

Therapeutic Goods Bill 2019

Explanatory Notes

Short title

The short title of the Bill is the Therapeutic Goods Bill 2019 (Bill).

Policy objectives and the reasons for them

In Australia, responsibility for the regulation of medicines, poisons and therapeutic goods is shared between state, territory and Commonwealth governments. This has resulted in some duplication between the regulatory regimes in those jurisdictions.

The Bill will enhance national consistency, reduce the regulatory burden and ensure appropriate safeguards are implemented to protect the health and safety of the community. In particular, the Bill gives effect to the recommendation of a national review of medicines and poisons regulation commissioned by the Council of Australian Governments (COAG), the *National Competition Review of Drugs, Poisons and Controlled Substances Legislation* (Galbally Review). This review focused on key systemic issues, such as licensing, packaging and labelling, and scheduling and advertising, and recommended all states and territories adopt the *Therapeutic Goods Act 1989* (Cth) as a law of that jurisdiction. Queensland and Western Australia are the only states that have not adopted the Therapeutic Goods Act into law to date.

The Commonwealth Therapeutic Goods Act places standardised controls on the manufacture, import, export, supply and use of safe and effective therapeutic goods in Australia. Due to constitutional limitations, currently the Therapeutic Goods Act only applies to corporations and Queensland entities of any structure that trade interstate or overseas. While this captures the vast majority of medicines manufacturers in Queensland, it does not apply to manufacturing entities trading as non-bodies corporate such as partnerships, trusts or sole traders who are not engaged in trade outside Queensland. The quality, safety, efficacy and timely availability of the therapeutic goods that these entities produce are not regulated. This has the potential to lead to safety issues for those purchasing unregulated manufactured therapeutic goods such as herbal medicines and vitamin supplements.

The adoption of the Therapeutic Goods Act in Queensland will ensure equitable application of therapeutic goods regulation, and better align Queensland with other jurisdictions and international requirements for the manufacture of therapeutic goods. This will provide competitive fairness in the marketplace, and ensure the safety of products manufactured and sold within Queensland.

Adopting the Therapeutic Goods Act requirements in Queensland will also reduce regulatory duplication by removing the need for the separate manufacturing, advertising, labelling and packaging requirements in the Queensland regulatory framework for medicines and poisons.

Achievement of policy objectives

To promote greater national consistency and meet the recommendation of the Galbally Review, the Bill adopts the Commonwealth Therapeutic Goods Act as a law of Queensland.

Adopting the Therapeutic Goods Act will ensure national regulatory controls apply consistently to Queensland-based manufacturers of therapeutic goods. The Therapeutic Goods Act already applies to corporations and entities that trade interstate or across national borders. Almost all Queensland medicines manufacturers fall within this category. Adopting the Therapeutic Goods Act will mean it also applies to non-corporate entities such as sole traders and partnerships who only trade within Queensland. This will ensure these manufacturers will be subject to the same Commonwealth requirements as all other therapeutic goods manufacturers. Queensland Health is not aware of any current traders who will be affected by this change. However, as a precaution, the Bill provides a transitional period of two years from the commencement of the Bill to ensure persons are not liable to be prosecuted for dealing with goods in a way that is unlawful under the Bill but was not unlawful prior to the Bill's commencement.

For matters arising in relation to the Therapeutic Goods Act as applied, the Bill ensures that the Commonwealth's administrative laws, such as those relating to freedom of information, privacy, and administrative appeals apply as laws of Queensland. The Bill also contains provisions ensuring that the Commonwealth's criminal laws apply to offences against the Therapeutic Goods Act as applied in Queensland. These criminal laws include those relating to the investigation and prosecution of offences, sentencing, fines and penalties and forfeitures. The Bill also contains provisions to ensure the consistent operation of courts and Commonwealth entities.

Alternative ways of achieving policy objectives

The Bill reflects a national approach to make medicines, poisons and therapeutic goods regulation nationally consistent. There is no alternative way to apply the Therapeutic Goods Act in Queensland, as there are constitutional limitations on the entities the Commonwealth Act applies to.

Estimated cost for government implementation

The cost of implementing the new regulatory framework will be met within existing budget allocations, and the resources used to manage the existing regulatory framework will continue to be utilised under the new framework.

Consistency with fundamental legislative principles

The Bill 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(4)(a) of the Legislative Standards Act provides that whether a Bill has sufficient regard to the institution of Parliament depends on whether the Bill allows the delegation of legislative power only in appropriate cases and to appropriate persons. Adopting the

Commonwealth Therapeutic Goods Act as a law of Queensland through the Bill may be considered not to have sufficient regard to the institution of Parliament. Adopting the Therapeutic Goods Act (clause 7) will establish and maintain a nationally uniform system of controls relating to the quality, safety and efficacy of therapeutic goods, thereby reducing the complexity of the regulatory burden applying to this field. This adoption gives effect to the recommendations of the Galbally Review, which identified net benefits to the Australian community from having a comprehensive national legislative framework for the regulation of drugs, poisons and controlled substances. It is appropriate to adopt a Commonwealth law as a law of Queensland as the Therapeutic Goods Administration (TGA), which administers the Therapeutic Goods Act, has the relevant expertise and facilities necessary to ensure the safety, efficacy and quality of medicines available for sale in Australia. If Queensland was to examine the safety, efficacy and quality of medicines manufactured by individuals, this would require duplication of expertise and facilities.

Importantly, the Queensland Parliament will retain its authority over the matters subject to the Commonwealth legislative scheme. Further, clauses 7, 9 and 11 of the Bill allow the application of the Therapeutic Goods Act and the application of other Commonwealth laws to be modified by regulation.

Section 4(4)(c) of the Legislative Standards Act requires that a Bill has sufficient regard to the institution of Parliament by authorising the amendment of an Act only by another Act. As outlined above, clauses 7, 9 and 11 of the Bill allow the application of the Therapeutic Goods Act and the application of other Commonwealth laws to be modified by regulation. This is justified as it ensures that the Queensland Government can respond flexibly and quickly to issues that require modification to suit the Queensland context.

Section 4(2)(a) of the Legislative Standards Act requires that legislation has sufficient regard to the rights and liberties of individuals. Adopting the Therapeutic Goods Act as a law of Queensland (clause 7) will mean it applies to non-corporate entities such as sole traders and partnerships who only trade within Queensland. As a result, these manufacturers will be subject to the same Commonwealth requirements as all other therapeutic goods manufacturers. This could be seen to not have sufficient regard to the rights and liberties of these individuals. As noted above, Queensland Health is not aware of any current traders who will be affected. However, as a precaution the Bill provides a transitional period of two years from the commencement of the Bill to ensure persons are not liable to be prosecuted for dealing with goods in a way that is unlawful under the Bill but was not unlawful prior to the Bill's commencement. This will ensure equitable application of therapeutic goods regulation in Queensland, but provide any affected businesses with a transitional period in which to adjust their practices to comply with the Commonwealth requirements.

Consultation

Consultation on the Bill was undertaken in September to October 2018 as part of an extensive consultation process on the broader Medicines and Poisons framework, which comprises 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. Stakeholders did not provide any feedback on the Therapeutic Goods Bill, with feedback focused on other aspects of the Medicines and Poisons framework.

The TGA was consulted on the proposal to adopt the Commonwealth Therapeutic Goods Act as a law of Queensland. No concerns were raised and the TGA confirmed that the Queensland Bill could be prescribed as a corresponding state law under the Commonwealth *Therapeutic Goods Regulations 1990* once enacted.

The Bill was assessed by the Office of Best Practice Regulation as part of their review of the Medicines and Poisons legislative framework in March 2019. 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.

Consistency with legislation of other jurisdictions

The Bill is specific to the State of Queensland, however it supports a COAG commitment to adopt a nationally-consistent approach to the management of medicines, poisons and therapeutic goods. The Bill has been informed by national initiatives including the Galbally Review. With the exception of Queensland and Western Australia, every other Australian jurisdiction has applied the Commonwealth Therapeutic Goods Act.

Notes on provisions

Part 1 Preliminary

Short Title

Clause 1 provides that, when enacted, the short title of the Act will be the *Therapeutic Goods Act 2019*.

Commencement

Clause 2 provides for the commencement of the Act.

The Act will commence on a day to be fixed by proclamation.

Act binds all persons

Clause 3 provides that the Act binds all persons, including the State. However, nothing in the Act makes the State liable to be prosecuted for an offence.

Purpose of Act

Clause 4 provides the purpose of the Act, which is to manage health and safety risks posed by therapeutic goods by applying Commonwealth regulatory controls on therapeutic goods in Queensland, to the extent those controls do not otherwise apply.

Clause 4 provides that the purpose is achieved by applying relevant Commonwealth laws in Queensland in a way that allows the uniform administration of the applied laws by Commonwealth entities and allows offences against the applied laws to be treated as if they were offences against Commonwealth laws.

Definitions

Clause 5 provides definitions for the Act. *Commonwealth Therapeutic Goods Laws* is defined to include the Therapeutic Goods Act and regulations, orders and manufacturing principles under the Therapeutic Goods Act.

Clause 5 also provides that other terms used in the Act that are defined in the Commonwealth Therapeutic Goods Laws have the same meanings as they do in the Commonwealth Therapeutic Goods Laws, to the extent the context permits.

Interpretation of applied laws

Clause 6 provides for the interpretation of Commonwealth laws as applied as a law in Queensland under the Act (an *applied law*).

For applied laws, the Commonwealth *Acts Interpretation Act 1901* applies in relation to their interpretation as if the applied law were a Commonwealth law and not a Queensland law. To the extent that the Commonwealth *Acts Interpretation Act 1901* applies, the Queensland *Acts Interpretation Act 1954* and *Statutory Instruments Act 1992* do not apply.

Part 2 Applied therapeutic goods provisions

Application of Commonwealth Therapeutic Goods Laws

Clause 7 applies the Commonwealth Therapeutic Goods Laws, as defined in clause 5, as laws of Queensland. The provision recognises that the Commonwealth Therapeutic Laws already apply in Queensland to corporations and to entities that are not corporations that trade across state or national borders. Under clause 7, the Commonwealth Therapeutic Goods Laws are extended to things done or omitted to be done by entities that are not corporations and things done or omitted to be done in the course of trade and commerce within the limits of Queensland.

Subsection (2) provides that a regulation may modify the application of the Commonwealth Therapeutic Goods Law as a law of Queensland.

Subsection (3) defines the Commonwealth Therapeutic Goods Laws, as applied and modified under this section, as the *applied therapeutic goods provisions*.

Functions and powers of Commonwealth entities

Clause 8 provides that Commonwealth entities that have a power or function under the Commonwealth Therapeutic Goods Laws are taken to have the same function or power under the applied therapeutic goods provisions.

Subsection (3) requires a Commonwealth entity, to the extent practicable, to act as if the entity were performing a function or exercising a power under the Commonwealth Therapeutic Goods Laws when performing that function or exercising that power under the applied therapeutic goods provisions.

Subsection (4) makes clear that delegations and appointments of persons made by a Commonwealth entity in the performance of a function or exercise of a power under the Commonwealth Therapeutic Goods Laws are taken to have effect for the applied therapeutic goods provisions.

Part 3 Administrative matters

Application of Commonwealth administrative laws

Clause 9 sets out the Commonwealth laws that will apply as laws of Queensland to administrative matters arising in relation to the applied therapeutic goods provisions, as if the provisions were Commonwealth laws and not Queensland laws.

Subsections (1) and (2) ensure that administrative matters arising in relation to the applied therapeutic goods provisions are dealt with under the relevant Commonwealth administrative laws rather than Queensland administrative laws, to the extent constitutionally permissible. For example, if a person was seeking access to information held by the Therapeutic Goods Administration in relation to a matter arising under the applied therapeutic goods provisions, the person would need to make an access application under the *Freedom of Information Act 1982 (Cth)* rather than the *Right to Information Act 2009 (Qld)*.

If this lead to an undesirable result in the future, subsection (3) allows the application of the relevant Commonwealth administrative laws to be modified by regulation.

Functions and powers of Commonwealth entities for administrative matters

Clause 10 provides that Commonwealth entities that have a power or function under the administrative laws mentioned in clause 9 are taken to have the same function in relation to matters that arise under the applied therapeutic goods provisions. Subsection (3) requires the Commonwealth entity, to the extent practicable, to act as if the entity were performing a function or exercising a power under the Commonwealth law mentioned in clause 9 when performing that function or exercising that power under the applied therapeutic goods provisions.

Part 4 Criminal matters

Application of Commonwealth criminal laws

Clause 11 provides that Commonwealth laws relevant to an offence against the Commonwealth Therapeutic Goods Laws, relating to criminal matters such as investigation and prosecution of offences, arrest, custody, bail, trial and conviction of persons, will apply to as a law of Queensland in relation to an offence against the applied therapeutic goods provisions as if the provisions were Commonwealth laws and not Queensland laws.

Subsections (1) - (3) ensure that criminal matters arising in relation to the applied therapeutic goods provisions are dealt with under the relevant Commonwealth criminal laws rather than Queensland criminal laws, to the extent constitutionally permissible. If this lead to an undesirable result in the future, subsection (4) allows the application of the relevant Commonwealth criminal laws to be modified by regulation.

Functions and powers of Commonwealth entities for criminal matters

Clause 12 provides Commonwealth entities that have a function or power under a Commonwealth law mentioned in clause 11(1), that is, functions or powers related to Commonwealth criminal laws, are taken to have the same function or power in relation to an offence against the applied therapeutic goods provisions. Subsection (3) requires the Commonwealth entity, to the extent practicable, to act as if the entity were performing a function or exercising a power under the Commonwealth law mentioned in clause 11 when performing that function or exercising that power under the applied therapeutic goods provisions.

No double jeopardy for offences

Clause 13 provides that where an act or omission constitutes an offence against both the applied therapeutic goods provisions and the Commonwealth Therapeutic Goods Laws, and a person has been punished for the offence under the Commonwealth Therapeutic Goods Laws, they cannot also be punished under the under the applied therapeutic goods provisions.

Part 5 **Miscellaneous**

Commonwealth may keep fees

Clause 14 provides that the Commonwealth may keep fees paid to or recovered by the Secretary for the exercise of any of their functions conferred on them under the applied therapeutic goods provisions.

References in Commonwealth laws

Clause 15 provides that in clauses 9 and 11, a reference in a Commonwealth law to a provision of that law or another Commonwealth law is taken to be a reference to that provision as applying because of those clauses.

Part 6 **Transitional provision**

Liability of particular individuals for offences

Clause 16 provides a transitional period for persons affected by the Act.

The clause applies to a person if immediately before the Act's commencement, it was not unlawful for the person to deal with goods, but on the Act's commencement, the goods are therapeutic goods under the applied therapeutic goods provisions, and if not for the transitional provision, the person would be liable to be prosecuted, or subject to a civil proceeding, for contravention of an applied offence provision for dealing with the goods.

The provision will allow the person to deal with the goods to the same extent the person was dealing with the goods immediately before commencement for a period of two years after the commencement without being liable for prosecution or subject to a civil proceeding for contravention of an applied offence provision.

Subsection (3) provides that the transitional arrangements do not prevent the person from complying with the applied offence provision.

Subsection (4) defines *applied offence provision* for the clause as an applied therapeutic goods provision creating an offence or civil penalty, and *deal* with goods as to import, export, manufacture, supply or otherwise use the goods.