Therapeutic Goods Regulation 2021

Explanatory notes for SL 2021 No. 143

made under the

Therapeutic Goods Act 2019

General Outline

Short title

Therapeutic Goods Regulation 2021

Authorising law

Section 7 of the *Therapeutic Goods Act 2019*.

Policy objectives and the reasons for them

The *Therapeutic Goods Act 2019* (Act) and *Medicines and Poisons Act 2019* were passed by the Legislative Assembly on 17 September 2019 and received Royal Assent on 26 September 2019.

On 13 August 2020, a postponement regulation (SL 2020 No. 151) was made under section 15DA of the *Acts Interpretation Act 1954*, postponing the automatic commencement of the Act by one year, until the end of the day on 26 September 2021. The scheme was originally planned to commence in mid-2020 but was delayed due to the impact of COVID-19.

The Act and Medicines and Poisons Act automatically commence on 27 September 2021. Their supporting regulations will also commence on 27 September 2021.

The *Therapeutic Goods Act 2019* (Act) adopts the *Therapeutic Goods Act 1989* (Cwlth) (Commonwealth Act) and the regulations, orders and manufacturing principles under the Commonwealth Act as laws of Queensland. The Act uses the defined term ‘Commonwealth Therapeutic Goods Laws’ to collectively refer to these Commonwealth laws and instruments.

The Act ensures national regulatory controls apply consistently to Queensland-based manufacturers of therapeutic goods. The Commonwealth Act already applies to corporations and entities that trade interstate or across national borders. Almost all Queensland manufacturers are within this category. Adopting the Commonwealth Act as a law of Queensland means it also applies to non-corporate entities such as sole traders and partnerships that only trade within Queensland. These manufacturers will be subject to the same Commonwealth requirements as all other manufacturers.

The Act allows a regulation to modify the application of the Commonwealth Therapeutic Goods Laws as laws of Queensland.

The Central Pharmacy Manufacturing Unit (Central Pharmacy) is a commercialised business unit of Queensland Health. Central Pharmacy conducts bespoke manufacturing of individual medicines for individual patients, small-scale batch manufacturing of products that are not commercially available and the repackaging of some medicines. These medicines are provided for patients in Hospital and Health Services, dental clinics, Queensland Ambulance Service sites and private patients of hospitals within Queensland.

Central Pharmacy manufactures approximately 180 different specialist pharmaceutical product lines. The medicines include vision saving eye drops for severe fungal infections, specialised dosage forms for children such as melatonin (a sleep aid for children with sleep disorders), solutions for bathing burns victims, and pre-packing and labelling medicines to assist clinicians supplying medicines to patients in an emergency department.

The Act binds all persons, including the State. Without modifying the application of the Commonwealth Act through a regulation, this would result in the requirements of the Commonwealth Act applying to the State, including to Queensland Health employees. This would mean that Central Pharmacy may be required to obtain manufacturing licences and register some therapeutic goods on the Australian Register of Therapeutic Goods unless covered by an exemption. The costs and administrative processes associated with registering therapeutic goods are significant, and not obtaining the relevant approvals may expose Queensland Health staff to the risk of criminal offences and civil penalties under the Commonwealth Act.

Requiring Central Pharmacy to obtain licences and register medicines under the Commonwealth Act would represent a prohibitive cost and administrative burden that would not improve safety or quality outcomes for patients. In practice, it is likely that imposing such requirements would lead to adverse outcomes for patients, as Central Pharmacy would be likely to cease manufacturing of some medicines. This would disadvantage Queensland patients. For example, parents would not have access to medicines in a suitable form to give to infants. Instead, they would be forced to undertake complicated manipulation of adult dose forms that would carry a risk of error. Similarly, Central Pharmacy prepares a mouthwash that is the recommended treatment in national therapeutic guidelines to stop bleeding after dental extraction for people taking anticoagulant medication. This drug is not commercially available in a mouthwash form. If Central Pharmacy was unable to prepare this mouthwash, patients would be required to open oral capsules and disperse them in a quantity of water each time an oral rinse was required. Treatment such as sterile eye drops for rare eye conditions may also be delayed or would not be available at the hospital at which the patient was being treated. Access to the expertise and facilities for safe preparation of medicines is not widely available in Queensland public hospitals and clinicians would be limited in their treatment options for patients.

Achievement of policy objectives

To ensure Central Pharmacy can continue to conduct bespoke manufacturing for the benefit of patients in health services across Queensland, the Therapeutics Goods Regulation 2021 modifies the application of the Commonwealth Therapeutic Goods Laws in Queensland so that they do not apply to departmental employees involved in the manufacture, supply or use of unregistered therapeutic goods, or to other individuals supplying or using therapeutic goods manufactured by a departmental employee.

Exempting Central Pharmacy from the application of the Commonwealth Act is not expected to impact on the safety and quality of the products manufactured. Medicines that are manufactured and repackaged within Queensland Health are done with the highest standards of safety and quality. Central Pharmacy currently holds a manufacturing licence under the *Health (Drugs and Poisons) Regulation 1996* which will be replaced by a manufacturing licence under the *Medicines and Poisons Act 2019*. This will ensure Central Pharmacy is required to adhere to the provisions of the Medicines and Poisons framework including safe packaging and labelling, and appropriate storage and record keeping for wholesale supply. It will also be subject to offences under the Medicines and Poisons Act. Central Pharmacy will also be required to manufacture goods under the relevant code of good manufacturing practice (PIC/S10 - Guide to good practices for the preparation of medicinal products in healthcare establishments). Under this code, Central Pharmacy will be required, for example, to have suitable facilities and trained staff, to prepare and keep batch records and to undertake quality control activities.

Consistency with policy objectives of authorising law

The Therapeutic Goods Regulation is consistent with the policy objectives of the 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 Therapeutic Goods Regulation is the only effective means of ensuring that Central Pharmacy is able to continue to manufacture and repackage medicines for patients without being subject to significant costs and administrative barriers.

Benefits and costs of implementation

Implementation of the Therapeutic Goods Regulation will not result in any costs.

The Therapeutic Goods Regulation will ensure Central Pharmacy can continue to conduct bespoke manufacturing for the benefit of patients in health services across Queensland.

Consistency with fundamental legislative principles

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

Consultation

In September 2018, consultation was undertaken on the Therapeutic Goods Regulation as part of the broader consultation on the Medicines and Poisons framework. Consultation was undertaken with a broad range of stakeholders, including licenced manufacturers, complementary medicines manufacturers and relevant professional and industry peak bodies.

The Therapeutic Goods Administration was consulted on the application of the Commonwealth Act in Queensland and the proposed exemption for Central Pharmacy, with no concerns raised.

Other stakeholders did not provide any specific feedback on the Therapeutic Goods Regulation, with feedback focused on other aspects of the broader Medicines and Poisons framework.

The Therapeutic Goods Regulation was assessed by the Office of Best Practice Regulation as part of their review of the Medicines and Poisons legislative framework. The Office of Best Practice Regulation advised that no further regulatory impact assessment was required.

Notes on provisions

Short title

Clause 1 states the short title of the regulation is the *Therapeutic Goods Regulation 2021*.

Commencement

Clause 2 states this regulation commences on 27 September 2021.

Modification of application of Commonwealth Therapeutic Goods Laws – Act, s 7

Clause 3 modifies the application of the Commonwealth Therapeutic Goods Laws (as defined in section 5 of the *Therapeutic Goods Act 2019*) in Queensland.

Clause 3(2) provides that the Commonwealth Therapeutic Goods Laws do not apply to a thing done in Queensland by a departmental employee for the manufacture, supply or use of unregistered therapeutic goods, or by another individual supplying or using unregistered therapeutic goods manufactured by a departmental employee.

Clause 3(3) provides definitions for *departmental employee* and *unregistered therapeutic goods*.