Therapeutic Goods Regulation 2019

Explanatory notes for SL 2019 No. ###

made under the

Therapeutic Goods Act 2019

General Outline

Short title

Therapeutic Goods Regulation 2019

Authorising law

Section 7 of the Therapeutic Goods Act 2019

Policy objectives and the reasons for them

The Therapeutic Goods Act 2019 (the Act) adopts the *Therapeutic Goods Act 1989* (Cth) (Commonwealth Act) and its related laws as laws of Queensland.

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 who only trade within Queensland, ensuring these manufacturers will be subject to the same Commonwealth requirements as all other manufacturers.

The Act includes provisions that allow a regulation to modify the application of the Commonwealth Act (and its related laws) as laws of Queensland.

The Central Pharmacy Manufacturing Unit (Central Pharmacy) is a commercialised business unit of Health Support Queensland within 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 and Queensland Ambulance Service sites.

In emergency circumstances, Central Pharmacy also prepares products for private patients of hospitals within Queensland. However, Central Pharmacy primarily manufactures medicines for the more complex and rare conditions that are treated in tertiary and quaternary public hospitals, rather than in private hospitals. The medicines made by Central Pharmacy are included under the governance framework of the statewide *List of Approved Medicines*, where medicines are assessed for safety, efficacy and need.

Central Pharmacy manufactures approximately 180 different specialist, bespoke pharmaceutical product lines in small quantities. 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-packed and labelled 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, technical requirements 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 potentially 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 that Central Pharmacy can continue to conduct bespoke manufacturing for the benefit of patients in health services across Queensland, the Regulation modifies the application of the Commonwealth Act 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 previously held 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 such as safe packaging and labelling, appropriate storage and record keeping for wholesale supply and will be subject to offences under that Act. Central Pharmacy will also be required to manufacture goods under the relevant code of good manufacturing practice (*PIC/S Guide to good practices for the preparation of medicinal products in healthcare establishments* (PIC/S 10)). 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 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 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 Regulation will not result in any costs.

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

Consistency with fundamental legislative principles

The Regulation has been drafted with regard to the fundamental legislative principles in the *Legislative Standards Act 1992*. Potential breaches of fundamental legislative principles are addressed below.

Section 4(3)(a) of the Legislative Standards Act provides that whether legislation has sufficient regard to the rights and liberties of individuals depends on whether, for example, the legislation does not confer immunity from proceeding or prosecution without adequate justification.

As outlined above, clause 2 of the Regulation modifies the application of the Commonwealth Act in Queensland so that it does 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. This is necessary to ensure that Central Pharmacy can continue to conduct bespoke manufacturing for the benefit of patients in health services across Queensland, and is considered justified noting the range of other requirements departmental employees will be subject to, as outlined above.

Clause 2 may also be seen to breach section 4(5)(d) of the Legislative Standards Act, which requires that subordinate legislation have sufficient regard to the institution of Parliament by amending statutory instruments only. As outlined above, it is necessary to modify the application of the Commonwealth Act by regulation to ensure that Central Pharmacy can continue to conduct bespoke manufacturing for the benefit of patients in health services across Queensland. This modification is included in the Regulation, rather than in the Act, to provide flexibility in the instance that another modification to the Commonwealth Act is identified in future, for example, if the Commonwealth Act was amended in a way that affected its application in Queensland, or Central Pharmacy's functions changed.

Consultation

Consultation on the Regulation was undertaken in September to October 2018 as part of an extensive consultation process on the broader Medicines and Poisons framework, which comprised the:

- Medicines and Poisons Bill 2019;
- Therapeutic Goods Bill 2019;
- Medicines and Poisons (Medicines) Regulation 2019;
- Medicines and Poisons (Pest Management, Poisons and Other Regulated Substances) Regulation 2019; and
- Therapeutic Goods Regulation 2019.

Targeted consultation was undertaken with a broad range of stakeholders, including licenced manufacturers, complementary medicines manufacturers and relevant professional and industry peak bodies. The draft Bills and accompanying Regulations were released on the GetInvolved website for targeted stakeholder feedback, along with a detailed consultation paper and tailored fact sheets. 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 feedback on the Therapeutic Goods Regulation, with feedback focused on other aspects of the Medicines and Poisons framework.

The regulation was assessed by the Office of Best Practice Regulation in March 2019 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 under the Regulatory Impact Statement system as any impacts have been adequately assessed.

Notes on provisions

Short Title

Clause 1 provides the short title of the regulation.

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

Clause 2 modifies the application of the Commonwealth Act (as defined in section 7 of the Therapeutic Goods Act 2019) in Queensland. The clause provides that the Commonwealth Act does 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.

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