Parliamentary Committees



Therapeutic Goods Bill 2019

Report No. 31, 56th Parliament
State Development, Natural Resources and Agricultural Industry Development Committee

July 2019

State Development, Natural Resources and Agricultural Industry Development Committee

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Acknowledgements

The committee acknowledges the assistance provided by the Department of Health.

Contents

Abbreviations

Act	*Therapeutic Goods Act 1989* (Cth)
ARTG	Australian Register of Therapeutic Goods
Bill	Therapeutic Goods Bill 2019
COAG	Council of Australian Governments
Department	Department of Health, Queensland Government
Draft regulation	Draft Therapeutic Goods Regulation 2019
Galbally Review	National Competition Review of Drugs, Poisons and Controlled Substances Legislation, Rhonda Galbally, December 2000
LSA	*Legislative Standards Act 1992*
OQPC Notebook	Office of the Queensland Parliamentary Counsel, *Fundamental Legislative Principles: The OQPC Notebook*, 2008
PSA	Pharmaceutical Society of Australia
TGA	Therapeutic Goods Administration, Department of Health, Australian Government

Chair's foreword

This report presents a summary of the State Development, Natural Resources and Agricultural Industry Development Committee's examination of the Therapeutic Goods Bill 2019.

The committee's task was to consider the policy to be achieved by the legislation and the application of fundamental legislative principles – that is, to consider whether the Bill has sufficient regard to the rights and liberties of individuals, and to the institution of Parliament.

The Therapeutic Goods Bill 2019 proposes to manage health and safety risks posed by therapeutic goods by applying Commonwealth regulatory controls as outlined in the commonwealth *Therapeutic Goods Act 1989* in Queensland. Importantly, the Bill gives effect to a recommendation of a national review of medicines and poisons regulation commissioned by the Council of Australian Governments.

On behalf of the committee, I thank Pharmaceutical Society of Australia for making a written submission on the Bill. I also thank our Parliamentary Service staff and representatives from the Department of Health for their assistance throughout.

I commend this report to the House.

Chris Whiting MP

Chair

Recommendations

The committee recommends the Therapeutic Goods Bill 2019 be passed.

1 Introduction

1.1 Role of the committee

The State Development, Natural Resources and Agricultural Industry Development Committee (committee) is a portfolio committee of the Legislative Assembly which commenced on 15 February 2018 under the *Parliament of Queensland Act 2001* and the Standing Rules and Orders of the Legislative Assembly.[1]

The committee's areas of portfolio responsibility are:

- State Development, Manufacturing, Infrastructure and Planning
- Natural Resources, Mines and Energy, and
- Agricultural Industry Development and Fisheries.

Section 93(1) of the *Parliament of Queensland Act 2001* provides that a portfolio committee is responsible for examining each bill and item of subordinate legislation in its portfolio areas to consider:

- the policy to be given effect by the legislation
- the application of fundamental legislative principles, and
- for subordinate legislation – its lawfulness.

The Therapeutic Goods Bill 2019 (the Bill) was introduced into the Legislative Assembly on 14 May 2019 and referred to the committee on 16 May 2019. The committee is to report to the Legislative Assembly by 11 July 2019.

1.2 Inquiry process

On 20 May 2019, the committee invited stakeholders and subscribers to make written submissions on the Bill. One submission was received and is listed in Appendix A.

The committee received a public briefing about the Bill from representatives from the Department of Health (the department) on 27 May 2019. A list of officials is provided at Appendix B.

The department also provided a written response to the submission received and a number of supplementary questions from the committee.

The transcript, submission, and correspondence from the Department of Health is available on the committee's webpage.

This inquiry was conducted concurrently with the committee's examination of the Medicines and Poisons Bill 2019. Information relating to this inquiry is available on the inquiry webpage.

1.3 Policy objectives of the Bill

The objectives of the Bill as set out in the explanatory notes are to:

- promote greater national consistency in the regulation of therapeutic goods in Australia through the adoption of the commonwealth *Therapeutic Goods Act 1989* (the Act) as law in Queensland
- ensure national regulatory controls apply consistently to all Queensland based manufacturers of therapeutic goods, thereby promoting competitive fairness in the therapeutic goods marketplace and ensuring the safety of products manufactured and sold in Queensland

[1] *Parliament of Queensland Act 2001*, section 88 and Standing Order 194.

- reduce regulatory duplication by removing the need for separate manufacturing, advertising, labelling and packaging requirements in the Queensland regulatory framework for medicines and poisons.[2]

1.4 Government Consultation on the Bill

Consultation on the Bill was undertaken in 2018 as part of the Queensland Government's consultation on the proposed reforms for the broader Medicines and Poisons framework.[3] The explanatory notes described the consultation as 'extensive' and targeted stakeholders included licensed manufactures, complementary medicines manufacturers and relevant professional and industry peak bodies.[4]

The explanatory notes state that no feedback was received relating to the Bill.[5]

The Therapeutic Goods Administration (TGA), the Commonwealth body responsible for regulating therapeutic goods in Australia, was consulted and raised no concerns with the proposal to adopt the Commonwealth Act as law in Queensland.[6]

The Office of Best Practice and Regulation considered the broader Medicines and Poisons framework in March 2019 and advised that 'no further regulatory impact assessment was required under the Regulatory Impact Statement system as impacts have been adequately addressed'.[7]

Committee comment

The committee notes that stakeholders provided no feedback on the Therapeutic Goods Bill 2019 during the government's consultation on the Bill.

1.5 Should the Bill be passed?

Standing Order 132(1) requires the committee to determine whether or not to recommend that the Bill be passed.

After examination of the Bill, including consideration of the policy objectives to be implemented, stakeholders' views and information provided by the Department of Health, the committee recommends that the Bill be passed.

Recommendation 1

The committee recommends the Therapeutic Goods Bill 2019 be passed.

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2 Therapeutic Good Bill 2019, explanatory notes, p 1.

3 The broader Medicines and Poisons framework comprises the Medicines and Poisons Bill 2019, Therapeutic Goods Bill 2019, Draft Medicines and Poisons (Medicines) Regulation 2019, Draft Medicines and Poisons (Pest Management, Poisons and Other Regulated Substances) Regulation 2019, and the Draft Therapeutic Goods Regulation 2019.

4 Therapeutic Good Bill 2019, explanatory notes, p 4.

5 Therapeutic Good Bill 2019, explanatory notes, p 4.

6 Therapeutic Good Bill 2019, explanatory notes, p 4.

7 Therapeutic Good Bill 2019, explanatory notes, p 4.

2 Examination of the Bill

This section discusses key issues considered during the committee's examination of the Bill.

2.1 Policy overview

Therapeutic goods comprise a diverse range of products including those that treat serious conditions, such as prescription medicines and surgical implants, to every day products such as vitamin tablets and sunscreens.[8] In Queensland, responsibility for the regulation of therapeutic goods is shared between state, and Commonwealth governments.[9]

Currently, all corporations and entities in Queensland that trade therapeutic goods interstate or overseas are regulated by the Commonwealth *Therapeutic Goods Act 1989*. The explanatory notes state that 'almost all Queensland medicines manufacturers fall within this category'.[10]

However, due to constitutional limitations, the Act does not apply to manufacturers that trade only in Queensland. This includes non-corporate entities such as partnerships, trusts or sole traders. As a result, the quality, safety, efficacy and timely availability of these therapeutic goods is not regulated. The explanatory notes report that this has the potential to lead to safety issues for those purchasing these goods.[11] The explanatory notes state that Queensland Health is not aware of any current traders who fall into this category.[12]

2.1.1 Purpose of Bill

The purpose of the Therapeutic Goods Bill 2019 (the Bill) is to adopt the Commonwealth *Therapeutic Goods Act 1989* (the Act) as Queensland law. According to the explanatory notes, this will 'enhance national consistency in the regulation of therapeutic goods, reduce regulatory burden and ensure appropriate safeguards are implemented to protect the health and safety of the community'.[13]

2.1.2 *Therapeutic Goods Act 1989*

The Act places 'standardised controls on those wishing to import, export and manufacture therapeutic goods in Australia to protect the health and wellbeing of the community'.[14] The Act is administered by the Therapeutic Goods Administration (TGA), a division of the Australian Government's Department of Health.[15]

A key requirement of the Act is the registration of therapeutic goods that can be lawfully supplied in Australia on the Australian Register of Therapeutic Goods (ARTG). The TGA evaluates and monitors therapeutic goods against certain standards and issues authorisations to entities which enable them to supply therapeutic goods and be listed on the ARTG.[16]

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8 Australian Government, Therapeutic Goods Administration, *Basics of therapeutic goods regulation*, https://www.tga.gov.au/book-page/my-product-therapeutic-good.

9 Therapeutic Good Bill 2019, explanatory notes, p 1.

10 Therapeutic Good Bill 2019, explanatory notes, p 1.

11 Therapeutic Good Bill 2019, explanatory notes, p 1.

12 Therapeutic Good Bill 2019, explanatory notes, p 2.

13 Therapeutic Good Bill 2019, explanatory notes, p 1.

14 Therapeutic Good Bill 2019, explanatory notes, p 1.

15 Department of Health, correspondence dated 12 June 2019, attachment 1c, p 6.

16 Department of Health, correspondence dated 12 June 2019, attachment 1c, p 6.

The Act also requires:

- manufacturers of medicines to hold a licence to manufacture and demonstrate compliance with the *Good Manufacturing Practice for Medicinal Products* (a set of principles and procedures to ensure that therapeutic goods are of a high quality).[17]
- medicines for supply in Australia to be packaged and labelled in compliance with Part 2 of the Commonwealth *Standard for the Uniform Scheduling of Medicines and Poisons (*a record of decisions regarding the classification of medicines and chemicals into Schedules for inclusion in relevant legislation of the states and territories).[18]
- advertising of therapeutic goods to be in compliance with the *Therapeutic Goods Advertising Code to* ensure that the marketing and advertising is conducted in a socially responsible manner that promotes the quality of use of and does not mislead or deceive the public.[19]

2.1.3 The Medicines and Poisons framework

The Bill is part of a package of legislative proposals which seek to reform and modernise the regulation of medicines and poisons in Queensland. Central to this reform, is the Medicines and Poisons Bill 2019. The Medicines and Poisons Bill will repeal existing legislation that regulates medicines, poisons and pest management in Queensland and establish a new framework to ensure:

> *Medicines and poisons, are made, sold, used and disposed on in an appropriate, effective and safe way; to ensure health risks arising from the use of the substances are appropriately managed; and to ensure persons who are authorised carry out activities using the substances have the necessary competencies to do so safety.*[20]

The Bill supports the Medicines and Poisons framework by improving the regulation of medicine safety and quality assurance, and enhancing national uniformity in the regulation of therapeutic goods. The Bill is supported by the draft Therapeutic Goods Regulation 2019, which is discussed further in section 2.4 below.

Dr Jeanette Young, Chief Health Officer and Deputy Director-General, Department of Health, advised that subject to the passage of the two bills and the supporting regulation, the new framework is expected to commence in 2020. Dr Young advised that this will provide sufficient time for implementation and education activities to take place, and for industry stakeholders to familiarise themselves with the new requirements.[21]

Dr Young also advised that the Bills are being progressed separately so as to improve clarity of the requirements and ease of access for stakeholders.[22]

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17 Department of Health, correspondence dated 12 June 2019, attachment 1c, p 6.; Australian Government, Department of Health, Therapeutic Goods Administration, *Manufacturing principles for medicinal products*, https://www.tga.gov.au/publication/manufacturing-principles-medicinal-products.

18 Department of Health, correspondence dated 12 June 2019, attachment 1c, p 7; Australian Government, Department of Health, Therapeutic Goods Administration, *The Poisons Standard (the SUSMP),* https://www.tga.gov.au/publication/poisons-standard-susmp.

19 Department of Health, correspondence dated 12 June 2019, attachment 1c, p 7; Australian Government, Department of Health, Therapeutic Goods Administration, *Therapeutic goods advertising code,* https://www.tga.gov.au/publication/therapeutic-goods-advertising-code.

20 Dr Jeanette Young, Chief Health Officer and Deputy Director-General, Department of Health, Public briefing transcript, Brisbane, 27 May 2019, p 2.

21 Dr Jeannette Young, Chief Health Officer and Deputy Director-General, Department of Health, Public briefing transcript, 27 May 2019, p 2.

22 Dr Jeannette Young, Chief Health Officer and Deputy Director-General, Department of Health, Public briefing transcript, 27 May 2019, p 2.

2.1.4 Enhancing national uniformity

The Bill gives effect to a recommendation of a national review into the regulation of medicines and poisons in Australia, which was commissioned by the Council of Australian Governments (COAG) and subsequently endorsed in 2005.[23]

The *National Competition Review of Drugs, Poisons and Controlled Substances Legislation* (also known as the Galbally Review) examined legislation regulating medicines and poisons in Australia against a set of national competition principles. The final report made a number recommendations for national uniformity of regulation across Australia. This included the recommendation that all State and Territory jurisdictions agree to adopt the *Therapeutic Goods Act 1989*, by reference.[24]

The explanatory notes report that Queensland and Western Australia are the only states not to have adopted the Act into law to date.[25]

Committee comment

The committee notes that the adoption of the *Therapeutic Goods Act 1989* by all states and territories was a key recommendation of the Galbally Review and was endorsed by COAG in 2005. The committee considers that adoption of the Commonwealth Act will enhance national uniformity in the regulation of therapeutic goods and bring Queensland in line with most other Australian jurisdictions.

2.1.5 Reducing regulatory burden

Currently, specific requirements for the manufacturing, advertising, labelling and packaging of therapeutic goods are set out within Queensland's Health Regulation 1996 and Health (Drugs and Poisons) Regulation 1996.[26] The explanatory notes state that adoption of the Bill will 'reduce regulatory duplication by removing the need for separate manufacturing, advertising, labelling and packaging requirements in the Queensland regulatory framework for medicines and poisons'.[27]

Committee comment

The committee notes that adoption of the Commonwealth *Therapeutic Goods Act 1989* will remove the need for duplicate regulation in Queensland law.

2.2 Stakeholder views on the Bill

The committee sought submissions on the Bill. One submission was received from the Pharmaceutical Society of Australia (PSA), the national peak body representing Australian pharmacists.

In its submission, the PSA outlined its support for the Bill:

> *PSA supports the proposed Therapeutic Goods Bill 2019 to adopt the* Therapeutic Goods Act 1989 *(Cth) and its related laws as laws in Queensland. Adopting the Commonwealth Act as law in*

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23 Therapeutic Goods Bill 2019, Explanatory notes, p 1; Australian Government, Department of Health, Therapeutic Goods Administration, *Review of drugs, poisons and controlled substances legislation (The Galbally Review),* https://www.tga.gov.au/publication/review-drugs-poisons-and-controlled-substances-legislation-galbally-review.

24 Australian Health Ministers' Advisory Council Working Party, Response to the Review of Drugs, Poisons and Controlled Substances legislation (The Galbally Review), April 2003, p 4. https://www.tga.gov.au/sites/default/files/review-galbally-050628-ahmac.pdf.

25 Therapeutic Goods Bill 2019, explanatory notes, p 1.

26 Requirements relating to labelling, advertising and packaging of therapeutic and other goods are set out in the Health Regulation 1996 and the Health (Drugs and Poisons) Regulation 1996.

27 Therapeutic Goods Bill 2019, explanatory notes, p 5.

> *Queensland ensures national regulatory control apply consistently to Queensland-based manufacturers of therapeutic goods and reduces regulatory burden.*[28]

Committee comment

The committee notes that the Pharmaceutical Society of Australia supports adoption of the Commonwealth Act as Queensland law.

2.3 Transitional provisions for affected parties

Clause 16 of the Bill provides a transitional period of two years from commencement of the Bill for affected parties to comply with the Act.[29] This clause is discussed further in section 3.1.1.

Dr Young confirmed that Queensland Health was not aware of any traders who would be affected by the Bill, however acknowledged that there could be some. Dr Young explained that a transitional period was appropriate because a significant amount of work was required to achieve the necessary authorisation to supply therapeutic goods under the Act.[30]

Dr Young further advised that the department would be undertaking a 'very thorough' communication strategy to increase awareness of the Bill and its implications.[31]

Committee comment

The committee is satisfied that the transitionary arrangements outlined within the Bill are appropriate to ensure that those affected by the Bill have sufficient time to comply with the requirements of the Commonwealth Act.

2.4 Draft regulation

The draft Therapeutic Goods Regulation 2019 (draft regulation) was tabled alongside the Bill and proposes to exempt Central Pharmacy, the commercialised business unit of Health Support Queensland and Queensland Health, from the requirements of the Commonwealth Act.

Currently, Central Pharmacy undertakes 'bespoke manufacturing of individual medicines, small-scale batch manufacturing of products that are not commercially available, and the repackaging of some medicines'.[32] It manufactures approximately 180 products including vison saving eye drops, specialised dosage forms for children, and solutions for bathing burns victims.[33]

The explanatory notes state that the exemption is necessary as:

> *… 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.* [34]

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28 Submission 1, Pharmacy Society of Australia, p 1.

29 Therapeutic Goods Bill 2019, Clause 16; Dr Jeannette Young, Chief Health Officer and Deputy Director-General, Department of Health, Public briefing transcript, 27 May 2019, p 4.

30 Dr Jeannette Young, Chief Health Officer and Deputy Director-General, Department of Health, Public briefing transcript, 27 May 2019, p 10.

31 Public briefing, Dr Young, p 10.

32 Draft Therapeutic Goods Regulation 2019, explanatory notes, p 1.

33 Draft Therapeutic Goods Regulation 2019, explanatory notes, p 2.

34 Draft Therapeutic Goods Regulation 2019, Explanatory notes, p 2.

The explanatory notes also state that the exemption was not expected to have an impact on the safety and quality of the products manufactured by Central Pharmacy:

> *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 of standards of safety and quality. Central pharmacy previously held a manufacturing licence under the Health (Drugs and Poisons) Regulation which will be replaced by a manufacturing licence under the* Medicines and Poisons Act 2019*. This will ensure that 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 the Act…*[35]

Committee comment

The committee's remit was to examine the Bill only. While the draft regulation has provided the committee with further understanding of the full effect of the Bill, the regulation will be considered by the relevant portfolio committee in terms of the policy to be given effect, fundamental legislative principles and its lawfulness, when tabled in Parliament.

That said, the committee has reviewed the information contained within the draft regulation. The committee notes the rationale provided for exempting the Central Pharmacy from the requirements of the Commonwealth Act, however emphasises the importance of ensuring that the highest levels of safety and quality are maintained in the manufacture and supply of therapeutic goods in Queensland. The measures identified within the explanatory notes to maintain safety and quality are appropriate and the committee encourages the government to ensure that new licencing arrangements are secured expediently upon the commencement of any new legislation.

[35] Draft Therapeutic Goods Regulation 2019, Explanatory notes, p 3.

3 Compliance with the *Legislative Standards Act 1992*

3.1 Fundamental legislative principles

Section 4 of the *Legislative Standards Act 1992* (LSA) states that 'fundamental legislative principles' are the 'principles relating to legislation that underlie a parliamentary democracy based on the rule of law'. The principles include that legislation has sufficient regard to:

- the rights and liberties of individuals, and
- the institution of Parliament.

The committee has examined the application of the fundamental legislative principles to the Bill. The committee brings the following to the attention of the Legislative Assembly in relation to clauses 7, 9 and 11.

3.1.1 Rights and liberties of individuals

Section 4(2)(a) of the LSA requires that legislation has sufficient regard to the rights and liberties of individuals.

3.1.1.1 Summary of relevant clauses

Clause 7 adopts the *Therapeutic Goods Act 1989* (the Act) as a law in Queensland, meaning that it will apply to non-corporate entities which only trade within Queensland. These entities will be subject to the same commonwealth requirements as all other therapeutic goods manufacturers.

3.1.1.2 Fundamental legislative principle issue

Reasonable and fairness

The reasonableness and fairness of treatment of individuals is relevant in deciding whether legislation has sufficient regard to rights and liberties of individuals. The imposition of additional regulatory obligations on manufacturers in Queensland could be seen as affecting their rights and liberties, particularly regarding the manner in which they ordinarily operate their business.

While the explanatory notes acknowledge that there are no known individuals affected by the introduction of the Bill, a precaution has been built into the Bill at clause 16, which provides for a two year transition period.

As discussed in section 2.3, the clause applies to a person if it was not unlawful for the person to deal with the therapeutic goods immediately before the commencement of the Act, but on commencement of the Act, the person would be in contravention of an applied offence provision if it were not for the transitional provision. [36]

The explanatory notes provide the following justification for clause 16:

> *… it 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.* [37]

Committee comment

The committee notes that the imposition of additional regulatory obligations on manufacturers could be seen as affecting their rights and liberties. However, the committee considers that the transitional provision tempers any impact on affected parties by providing a period of two years to comply with

[36] Therapeutic Goods Bill, explanatory notes, p 8.

[37] Therapeutic Goods Bill, explanatory notes, p 3.

the Act. The committee also notes that adoption of the Bill will ensure equitable application of therapeutic goods regulation in Queensland.

On balance, the committee is therefore satisfied that the potential breach of fundamental legislative principle is sufficiently justified and that the rights and liberties of individuals have been appropriately considered.

3.1.2 Institution of Parliament

Section 4(2)(b) of the LSA requires legislation to have sufficient regard to the institution of Parliament.

Two issues of fundamental legislative principle were identified and are discussed below.

3.1.2.1 Summary of relevant provisions

Clause 7 applies the Commonwealth Therapeutic Goods Laws, as defined in clause 5, as laws of Queensland. The provision recognises that these laws already apply in Queensland 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.

Clause 7(2) provides that a regulation may modify the application of the Commonwealth Therapeutic Goods Laws as a law of Queensland. Clause 7(3) defines the laws, as applied and modified under the section, as the *applied therapeutic goods provisions*.

Clause 7(2) provides that a regulation may modify the application of the Commonwealth Therapeutic Goods Law as a law of Queensland. Clause 7(3) defines the commonwealth therapeutic goods laws, as applied and modified under the section, as the *applied therapeutic goods provisions*.

Clause 9 provides that the following commonwealth laws will apply as laws of Queensland, as if the provisions were commonwealth laws and not Queensland laws:

- the *Administrative Appeals Tribunal Act 1975*
- the *Freedom of Information Act 1982*
- the *Ombudsman Act 1976*
- the *Privacy Act 1988*
- a regulation made under any of these Commonwealth Acts.

Clause 9(2) provides that for applying a Queensland law, matters arising in relation to the applied therapeutic goods provisions are taken to arise in relation to a Commonwealth law, and not a Queensland law.

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 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.

Under subsection (2), the Commonwealth law applies as a law of Queensland in relation to an offence as if the provisions were Commonwealth laws and not Queensland laws.

And when applying a Queensland law, subsection (3) provides that an offence is taken to be an offence against a Commonwealth law and not an offence against a Queensland law.

Subsection (4) allows the application of the relevant Commonwealth criminal laws to be modified by regulation.

3.1.2.2 Fundamental legislative principle issue

Delegation of legislative power

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.[38] Generally, the greater the level of political interference with individual rights and liberties, or the institution of Parliament, the greater the likelihood that the power should be prescribed in an Act of Parliament and not delegated below Parliament.

The adoption of the Commonwealth Act could be seen as delegating the law making function to the Commonwealth, rather than to the Queensland Parliament.

As noted above, **Clause 9** provides that a number of commonwealth laws will apply as laws of Queensland, as if the provisions were commonwealth laws and not Queensland laws: The explanatory notes provide this example of the operation of clause 9(2) and (3):

> *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 leads to an undesirable result in the future, subsection (3) allows the application of the relevant Commonwealth administrative laws to be modified by regulation.*[39]

As the explanatory notes record:

> *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.*[40]

The explanatory notes set out this justification:

> *Adopting the Therapeutic Goods Act … 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.*[41]

Committee comment

While the adoption of the Commonwealth Act could be seen as delegating the law making function to the Australian Government rather than to the Queensland Parliament, the committee notes the benefits of implementing the Commonwealth law. As discussed within this report, benefits include: enhanced national consistency in the regulation of therapeutic goods to ensure appropriate safeguards are implemented to protect the health and safety of the community, and the expertise and

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38 *Legislative Standards Act 1992*, section 4(4)(a).

39 Therapeutic Goods Bill 2019, explanatory notes, p 6.

40 Therapeutic Goods Bill 2019, explanatory notes, p 5.

41 Therapeutic Goods Bill 2019, explanatory notes, p 3.

facilities that can be provided by the TGA, thereby reducing the need for duplicate resources in this State. The committee is therefore, on balance, satisfied that the proposed adoption of commonwealth law is sufficiently justified.

Parliament's sovereign power

The adoption of a national scheme law is a delegation of decision making power to the Commonwealth government, rather than the Queensland Parliament. Therefore consideration must be given as to whether any limitations on the sovereignty of the Queensland Parliament is justified.

The implementation of a national scheme raises concerns of fundamental legislative principle regarding regard for the institution of Parliament:

> *Parliament's sovereign power to make laws for Queensland should not be compromised by administrative agreements made between Australian executive governments that bind the parties to obtain specific laws from their Parliaments without amendment by their Parliaments.*
>
> *The need for governments of more than 1 parliamentary jurisdiction in a federation to agree on legislation to be passed in jurisdictions to some extent may cause a practical difficulty for the independence of their Parliaments.*
>
> *… A tension is therefore created between the efficient collaboration between the several jurisdictions of Australia and the independence of action of each of their sovereign Parliaments.*[42]

This point is reiterated at paragraph 4.2.4 of the OQPC Notebook:

> *The Scrutiny Committee is generally very wary of national scheme legislation because it believes that when the legislation is introduced or tabled in Parliament following the national agreement on the laws under administrative arrangements, there is little real capacity of the Parliament to amend, refuse to pass, or disallow the law.*

Committee comment

The adoption of the Commonwealth laws raises a potential issue about the Queensland Parliament's ability to propose amendments to the law and whether it be bound by changes made at the Commonwealth level. The committee notes that the explanatory notes address this issue:

> *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.*[43]

The committee is satisfied that issues relating to Parliament's sovereign power can be sufficiently allayed through the ability of the Queensland government to modify the Commonwealth laws by regulation. This is discussed further in the section below. On balance, the committee is therefore satisfied that the breach of fundamental legislative principle is sufficiently justified.

3.1.2.3 Amendment of an Act only by another Act

Section 4(4)(c) LSA requires that a Bill should only authorise the amendment of an Act by another Act.[44] A clause in an Act, which enables the Act to be expressly or impliedly amended by subordinate legislation or executive action is defined as a Henry VIII clause.

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42 Office of the Queensland Parliamentary Counsel, *Fundamental Legislative Principles: The OQPC Notebook,* p 176.

43 Therapeutic Goods Bill 2019, explanatory notes, p 3.

44 *Legislative Standards Act 1992*, section 4(4)(c).

Clauses 7, 9 and 11 of the Bill allow for the application of the Commonwealth Act and the application of other commonwealth laws to be modified by regulation. These are Henry VIII clauses as the regulation will amend the law, rather than by a Bill.

Committees in the past have considered the possible use of Henry VIII clauses in the following limited circumstances:

- to facilitate immediate executive action
- to facilitate the effective application of innovative legislation
- to facilitate transitional arrangements
- to facilitate the application of national scheme legislation.[45]

The OQPC Notebook explains that the existence of the above circumstances do not automatically justify the use of Henry VIII clauses. It also states that if the Henry VIII clause does not fall within any of the above situations, former committees have classified the clause as 'generally objectionable'.[46]

The explanatory notes presents the justification for the use of the clause as follows:

> *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.*[47]

Committee comment

The committee notes that the use of Henry VIII clauses can be more readily accepted in certain circumstances, such as for the facilitation of the application of national scheme legislation. Having considered the objectives of the Bill, and the rationale provided for the use such clauses, the committee is satisfied, amendment of the Bill by regulation is appropriate and sufficiently justified.

3.2 Explanatory notes

Part 4 of the *LSA* provides that an explanatory note be circulated when a Bill is introduced into the Legislative Assembly, and sets out the Information an explanatory notes should contain.

Explanatory notes were tabled with the introduction of the Bill. The notes are fairly detailed and contain the information required by Part 4 and a sufficient level of background information and commentary to facilitate understanding of the Bill's aims and origins.

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45 Office of the Queensland Parliamentary Counsel, *Fundamental Legislative Principles: The OQPC Notebook*, p 159.

46 Office of the Queensland Parliamentary Counsel, *Fundamental Legislative Principles: The OQPC Notebook,* p 159; Alert Digest 2006/10, p 6, paras 21-24; Alert Digest 2001/8, p 28, para 31.

47 Therapeutic Goods Bill 2019, explanatory notes, p 3.

Appendix A – Submitters

Sub #	Submitter
001	The Pharmaceutical Society of Australia

Appendix B – Officials at public departmental briefing

Department of Health

- Dr Jeanette Young, Chief Health Officer and Deputy Director-General, Prevention Division
- Mr David Harmer, Senior Director, Strategic Policy and Legislation Branch, Strategy Policy and Planning Division
- Ms Eve Gibson, Acting Manager, Legislative Policy Unit, Strategy Policy and Planning Division