with a regulated substance. Extended practice authorities include details such as the route of administration, the specific dose, quantity, duration and restrictions placed on substances and the circumstances in which they may be administered. The extended practice authority is monitored and updated when necessary, aligns with clinical best practice and is published on the Queensland Health website. When making or amending an extended practice authority, relevant individuals or organisations with expertise in, or experience of, the matters under consideration are consulted.

Extended practice authorities are updated regularly, with consideration given to the healthcare needs of specific patient populations, how care can be provided in a timely and safe manner and requirements for medical advice, referral or transfer to other individuals qualified to provide higher levels of care, and the individual qualifications, skills and experience of the class of health practitioners who will act under the particular authority. Schedule 1, part 1 (Approved extended practice authorities) of the Medicines Regulation details the name of each extended practice authority made by the chief executive and its version number. The regulation is updated to reflect the name and new version number of the extended practice authority each time a new version is made. A copy of the updated extended practice authority is tabled as extrinsic material each time the regulation is amended, to reflect the updated document. The Act provides that an extended practice authority has effect in relation to an approved person

only if a provision of a regulation states it applies to the particular class of persons, as approved persons.

By including a list of extended practice authorities in the schedule of the Medicines Regulation, it creates certainty for the relevant professions and the public about the status of extended practice authorities published on the Queensland Health website and the date when these took effect.

It is considered the rigour surrounding the development of extended practice authorities, their use in ensuring Queenslanders receive health care based on best clinical practice and the detailed nature of the documents, justifies the need to sub-delegate by referring to external documents in the Medicines Regulation.

Consultation

In July 2022, formal targeted consultation on the changes to the extended practice authority for pharmacists was undertaken. Stakeholders included Health Consumers Queensland, the Australian Medical Association Queensland, the Royal Australian College of General Practitioners, the Australian College of Rural and Remote Medicine, the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia and Pharmacy Board of Australia, Professional Pharmacists Australia, the Queensland Nurses and Midwives' Union, the Australian College of Nurse Practitioners and the Australian Primary Health Care Nurses Association.

The medical organisations do not support the proposed amendments to the Pharmacists extended practice authority and cited ongoing concern regarding prescribing by pharmacists, the safety and appropriateness of the service for consumers, clinical governance within the community pharmacy setting, and the potential for further fragmentation of primary health care services.

The changes were supported by the pharmacy professional associations, who indicated that the UTI pharmacy service should transition to usual practice, and that all community pharmacies be eligible to offer the service if they have completed the required training.

Transitioning the model of care for the treatment of UTIs by community pharmacists to usual practice is supported by consumer groups, who reported that pharmacists working to their full scope, including prescribing, is integral to the provision of timely, consumer-centred health care.

The Amendment Regulation was assessed by the Office of Best Practice Regulation in accordance with *The Queensland Government Guide to Better Regulation* as being excluded from further regulatory impact analysis under category (k) – regulatory proposals designed to reduce the burden of regulation, or that clearly do not add to the burden, and it is reasonably clear there are no significant adverse impacts.

Notes on provisions

Short Title

Clause 1 states the short title is the *Medicines and Poisons (Medicines) Amendment Regulation (No. 2) 2022*.

Commencement

Clause 2 provides for the commencement of the regulation on 1 October 2022.

Regulation amended

Clause 3 provides that the regulation amends the *Medicines and Poisons (Medicines) Regulation 2021*.

Amendment of sch 1 (Extended practice authorities and departmental standards)

Clause 4 amends schedule 1, part 1, by replacing the reference to version 1 of the extended practice authority with version 2 for the entry for Pharmacists.