

41ST PARLIAMENT



Report 146

STANDING COMMITTEE ON UNIFORM LEGISLATION AND STATUTES REVIEW

Therapeutic Goods Law Application Bill 2023

Presented by
Hon Donna Faragher MLC (Chair)
February 2024

Standing Committee on Uniform Legislation and Statutes Review

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EXECUTIVE SUMMARY

- 1 The Therapeutic Goods Law Application Bill 2023 (Bill) proposes to apply the *Therapeutic Goods Act 1989* (Cth) (National Law) as a law of Western Australia. The National Law provides a national framework for the import, export, manufacture, and supply of all therapeutic goods in Australia.
- 2 The National Law already applies in Western Australia to corporations operating within the state and to sole traders in the state who operate inter-state. However, its application does not (and cannot, constitutionally) extend to those within the state who are neither corporations nor operating inter-state. The Bill's application of the National Law in Western Australia will extend its operation to that currently excluded group.
- 3 Some provisions within the National Law and Bill may impact upon Western Australian Parliament's sovereignty and law-making powers.
- 4 In particular:
 - the Bill contains:
 - a commencement clause providing that the majority of the Bill comes into operation on a date fixed by proclamation
 - an applied legislation disallowance mechanism
 - a clause with a Henry VIII effect in relation to the publication of regulations and instruments
 - no review clause
 - three Henry VIII clauses
 - the National Law contains various clauses with a Henry VIII effect.
- 5 The Committee has made 11 findings and four recommendations regarding these parliamentary sovereignty issues for the Legislative Council's consideration during debate on the Bill.
- 6 Of particular note, the Committee wishes to draw attention to recommendations 1 and 2 which are in response to parliamentary sovereignty issues and legitimate concerns raised by the Minister about the re-publication of Commonwealth instruments.

Findings and recommendations

Findings and recommendations are grouped as they appear in the text at the page number indicated:

FINDING 1

Page 7

The complementary applied scheme approach to uniform legislation adopted by the Therapeutic Goods Law Application Bill 2023 erodes the Western Australian Parliament's sovereignty and law-making powers.

FINDING 2

Page 8

The disallowance mechanism in Part 2 of the Therapeutic Goods Law Application Bill 2023 provides a level of parliamentary oversight and scrutiny that reduces its impact on parliamentary sovereignty and law-making powers.

FINDING 3

Page 9

Clause 12(2)(d) of the Therapeutic Goods Law Application Bill 2023 erodes the Western Australian Parliament's sovereignty and law-making powers.

RECOMMENDATION 1

Page 10

The Therapeutic Goods Law Application Bill 2023 be amended as follows:

Clause 12

Page 9, lines 23 and 24 - To delete the lines.

RECOMMENDATION 2

Page 10

Clause 12(3) of the Therapeutic Goods Law Application Bill 2023 be amended to insert the words 'or Commonwealth' following the word 'State'.

FINDING 4

Page 10

The lack of a review clause in the Therapeutic Goods Law Application Bill 2023 is justified.

FINDING 5

Page 11

The application of Commonwealth interpretation laws in Western Australia by clause 14 of the Therapeutic Goods Law Application Bill 2023 erodes the Western Australian Parliament's sovereignty and law-making powers.

FINDING 6

Page 11

Applying laws of another jurisdiction in Western Australia enables a nationally consistent application of these laws as part of a national uniform scheme.

FINDING 7

Page 12

The risk that the Government may fail to follow procedural requirements is an inappropriate justification for a Henry VIII clause.

RECOMMENDATION 3

Page 12

The Minister representing the Minister for Health provide a further explanation to the Legislative Council about why the Minister considers a failure to follow procedural requirements is a justification for a Henry VIII clause.

FINDING 8

Page 14

The application of Commonwealth accountability laws in Western Australia by clause 22 of the Therapeutic Goods Law Application Bill 2023 erodes the Western Australian Parliament's sovereignty and law-making powers.

FINDING 9

Page 14

Applying laws of another jurisdiction in Western Australia enables a nationally consistent application of these laws as part of a national uniform scheme.

FINDING 10

Page 15

Clause 31 of the Therapeutic Goods Law Application Bill 2023 erodes the Western Australian Parliament's sovereignty and law-making powers.

FINDING 11

Page 15

Clause 31 of the Therapeutic Goods Law Application Bill 2023 is justifiable in order to effect a smooth transition to the National Law as amended.

RECOMMENDATION 4

Page 16

The Minister representing the Minister for Health explain to the Legislative Council the basis for retaining clauses in the *Therapeutic Goods Act 1989* (Cth) with a Henry VIII effect when applying that Act as law of Western Australia.

1 Introduction

- 1.1 On 29 November 2023 the Therapeutic Goods Law Application Bill 2023 (Bill) was introduced into the Legislative Council. It was referred to the Standing Committee on Uniform Legislation and Statutes Review (Committee) under Standing Order 126.
- 1.2 The Committee must report by 27 February 2024.¹
- 1.3 The Bill's purpose is to:
 - apply the National Law and legislative instruments as laws of the State; and
 - amend the *Human Tissue and Transplant Act 1982* and *Medicines and Poisons Act 2014*.

2 Inquiry procedure

- 2.1 The Committee posted the inquiry on its webpage.²
- 2.2 The Committee's terms of reference confine it to investigating whether a Bill may impact upon the Western Australian Parliament's sovereignty and law-making powers.
- 2.3 The Committee is not able to consider any other matter, including the policy of the Bill. Accordingly, no submissions were sought.

3 Supporting documents

- 3.1 The Committee received copies of the Bill, its second reading speech and Explanatory Memorandum (EM) when the Bill was introduced into the Legislative Council.
- 3.2 Standing Order 126(5) states:

The member in charge of a Bill referred to the Committee shall ensure that all documentation required by the Committee is provided to the Committee within 3 business days after referral...
- 3.3 The Committee thanks the Minister for Health (Minister) for providing the information required by Ministerial Office Memorandum 2022/01³ within this timeframe.

4 Background

- 4.1 The Council of Australian Governments conducted a National Competition Review of Drugs, Poisons and Controlled Substances Legislation, which returned a report in 2001. Included within the recommendations was the following:

That all Commonwealth, State and Territory jurisdictions agree that all States and Territories adopt the *Therapeutic Goods Act 1989* by reference into the relevant legislation.⁴

¹ On 1 February 2024 the Legislative Council suspended such standing orders as necessary to enable the Committee to report by 27 February 2024. Otherwise, the Committee would have been required to report on 1 February 2024 due to the Joint Sitting of both Houses.

² Legislative Council, [Standing Committee on Uniform Legislation and Statutes Review](#), Parliament of Western Australia, 2023, accessed 2 February 2024.

³ M McGowan, [Ministerial Office Memorandum, Uniform Legislation and Statutes Review Committee](#), Executive Government Services, 3 August 2022, accessed 6 February 2024 (MM2022/01).

⁴ R Galbally, *Review of Drugs, Poisons & Controlled Substances Legislation*, January 2001, National Competition Policy,

- 4.2 The National Law has been implemented in all jurisdictions except Western Australia.
- 4.3 This Committee previously scrutinised the Medicines, Poisons and Therapeutic Goods Bill 2013 (2013 bill). Part 6 of that bill, as introduced into the Legislative Council, proposed to implement the National Law in Western Australia. The Committee recommended the bill be withdrawn for reasons including:
- The anticipated implementation of a joint Australian New Zealand Therapeutic Products Agency (ANZTPA) by 2016, which would require the repeal of the National Law.
 - There were no provisions for review of the operation of Part 6 of the bill, which implemented the National Law.
 - The Commonwealth was amending 16 Schedules of the National Law, including amendments to the term 'therapeutic good'.⁵
- 4.4 The 2013 bill was amended to remove all clauses relating to the implementation of the National Law and passed on 15 May 2014.
- 4.5 The current Bill differs significantly from the 2013 bill because:
- The Bill's primary purpose is to apply the National Law, while this was only one of the 2013 bill's purposes.
 - The Bill includes an applied legislation disallowance mechanism (disallowance mechanism) (see Part 6).
 - On 20 November 2014, a joint statement was released that efforts to establish ANZTPA would cease.⁶ This Committee is therefore not concerned that the National Law is likely to be repealed; and
 - The Commonwealth is not currently amending key provisions of the National Law, although it is likely that amendments will be made soon. However, any amendments will be subjected to scrutiny due to the disallowance mechanism and referral to the Joint Standing Committee on Delegated Legislation.

5 Structure of uniform legislation

- 5.1 The Bill uses the same disallowance mechanism as the Marine Safety (Domestic Commercial Vessel National Law Application) Bill 2023 (Marine Safety Bill), the Rail Safety National Law Application Bill 2023 (Rail Safety Bill), and the Health Practitioner Regulation National Law Application Bill 2023.⁷ It is therefore a complementary applied scheme.⁸

⁵ Standing Committee on Uniform Legislation and Statutes Review, report 84, *Medicines, Poisons and Therapeutic Goods Bill 2013*, Legislative Council, 18 February 2014, p 56.

⁶ New Zealand Government, *Joint Statement by Hon Peter Dutton MP, Minister for Health for Australia, and Hon Dr Jonathan Coleman, Minister of Health for New Zealand, regarding ANZTPA*, [[media release](#)], 21 November 2014, accessed 22 February 2024.

⁷ The Bill also uses a similar disallowance mechanism to the Legal Profession Uniform Law Application Bill 2021 and the Fair Trading Amendment Bill 2021.

⁸ This approach involves one jurisdiction enacting legislation, which is then applied in all other jurisdictions, achieving high consistency. It has the greatest impact on parliamentary sovereignty of all uniform schemes by future amendments coming into effect automatically without the requirement for an amendment Bill. See Standing Committee on Uniform Legislation and Statutes Review, report 89, *Gene Technology (Western Australia) Bill 2014*, Western Australia, Legislative Council, 10 March 2015, pp 13-16.

6 Provisions that impact upon parliamentary sovereignty and law-making powers

Clause 2 – Commencement

6.1 Clause 2 states:

This Act comes into operation as follows —

- (a) Part 1 — on the day on which this Act receives the Royal Assent;
- (b) Part 8 Division 1 —
 - (i) if the *Human Tissue and Transplant Amendment Act 2022* section 31 comes into operation on or before the day fixed under paragraph (c) — on the day fixed under paragraph (c); or
 - (ii) otherwise — immediately after the *Human Tissue and Transplant Amendment Act 2022* section 31 comes into operation;
- (c) the rest of the Act — on a day fixed by proclamation.

6.2 Clause 2(c) provides that the entirety of the Act aside from Part 1 and Part 8 Division 1 will come into operation on a day fixed by proclamation.

6.3 The Committee has set out in previous reports its position that such a clause is an erosion of parliamentary sovereignty. It results in the Executive controlling the commencement date, not Parliament. The Committee has previously stated that there should be sound reasons for Parliament to permit commencement by proclamation.⁹

6.4 The Second Reading speech noted:

The Cook government is committed to supporting national reforms and cooperation to tackle the increased misuse of therapeutic vaping products as well as non-therapeutic vapes. The application of the commonwealth act in WA will support these imminent reforms...¹⁰

6.5 The Minister's submission also stated the Bill:

...is being introduced urgently to ensure that a national framework is in place to support major intended reforms for the regulation of vaping products.¹¹

6.6 The Minister's response provides some assurance about the prompt proclamation of the majority of the Bill. The Committee also considered there is minimal risk the Bill will not be proclaimed. This is because it is intended to have a national framework in place to support major intended reforms for the regulation of vaping products in Autumn 2024.¹²

6.7 The Committee draws the lack of an express commencement date to the attention of the Legislative Council for consideration during debate on the Bill.

⁹ Standing Committee on Uniform Legislation and Statutes Review, report 136, [Legal Profession Uniform Law Application Bill 2020 and Legal Profession Uniform Law Application \(Levy\) Bill 2020](#), Legislative Council, 12 October 2021, p 6.

¹⁰ Legislative Council, *Debates*, 29 November 2023, p.6717b-6718a.

¹¹ Information from Hon Amber-Jade Sanderson MLA, Minister for Health, provided pursuant to MM2022/01.

¹² Submission from Minister for Health, received 1 December 2023, p 1.

Part 2 of the Bill – Applied legislation disallowance mechanism

- 6.8 Part 2 of the Bill contains the mechanisms for disallowance of Commonwealth amending Acts and Commonwealth and Western Australian instruments.
- 6.9 Clause 7 provides the disallowance mechanism for Commonwealth amending Acts. The Committee considered this mechanism in its 133rd and 136th reports.¹³ The Committee highlighted two parliamentary sovereignty matters in clause 9 of the Legal Profession Bill (which provided for the disallowance of amending Commonwealth Acts). Those issues were subsequently addressed, including by amending the Standing Orders of the Legislative Council.
- 6.10 Clause 13 provides the disallowance mechanism for Commonwealth and Western Australian instruments. This mechanism is similar to the disallowance mechanism within the Marine Safety (Domestic Commercial Vessel National Law Application) Bill 2023, considered in the Committee's 143rd report.
- 6.11 The only significant difference is the inclusion of clause 13(2)(a). This permits the publication of a 'notice of publication' in lieu of publication of the instrument itself (which was required by the Marine Safety (Domestic Commercial Vessel National Law Application) Bill 2023), where that notice has been published under section 12(2)(c).
- 6.12 The disallowance mechanism represents an approach to protecting parliamentary sovereignty which the Minister has described as follows:
- The tabling and disallowance mechanism outlined in part 2 protects parliamentary sovereignty, as future amendments to the commonwealth law only take effect in Western Australia if they are tabled and not disallowed by the WA Parliament.¹⁴
- 6.13 The Committee acknowledges the Government's approach to finding this balance between parliamentary sovereignty and efficacy, and observes:
- The adoption of the complementary applied scheme approach erodes parliamentary sovereignty and law-making powers by future amendments coming into effect without the requirement for an amendment Bill.
 - The disallowance mechanism:
 - provides a level of parliamentary oversight and scrutiny that reduces this erosion, especially considering amending Acts and instruments will not come into effect until parliamentary scrutiny has occurred
 - enables Western Australia to keep pace with future changes to national therapeutic goods regulation
 - enables the Joint Standing Committee on Delegated Legislation to scrutinise all relevant legislation to provide a level of parliamentary oversight

FINDING 1

The complementary applied scheme approach to uniform legislation adopted by the Therapeutic Goods Law Application Bill 2023 erodes the Western Australian Parliament's sovereignty and law-making powers.

¹³ Standing Committee on Uniform Legislation and Statutes Review, report 133, [Fair Trading Amendment Bill 2021](#), Legislative Council, 10 August 2021; Standing Committee on Uniform Legislation and Statutes Review, report 136, [Legal Profession Uniform Law Application Bill 2020 and Legal Profession Uniform Law Application \(Levy\) Bill 2020](#), Legislative Council, 12 October 2021.

¹⁴ Legislative Council, *Debates*, 29 November 2023, p.6717b-6718a.

FINDING 2

The disallowance mechanism in Part 2 of the Therapeutic Goods Law Application Bill 2023 provides a level of parliamentary oversight and scrutiny that reduces its impact on parliamentary sovereignty and law-making powers.

Clause 12 – Publication of therapeutic legislative instruments

6.14 Clause 12 provides for the publication of ‘therapeutic legislative instruments’, which clause 3 defines as:

...a regulation or other legislative instrument for the time being in force under the *Therapeutic Goods Act 1989* (Commonwealth).

6.15 Clause 12 states:

- (1) This section applies to a therapeutic legislative instrument made under the *Therapeutic Goods Act 1989* (Commonwealth) on or after 27 November 2023.
- (2) No later than 18 days after the day on which the therapeutic legislative instrument is made, 1 of the following must occur —
 - (a) the therapeutic legislative instrument is published in the *Gazette*;
 - (b) the therapeutic legislative instrument is published on the WA legislation website;
 - (c) notice is published in the *Gazette* —
 - (i) stating that the therapeutic legislative instrument is published on a website; and
 - (ii) stating the website on which the instrument is published;
 - (d) the therapeutic legislative instrument is published in the way set out in the local regulations.
- (3) For the purposes of subsection (2)(c), the website must be a website maintained by or on behalf of the State.

6.16 Clause 12 forms part of the disallowance mechanism within Part 2 of the Bill by providing the framework for publication of regulations and legislative instruments. Clauses 13(2) and (3) refer to publication (or notice of publication in the case of 12(2)(c)) when setting out the disallowance mechanism for therapeutic legislative instruments.

6.17 The publication of therapeutic legislative instruments is the first step within the disallowance mechanism. If publication does not occur, then the therapeutic legislative instrument ceases to have effect (under clause 13(3)(a)). Once a therapeutic legislative instrument has been published under clause 12, it must then be laid before each House of Parliament, where it may be subject to a notice of a resolution to disallow the instrument.

6.18 The publication stage is therefore a crucial step within the disallowance mechanism, the purpose of which is to reduce impact on parliamentary sovereignty.

6.19 Clause 12(2)(c) expands the flexibility of the mechanism by permitting ‘publication’ by a ‘notice of publication’ rather than publication of the instrument itself. This ‘notice’ is published in the *Gazette*, stating a website where the instrument itself has been published. Clause 12(2)(c) in the Bill has been constrained by clause 12(3), which requires the website to be maintained by or on behalf of the State.

- 6.20 A clause similar to clause 12(2)(d) has not been utilised in previous bills using the applied legislation disallowance mechanism. The Committee has concerns with its inclusion, and the possibility that it may be included in future bills to address government concern around the re-publication of Commonwealth instruments. This is referred to in the paragraphs below.
- 6.21 Clause 12(2)(d) allows the Government to publish therapeutic legislative instruments in ways not specified in the Act. The Committee is of the view that methods of publication should be set out within the Act, rather than in regulations, because publication of instruments is a central feature of the disallowance mechanism.
- 6.22 The Bill contains no criteria to govern the application of clause 12(2)(d). This results in a broad power with unlimited application. The EM does not explain the rationale for clause 12(2)(d).

FINDING 3

Clause 12(2)(d) of the Therapeutic Goods Law Application Bill 2023 erodes the Western Australian Parliament's sovereignty and law-making powers.

- 6.23 The Committee requested further clarification from the Minister, including any plans to make regulations under clause 12(2)(d) and what additional publication methods were anticipated.
- 6.24 The Minister initially advised that there were no plans to make regulations under clause 12(2)(d), nor were there any other publication methods anticipated.
- 6.25 The Minister noted:
- ...the Therapeutic Goods Administration which oversees the Commonwealth Act creates a large volume of therapeutic legislative instruments every year. In 2023, there were over 20 instruments made. Although the Parliamentary Counsel's Office prefers to have consolidated versions of any legislative instruments that apply in WA available on the WA legislation website, upon reviewing the various types of therapeutic legislative instruments, did not consider that all necessarily needed to be published on the WA legislation website. There are some concerns about the efficacy of re-publishing large amounts of Commonwealth therapeutic legislative instruments.
- 6.26 The Minister also stated that clause 12(2)(d):
- ...allows flexibility for meeting publication requirements. Local regulations may allow different type of instruments to be published in different ways or in different locations...
- 6.27 The Committee considered the Minister's initial response and sought a further explanation as to why clause 12(2)(d) is necessary.
- 6.28 The Minister advised that clause 12(2)(c):
- ...requires publication on a website maintained by or on behalf of the State (see clause 12(3)). Clause 12(2)(c) is intended to capture publication on the Department of Health website. This places an onerous burden on the State, both in terms of administration and costing, to re-publish and host therapeutic legislative instruments that are already published and hosted by the Commonwealth. As the therapeutic goods scheme is managed and regulated by the Commonwealth alone, it is current practice that all regulatory information is available from one central Commonwealth location.

- 6.29 The Minister then provided subsequent advice that clause 12(2)(d):
- ...will allow the Government to provide for a reference to the Commonwealth website by way of a notice in the Gazette or WALW.
- 6.30 The Minister also stated:
- The risk of not including 12(2)(d) would be that the State would be responsible for re-publishing everything that the Commonwealth has published on the Commonwealth website regarding the TGA amendments, which places a substantial burden on PCO.’
- 6.31 The Committee is supportive of reducing the need to duplicate Commonwealth instruments that have already been published in full. However, the Committee remains concerned that 12(2)(d) does have an impact on parliamentary sovereignty. The Committee considers that an alternative approach to reducing duplication which would satisfy the Government’s objective and reduce the impact on parliamentary sovereignty would be to do the following:
- Delete clause 12(2)(d)
 - Insert the words ‘or Commonwealth’ after the word ‘State’ in clause 12(3)
- 6.32 The Committee is of the view that recommendations 1 and 2 achieve this and puts forward this alternative approach to assist the House in its consideration of this important matter.

RECOMMENDATION 1

The Therapeutic Goods Law Application Bill 2023 be amended as follows:

Clause 12

Page 9, lines 23 and 24 - To delete the lines.

RECOMMENDATION 2

Clause 12(3) of the Therapeutic Goods Law Application Bill 2023 be amended to insert the words ‘or Commonwealth’ following the word ‘State’.

No review clause

- 6.33 The Bill does not contain a review clause.
- 6.34 The Committee has previously commented upon the importance of review clauses within uniform legislation.¹⁵ Clauses to provide for periodic review are standard drafting practice, and review clauses are an important mechanism for Parliamentary accountability and oversight of legislation.
- 6.35 Notwithstanding these views, the Committee has taken into account the Minister’s advice in Appendix 1 and considers the lack of a review clause in the Bill is justified in this instance.

FINDING 4

The lack of a review clause in the Therapeutic Goods Law Application Bill 2023 is justified.

¹⁵ Standing Committee on Uniform Legislation and Statutes Review, report 96, [Co-operatives Amendment Bill 2015, Legislative Council](#), 25 February 2016, p 17.

Clause 14 – Interpretation legislation

6.36 Clause 14 states:

(1) In this section —

Commonwealth interpretation laws means —

- (a) the *Acts Interpretation Act 1901* (Commonwealth); and
- (b) another law of the Commonwealth that is relevant to the interpretation of a Commonwealth Act or legislative instrument.

Example for this definition:

Legislation Act 2003 (Commonwealth) section 13.

(2) The *Interpretation Act 1984* does not apply to the applied therapeutic goods law.

(3) The Commonwealth interpretation laws apply as laws of the State in relation to the interpretation of the applied therapeutic goods law and so apply as if the applied therapeutic goods law were a Commonwealth Act or were a legislative instrument under a Commonwealth Act, as the case requires.

6.37 This clause excludes the application of the State interpretation legislation, and instead uses the Commonwealth interpretation legislation for the purpose of the applied National Law. In doing so, it delegates the ability to address matters of interpretation to the Commonwealth rather than leaving those matters to be addressed by the Western Australian Parliament.

6.38 The effect of clause 14 is an erosion of the Western Australian Parliament’s sovereignty and law-making powers. However, the Committee considers that consistent interpretation of the legislation in each participating jurisdiction is important. For the sake of consistency, the Commonwealth interpretation laws will need to apply.

FINDING 5

The application of Commonwealth interpretation laws in Western Australia by clause 14 of the Therapeutic Goods Law Application Bill 2023 erodes the Western Australian Parliament’s sovereignty and law-making powers.

FINDING 6

Applying laws of another jurisdiction in Western Australia enables a nationally consistent application of these laws as part of a national uniform scheme.

Clauses 15 and 26

6.39 Clause 15 states:

The local regulations may modify the applied therapeutic goods law.

6.40 Clause 26 states:

The Governor may make regulations prescribing matters —

- (a) required or permitted by this Act to be prescribed; or
- (b) necessary or convenient to be prescribed for giving effect to this Act or the applied therapeutic goods law.

- 6.41 Clauses 15 and 26 were acknowledged as Henry VIII clauses by the EM.
- 6.42 The Minister was requested to provide further explanation in relation to clauses 15 and 26. The Minister advised:
- ...These clauses are future proofing mechanisms, included in the Bill to allow for flexibility. While modifications to the applied therapeutic goods law are not currently required or anticipated, clause 15 ensures that the therapeutic goods law applying in Western Australia can be modified if it is in the best interests of the State.
- Clause 15 could also be utilised in the event of an unintentional procedural error, for example if an amending Act was not tabled as required under clause 6, or a therapeutic legislative instrument was not published as required under clause 12...
- 6.43 The Minister further advised that without clause 15, if there was a procedural error:
- ...rectifying these types of procedural errors would require the Commonwealth to pass another amending Act, or make another therapeutic legislative instrument, which could then bring into effect by following the required procedures.
- 6.44 In relation to the reasoning for future necessary refinements occurring through regulations rather than amendment Acts, the Minister advised:
- ...Should modifications be required, it would be most efficient for local regulations to provide this. One of the major issues with the WA historical approach of using corresponding laws to implement national laws is that the passage of amending Acts took substantial time and resources which have invariably left the State lagging behind in reforms. Using local regulations as the vehicle for modifications to the applied law is an efficient mechanism which still upholds Parliamentary sovereignty. Local regulations are subject to Parliamentary scrutiny through the tabling, review, and disallowance process.
- 6.45 The Committee recently considered clauses 7(1)(a) and 7(2)(a), and 7(1)(b) and 7(2)(b) within the Working with Children (Criminal Record Checking) Amendment Bill 2022.¹⁶ These clauses were intended to address a risk of overlooking the imposition of an appropriate condition and overlooking classification of new offences. The Committee found that risk of the Government overlooking those matters is an inappropriate justification for a Henry VIII clause.
- 6.46 The Committee holds the same view regarding clauses 15 and 26. The potential for procedural error is not a sufficient basis to justify prescribing matters by regulation.

FINDING 7

The risk that the Government may fail to follow procedural requirements is an inappropriate justification for a Henry VIII clause.

RECOMMENDATION 3

The Minister representing the Minister for Health provide a further explanation to the Legislative Council about why the Minister considers a failure to follow procedural requirements is a justification for a Henry VIII clause.

¹⁶ Standing Committee on Uniform Legislation and Statutes Review, report 139, *Working with Children (Criminal Record Checking) Amendment Bill 2022*, 15 November 2022, p 12.

Clause 22 – Commonwealth administrative Laws

6.47 Clause 22 states:

- (1) The Commonwealth administrative laws apply as laws of the State to any matter arising in relation to the applied therapeutic goods law as if the applied therapeutic goods law were a law of the Commonwealth and not a law of the State.
- (2) For the purposes of a law of the State, a matter arising in relation to the applied therapeutic goods law —
 - (a) is taken to be a matter arising in relation to laws of the Commonwealth in the same way as if the applied therapeutic goods law were a law of the Commonwealth; and
 - (b) is taken not to be a matter arising in relation to laws of the State.
- (3) Subsection (2) has effect for the purposes of a law of the State except as provided by the local regulations.
- (4) A provision of a Commonwealth administrative law applying because of this section that purports to confer jurisdiction on a federal court is taken not to have that effect.
- (5) For the purposes of this section, a reference in a provision of the *Administrative Appeals Tribunal Act 1975* (Commonwealth) (as that provision applies as a law of the State) to the whole or any part of Part IVA of that Act is taken to be a reference to the whole or part of that Part as it has effect as a law of the Commonwealth.

6.48 Clause 22 provides that the Commonwealth administrative laws apply as laws of Western Australia, as if the provision were a law of the Commonwealth and not a law of Western Australia.

6.49 The Commonwealth administrative laws are defined in clause 3(1) as:

- *Administrative Appeals Tribunal Act 1975* (Commonwealth) (excluding Part IVA);
- *Freedom of Information Act 1982* (Commonwealth);
- *Ombudsman Act 1976* (Commonwealth);
- *Privacy Act 1988* (Commonwealth);
- the legislative instruments in force under those Acts.

6.50 Rather than addressing any necessary matters through the Western Australian Parliament, this clause delegates that ability to the Commonwealth.

6.51 The EM noted that Part 5 (which includes clause 22):

...deals with the application of Commonwealth administrative laws to the operation of the applied therapeutic goods law. This ensures seamless operation regardless of the underlying constitutional framework.

6.52 Similar provisions have recently been considered by the Committee within reports 143 and 144.

6.53 The Committee is of the view that the application of Commonwealth accountability laws in Western Australia by clause 22 of the Therapeutic Goods Law Application Bill 2023 erodes the Western Australian Parliament's sovereignty and law-making powers. However, the

Committee recognises that applying laws of another jurisdiction in Western Australia enables a nationally consistent application of these laws as part of a national uniform scheme.¹⁷

FINDING 8

The application of Commonwealth accountability laws in Western Australia by clause 22 of the Therapeutic Goods Law Application Bill 2023 erodes the Western Australian Parliament's sovereignty and law-making powers.

FINDING 9

Applying laws of another jurisdiction in Western Australia enables a nationally consistent application of these laws as part of a national uniform scheme.

Clause 31

6.54 Clause 31 states:

(1) In this section —

publication day, in relation to transitional regulations, means the day on which the transitional regulations are published in accordance with the *Interpretation Act 1984* section 41(1)(a);

transitional regulations means local regulations made for the purposes of subsection (2).

(2) Local regulations may deal with matters of a transitional, savings or application nature arising in connection with the enactment of this Act.

(3) Transitional regulations cannot be made after the end of the period of 2 years beginning on commencement day.

(4) If transitional regulations provide that a state of affairs is taken to have existed, or not to have existed, on and from a day that is earlier than publication day, but not earlier than commencement day, the regulations have effect according to their terms.

(5) If transitional regulations contain a provision referred to in subsection (4), the provision does not operate so as to —

(a) affect, in a manner prejudicial to any person (other than the State or an authority of the State), the rights of that person existing before publication day; or

(b) impose liabilities on any person (other than the State or an authority of the State) in respect of anything done or omitted to be done before publication day.

6.55 Clause 31 is a Henry VIII clause. The EM states:

This power has been provided to allow for any future necessary refinements to the applies therapeutics goods laws that might be deemed necessary specifically during the transition period of 2 years that applies from commencement day of this Act.

¹⁷ The Committee has had the same view in the past, including in its 89th and 143rd reports.

6.56 The Minister was requested to provide further explanation in relation to clause 31. While the Minister did not set out any transitional matters, the Minister noted that clause 31:

...has been included to capture transitional matters which have not been anticipated but are necessary for the smooth transition to the new regulatory scheme.

6.57 The Minister also stated:

If a transitional matter arises, it needs to be dealt with expeditiously so that it does not hinder the proper operation of the Act. Dealing with the unanticipated transitional matters by regulation rather than amendment Acts enables a quick regulatory response. The lengthy process involved in the passage of an amendment Act means it is not a reasonable option for dealing with a matter that is of a transitional nature. Provisions enabling transitional regulations are commonly found throughout the WA statute book.

6.58 The Committee considers that a transitional regulation making power, despite having a Henry VIII effect, is justifiable in order to effect a smooth transition to the new regulatory scheme and acceptable by reason of its focused operation.

FINDING 10

Clause 31 of the Therapeutic Goods Law Application Bill 2023 erodes the Western Australian Parliament's sovereignty and law-making powers.

FINDING 11

Clause 31 of the Therapeutic Goods Law Application Bill 2023 is justifiable in order to effect a smooth transition to the National Law as amended.

National Law

6.59 The National Law provides for a significant number of matters to be dealt with in regulations or legislative instruments. Various provisions within the National Law enable this to qualify or expand the National Law's operation and are accordingly Henry VIII clauses.

6.60 Many of the regulation-making powers within the National Law appear to be of an acceptable nature. This is because they are of reasonable scope and relate to matters that are appropriate to be left to regulations. For example:

- Section 30H contains regulation-making powers to set out the means of storage, supply, destruction, export, or disposal of goods.
- Section 9K provides for regulations to prohibit the import, export, manufacture and/or supply of therapeutic goods where those therapeutic goods are the subject of an international agreement prescribed for the purpose of that section.

6.61 However, certain other provisions enable regulations or legislative instruments to exempt specified persons or items from the operation of the National Law itself. Examples of such provisions are:

- Section 7, which provides that the Secretary may, by legislative instrument, declare that classes of goods are or are not 'therapeutic goods' for the purpose of the National Law.
- Section 7AA, which provides the Minister with the power to use a legislative instrument to determine that specified goods are 'excluded goods' for the purpose of the National Law. Although this section provides specific matters that the Minister must 'have regard' to, the power itself remains broad.

- Section 32A, which provides the Secretary with the ability to use legislative instruments to determine that a specified thing is, or is not, a 'biological' for the purpose of the National Law.¹⁸
 - Section 32CA, which provides that regulations may exempt specified persons from the operation of Division 4 in relation to specified biologicals, or may exempt specified biologicals from the operation of Division 4.¹⁹
- 6.62 These provisions can expand or limit the operation of the National Law in a significant, and open-ended, manner.
- 6.63 Provisions of the National Law itself were not detailed within the EM. The Committee sought further explanation from the Minister regarding these provisions. Unfortunately, no response was received from the Minister regarding this matter.
- 6.64 The Committee is unable to fully consider the clauses within the National Law without further information from the Minister.
- 6.65 The Committee brings this matter to the attention of the Legislative Council.

RECOMMENDATION 4

The Minister representing the Minister for Health explain to the Legislative Council the basis for retaining clauses in the *Therapeutic Goods Act 1989* (Cth) with a Henry VIII effect when applying that Act as law of Western Australia.



Hon Donna Faragher MLC
Chair

¹⁸ 'Biologicals' are one type of therapeutic good regulated by the National Law, and are subject to specific regulation within Part 3-2A including criminal offences and civil penalties.

¹⁹ Division 4 provides for the inclusion of biologicals in the Australian Register of Therapeutic Goods, including application processes, criminal offences and civil penalties.

APPENDIX 1

MINISTER'S RESPONSE TO COMMITTEE QUESTIONS ON THE BILL

RESPONSE to the Standing Committee on Uniform Legislation and Statutes Review – Therapeutic Goods Law Application Bill 2023

The following advice was requested by the Committee on 12 January 2024, as part of its inquiry into the Bill:

Amendments

1.1 *Are there any other amendments to the Therapeutic Goods Act 1989 which have not yet come into operation?*

No.

1.2 *Are there any other Acts amended by the Bill which have not yet fully come into operation?*

The *Medicines and Poisons Act 2014* is amended by the Bill and has a principal provision which has not yet come into operation (section 14(2)) and amending provisions which have not yet come into operation (*Public Health (Consequential Provisions) Act 2016* Part 5 Division 14). None of the uncommenced provisions interact with the Bill.

No review clause

2.1 *Why does the Bill lack a review clause?*

A review clause is not included in the Bill because it applies a Commonwealth Act, and it is appropriate for review of a Commonwealth Act to take place at a national level. The Health Ministers Meeting, consisting of the Health Ministers of every State and Territory and the Commonwealth, considers legal and regulatory health matters covered under national laws. Any review undertaken locally would not only be a duplication of the function of the Health Ministers Meeting but would also not be expansive enough to capture the full extent of the operation of a Commonwealth Act.

It is noted that the *Marine Safety (Domestic Commercial Vessel National Law Application) Act 2023* and the *Legal Profession Uniform Law Application Act 2022* (respectively the *Marine Safety Act* and *Legal Profession Act*) include review clauses. This Bill can be differentiated from those two Acts as it does not include any unique jurisdictional modifications to the application of the Commonwealth Act. Review clauses in the *Marine Safety Act* and *Legal Profession Act* are warranted due to the extent to which the laws being applied are modified.

Further, the Commonwealth Act has been in operation for over 30 years, ensuring that health and medical products are safe and effective for Australian consumers. The Bill expands the operation of the Commonwealth Act to close an identified gap in regulation – that is sole traders who operate exclusively within WA to manufacture and supply therapeutic goods or make therapeutic claims. Capturing this category of business under the Commonwealth Act achieves more comprehensive protection for WA consumers and review of the Bill is not warranted. The Bill is intended to protect Western Australian consumers from all manufacturers and suppliers of therapeutic goods, not just those that trade interstate as is currently the case.

The Department of Health identified that this gap in regulation currently affects only one sole trader. All other manufacturers and suppliers of therapeutic goods in Western Australia are already subject to the Commonwealth Act. So any local review provided by a review clause would have minimal scope and impact.

Publication of therapeutic legislative instruments

3.1 *Are there plans to make regulations under clause 12(2)(d)?*

At this point in time there are no plans to make regulations under clause 12(2)(d).

3.2 *What publication methods, if any, are anticipated?*

At this point in time, there are no publication methods that are anticipated.

3.3 *If further publication methods are anticipated, why are those methods not set out in the Bill?*

Not applicable as no further publication methods are currently anticipated.

3.4 *If no additional publication methods are anticipated, what is the reason for including clause 12(2)(d)?*

The requirement to publish the therapeutic legislative instruments is included to match the requirements of the *Interpretation Act 1984 (WA)*, and to trigger the tabling and disallowance process for Parliamentary review.

However, the Therapeutic Goods Administration which oversees the Commonwealth Act creates a large volume of therapeutic legislative instruments every year. In 2023, there were over 20 instruments made. Although the Parliamentary Counsel's Office prefers to have consolidated versions of any legislative instruments that apply in WA available on the WA legislation website, upon reviewing the various types of therapeutic legislative instruments, did not consider that all necessarily needed to be published on the WA legislation website. There are some concerns about the efficacy of re-publishing large amounts of Commonwealth therapeutic legislative instruments.

Clause 12(2)(d) allows flexibility for meeting publication requirements. Local regulations may allow different types of instruments to be published in different ways or in different locations whilst still ensuring that all therapeutic legislative instruments will be tabled, subject to Parliamentary review and disallowance, and are freely available for access to anyone in WA who may be affected by them.

Clauses 15 and 26

4.1 *Is it expected that regulations will need to be made under clause 15 or 26? What will those regulations be?*

At this point in time, it is not expected that regulations will be needed under clause 15 or 26. These clauses are future proofing mechanisms, included in the Bill to allow for flexibility. While modifications to the applied therapeutic goods law are not currently required or anticipated, clause 15 ensures that the therapeutic goods law applying in Western Australia can be modified if it is in the best interests of the State.

Clause 15 could also be utilised in the event of an unintentional procedural error, for example if an amending Act was not tabled as required under clause 6, or a therapeutic legislative instrument was not published as required under clause 12. Without the flexibility which clause 15 provides, rectifying these types of procedural errors would require the Commonwealth to pass another amending Act, or make another therapeutic legislative instrument, which WA could then bring into effect by following the required procedures. There would also be implications for the gap in regulation while this process of rectification takes place, which may require further legislation to be enacted in WA.

Clause 15 provides a quick regulatory response while still upholding Parliamentary sovereignty as any regulations made pursuant to clause 15 are subject to the tabling, review and disallowance process.

4.2 *Why are modifications to the applied law not set out in the Bill?*

As mentioned above, modifications to the applied therapeutic goods law are not currently required so modifications are not set out in the Bill.

4.3 *Why are future modifications to the applied law to be provided via regulations rather than an amendment Act?*

Clause 15 enables protection of the State from the application of therapeutic goods laws that are not suitable for WA. Should modifications be required, it would be most efficient for local regulations to provide this. One of the major issues with the WA historical approach of using corresponding laws to implement national laws is that the passage of amending Acts took substantial time and resources which have invariably left the State lagging behind in reforms. Using local regulations as the vehicle for modifications to the applied law is an efficient

mechanism which still upholds Parliamentary sovereignty. Local regulations are subject to Parliamentary scrutiny through the tabling, review, and disallowance process.

Clause 31

5.1 *What transitional matter is anticipated for this clause?*

Clause 31 has been included to capture transitional matters which have not been anticipated but are necessary for the smooth transition to the new regulatory scheme. The regulation-making power in clause 31 is very limited, focussing only on matters of a transitional, savings or application nature. Further the power is time-limited, expiring 2 years after commencement day.

Clause 31 is in line with previous findings of the Committee: see Report 129 findings 22 and 24; Report 143 findings 3 and 4; Report 144 findings 6 and 7.

5.2 *Why are transitional matters dealt with by regulation rather than amendment Acts?*

If a transitional matter arises, it needs to be dealt with expeditiously so that it does not hinder the proper operation of the Act. Dealing with the unanticipated transitional matters by regulation rather than amendment Acts enables a quick regulatory response. The lengthy process involved in the passage of an amendment Act means it is not a reasonable option for dealing with a matter that is of a transitional nature. Provisions enabling transitional regulations are commonly found throughout the WA statute book.

Contact details for further information

Minister's Office - Office of the Minister for Health

[REDACTED]

[REDACTED]

APPENDIX 2

MINISTER'S SECOND RESPONSE TO COMMITTEE QUESTIONS ON THE BILL

RESPONSE to the Standing Committee on Uniform Legislation and Statutes Review – Therapeutic Goods Law Application Bill 2023

The following advice was requested by the Committee (by email) on 1 February 2024, as part of its inquiry into the Bill:

Amendments

1.1 Noting the publication options provided by clauses 12(2)(a) to (c), is the Minister able to provide an explanation for the inclusion of clause 12(2)(d)?

Clause 12(2)(c) requires publication on a website maintained by or on behalf of the State (see clause 12(3)). Clause 12(2)(c) is intended to capture publication on the Department of Health website. This places an onerous burden on the State, both in terms of administration and costing, to re-publish and host therapeutic legislative instruments that are already published and hosted by the Commonwealth. As the therapeutic goods scheme is managed and regulated by the Commonwealth alone, it is current practice that all regulatory information is available from one central Commonwealth location.

As mentioned in the Response to the Committee submitted on 19 January 2024, there are a significant number of therapeutic legislative instruments made each year in various formats. The Committee may wish to review the various therapeutic legislative instruments, as published by the Commonwealth: [Legislation and legislative instruments | Therapeutic Goods Administration \(TGA\)](#).

The publication requirement within clause 12 enables review by the WA Parliament. The method of publication is secondary to the review that the publication triggers. Allowing flexibility in the method of publication via clause 12(2)(d) supports the State's participation in the Commonwealth therapeutic goods scheme while ensuring that all instruments within the scheme are subject to scrutiny by the WA Parliament.

Contact details for further information

Minister's Office - Office of the Minister for Health

[Redacted contact information]

APPENDIX 3

MINISTER'S ADDITIONAL ADVICE ON THE BILL

Tysoe, Caris

From: [REDACTED]
Sent: Tuesday, 20 February 2024 8:50 AM
To: Legislation, Uniform
Cc: [REDACTED]
Subject: Further information regarding clause 12(2)(d)

You don't often get email from [REDACTED]. [Learn why this is important](#)

OFFICIAL

Dear Caris

On behalf of the Minister for Health, I submit further information regarding the necessity for the inclusion of clause 12(2)(d) of the Therapeutic Goods Law Application Bill 2023.

Disallowance

The interaction between 12(2)(d) and 13(2)(b) means that the JSCDL will still be able to disallow any instruments made under 12(2)(d) because the instrument will only be taken to be published when done so in accordance with the way set out in the local regulations. Parliamentary sovereignty is not impinged in any way. All that is occurring is reducing the publishing burden.

Type of website

Clause 12(2)(d) will allow the Government to provide for a reference to the Commonwealth website by way of a notice in the Gazette or WALW.

Clause 12(2)(c) will allow for publication on websites other than the DoH website, as long as they are State maintained. It is unlikely that 12(2)(c) read in conjunction with 12(3) could be taken to apply to publication on the Commonwealth legislation website. Section 12(2)(c) allows the Government to publish a notice in the Gazette stating the instrument is published on a website and state what the website is. Section 12(3) limits the application of 12(2)(c), namely the website must be maintained by or on behalf of the State. Therefore we could not make reference to the Commonwealth website under 12(2)(c), because the Commonwealth website is not a website maintained by or on behalf of the State.

Risks

The risk of not including 12(2)(d) would be that the State would be responsible for re-publishing everything that the Commonwealth has published on the Commonwealth website regarding the TGA amendments, which places a substantial burden on PCO.

In addition, duplicating publication would mean that there no longer is a single source of truth for that legislation.

Furthermore, given the recent amendments to the publication mechanism undertaken by PCO, 12(2)(d) stands as a future proofing provision. Without 12(2)(d), any refinements to the publication system in WA would likely result in requiring amendments to this Act, which is an onerous process.

I hope the Committee will take these points into consideration in finalising its position.

Kind regards
[REDACTED]



Office of the Hon. Amber-Jade Sanderson MLA
Minister for Health; Mental Health
Member for Morley

The Department of the Premier and Cabinet Legal Notice.

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GLOSSARY

Term	Definition
2013 bill	Medicines, Poisons and Therapeutic Goods Bill 2013
Bill	Therapeutic Goods Law Application Bill 2023
Committee	Standing Committee on Uniform Legislation and Statutes Review
Commonwealth administrative laws	Defined in clause 4 of the Bill as: (a) the <i>Administrative Appeals Tribunal Act 1975</i> 2 (Commonwealth) (excluding Part IVA); 3 (b) the <i>Freedom of Information Act 1982</i> (Commonwealth); 4 (c) the <i>Ombudsman Act 1976</i> (Commonwealth); 5 (d) the <i>Privacy Act 1988</i> (Commonwealth); 6 (e) the legislative instruments in force under those Acts;
Commonwealth interpretation laws	Defined in clause 14(1) of the Bill as: (a) the <i>Acts Interpretation Act 1901</i> (Commonwealth); and 17 (b) another law of the Commonwealth that is relevant to the 18 interpretation of a Commonwealth Act or legislative 19 instrument.
Disallowance mechanism	Applied legislation disallowance mechanism in Part 2 of the Bill
EM	Explanatory Memorandum
Marine Safety Bill	Marine Safety (Domestic Commercial Vessel National Law Application) Bill 2023
Minister	Hon Amber-Jade Sanderson MLA, Minister for Health
National Law	<i>Therapeutic Goods Act 1989</i> (Cth)
Rail Safety Bill	Rail Safety National Law Application Bill 2023

Standing Committee on Uniform Legislation and Statutes Review

Date first appointed:

17 August 2005

Terms of Reference:

The following is an extract from Schedule 1 of the Legislative Council Standing Orders:

'6. Uniform Legislation and Statutes Review Committee

- 6.1 *A Uniform Legislation and Statutes Review Committee is established.*
- 6.2 The Committee consists of 4 Members.
- 6.3 The functions of the Committee are –
 - (a) to consider and report on Bills referred under Standing Order 126;
 - (b) on reference from the Council, to consider or review the development and formulation of any proposal or agreement whose implementation would require the enactment of legislation made subject to Standing Order 126;
 - (c) to review the form and content of the statute book; and
 - (d) to consider and report on any matter referred by the Council.
- 6.4 In relation to function 6.3(a) and (b), the Committee is to confine any inquiry and report to an investigation as to whether a Bill or proposal may impact upon the sovereignty and law-making powers of the Parliament of Western Australia.'



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