THIRTY-NINTH PARLIAMENT

REPORT 84

STANDING COMMITTEE ON UNIFORM LEGISLATION AND STATUTES REVIEW

MEDICINES, POISONS AND THERAPEUTIC GOODS BILL 2013

Presented by Hon Kate Doust MLC (Chair)

February 2014

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 examine the provisions of any treaty that the Commonwealth has entered into or presented to the Commonwealth Parliament, and determine whether the treaty may impact upon the sovereignty and law-making powers of the Parliament of Western Australia;

(d) to review the form and content of the statute book; and

(e) 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."

Members as at the time of this inquiry:

Hon Kate Doust MLC (Chair)
Hon Brian Ellis MLC (Deputy Chair)
Hon Mark Lewis MLC
Hon Amber-Jade Sanderson MLC

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GLOSSARY

ACCC	Australian Competition and Consumer Commission
Agreement	The Agreement is the *Agreement between the Government of Australia and the Government of New Zealand for the establishment of a joint scheme for the regulation of therapeutic products.* Signed on 10 December 2003. (Sometimes referred to as the Treaty)
AHMAC	Australian Health Ministers' Advisory Council
AHMAC Working Party Response	Australian Health Ministers' Advisory Council Working Party. The AHMAC Working Party reported to the Australian Health Minister Advisory Council and produced the report, *AHMAC Working Party Response to the National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation*
ANZTPA	Australian New Zealand Therapeutic Products Agency, a transitional agency implementing the Agreement
ARTG	Australian Register of Therapeutic Goods
Bill	Medicines, Poisons and Therapeutic Goods Bill 2013
CPA	Competition Principles Agreement 1995
CPA 2007	Competition Principles Agreement - 11 April 1995 (as Amended to 13 April 2007)
Committee	Legislative Council Standing Committee on Uniform Legislation and Statutes Review
COAG	Council of Australian Governments
Cth TGA 1989	*Therapeutic Goods Act 1989* (Cth)
Department	Department of Health (Western Australia)
First Galbally Report	*National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation.* This report is the first of the two reports referred to in the text
Final Galbally Report	*Final Report of the National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation* presented to the AHMAC in 2001.

Galbally Review	*National Competition Policy Review of Drugs, Poisons and Controlled Substances*
Implementation Report 2006	A Report to the Australian Health Ministers' Conference on Implementation of the Review Recommendations (as endorsed by the Council of Australian Governments) by the National Coordinating Committee on Therapeutic Goods (NCCTG) 2006
NCP Agreement	*Agreement to Implement the National Competition Policy and Related Reforms*
NIA	National Interest Analysis (completed on the Treaty)
NCCTG	National Coordinating Committee on Therapeutic Goods
RIS	Regulation Impact Statement (completed on the Treaty)
SCOH	Standing Council on Health
State Minister	Western Australian Minister for Health
SUSMP	Standard for Uniform Scheduling of Medicines and Poisons
Therapeutic Goods Law (WA)	Includes the application of *Therapeutic Goods Act 1989* (Cth), regulations, orders, manufacturing principles into Western Australian law
Treaty	*The Agreement between the Government of Australia and the Government of New Zealand for the establishment of a joint scheme for the regulation of therapeutic products (signed on 10 December 2003)*

EXECUTIVE SUMMARY, FINDINGS AND RECOMMENDATIONS

EXECUTIVE SUMMARY

1 The Parliamentary Secretary representing the Minister for Health introduced the Medicines, Poisons and Therapeutic Goods Bill 2013 (**Bill**) in the Legislative Council on 17 October 2013. The Bill proposes to apply the *Therapeutic Goods Act 1989* (Cth) (***Cth TGA 1989***) to regulate and control the manufacture and supply of medicines, poisons and therapeutic goods in Western Australia. The 209 clauses of the Bill include the regulation of medicines for animals.

2 The Committee was advised that the Bill would close a loophole to regulate sole traders and that such a Bill is required as there is no other regulatory mechanism to do so. The Committee does not agree with this contention. Substantial reforms under the Australian Consumer Law (**ACL**) and the *Fair Trading Act 2010* (WA) appear to cover the field with regard to the regulation of small traders.

3 The genesis for the review of national therapeutic goods legislation is the National Competition Policy (**NCP**) in 1995 and the Competition Principles Agreement (**CPA**) and amended CPA in 2007 (**CPA 2007**). Despite repeated requests, there is no evidence of a signed CPA Agreement or a signed Intergovernmental Agreement (**IGA**) that specifically addresses the uniform legislation. The NCP was a significant incentive to review therapeutic goods legislation. The Committee also notes that recently (November 2013), the Commonwealth Government announced a substantial review of the NCP after 20 years' operation.

4 It is apparent that there has been discussion at the Council of Australian Government (**COAG**) and Australian Health Ministers' Council (**AHMC**) over some years for a review of therapeutic goods legislation. The Committee was informed that the AHMC agreed to regulatory reforms in an out-of-session process. There are no minutes of these discussions.

5 The Bill is the result of the work of the Australian Health Ministers' Advisory Council (**AHMAC**) and the AHMAC Working Party (**AHMAC Working Party**) that considered recommendations from the *National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation* (**Galbally Review**). Recommendation 23 proposed that all Commonwealth, State and Territory jurisdictions agree that all States and Territories adopt the *Cth TGA 1989* by reference into the relevant legislation.

6 COAG in an out-of-session process (2005) agreed to all recommendations proposed by the AHMAC Working Party response to the Galbally Review. The Department of Health (Western Australia) provided a letter from the former Premier of Western

Australia to the former Prime Minister endorsing the AHMAC Working Party Response and the COAG proposal to publish the AHMAC Working Party Response with the Final Report of the Galbally Review.

7 The Committee did not have access to the documentary evidence of a formal Intergovernmental Agreement having been signed by Western Australia for a uniform bill.

8 The (former) National Coordinating Committee on Therapeutic Goods (**NCCTG**) reported to the AHMAC in 2006 that it will be unnecessary for the States and Territories to adopt the new therapeutic products legislation to be administered by the Authority as the Australian Government will be able to regulate all individuals who supply (and/or manufacture for supply) therapeutic products only within a State or Territory (sole traders), through the use of the external affairs powers of the Treaty between Australia and New Zealand when that Treaty enters into force.

9 The Treaty allows for the establishment of a single regulatory body (for therapeutic goods) between Australia and New Zealand. The Committee found that whilst a Treaty was signed, it was not ratified. The arrangement with New Zealand has been variously referred to as an Agreement or a Treaty. The transitional agency overseeing the implementation of the single regulatory body is the Australia New Zealand Therapeutic Products Agency (**ANZTPA**). The transition process, once finalised (in 2016) will require the repeal of the *Cth TGA 1989* and regulations. Part 6 of the Bill before the Committee applies the *Cth TGA 1989*, Commonwealth regulations, orders and manufacturing principles into Western Australian law as part of *Therapeutic Goods Law* (WA).

10 Neither the Second Reading Speech nor Explanatory Memoranda identified the establishment of ANZTPA nor the likelihood of the repeal of the *Therapeutic Goods Act 1989* (Cth) as part of the process of implementing the new Australian New Zealand regulatory model by 2016.

11 The Committee considered the provisions under Part 6 of the Bill and found that there were few mechanisms in this Bill to scrutinise future Commonwealth amendments to the Therapeutic Goods Law. The Committee formed the view that the lack of Parliamentary oversight in the operation of the Clauses under Part 6 of the Bill challenged the law making powers of the WA Parliament.

FINDINGS AND RECOMMENDATIONS

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

Page 9

Finding 1: The Committee finds that the review of medicines, poisons and therapeutic goods legislation had its genesis with the National Competition Policy and the Competition Principles Agreement.

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Finding 2: The Committee finds that recommendation 23 (of the Galbally Review) is a key driver for Therapeutic Goods Law, however documentary evidence of a signed IGA (*Competition Principles Agreement*) could not be located.

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Finding 3: The Committee finds that the letter to the then Prime Minister Rt Hon. John Howard from the then Premier of Western Australia, Dr Geoff Gallop (dated 2004) agreed with the recommendations of and the publication of the AHMAC Working Party response to the Galbally Review.

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Finding 4: The Committee finds that COAG approved the recommendations of the Galbally Review in an out-of-session process by an exchange of letters.

Page 15

Finding 5: The Committee finds that COAG did not draft an Intergovernmental Agreement for uniform legislation on the Therapeutic Goods Law.

Page 19

Finding 6: The Committee finds that substantial discussions have occurred between the Commonwealth and New Zealand for the implementation of a joint Australian New Zealand Therapeutic Products Agency by 2016.

Page 20

Finding 7: The Committee finds that the adoption and ratification of the ANZTPA Treaty would require significant amendment to the Medicines, Poisons and Therapeutic Goods Act (the current Bill) to the extent of removing any reference to the *Therapeutic Goods Act 1989* (Cth) and the repeal of Part 6.

Page 20

Finding 8: The Committee finds that if and when the ANZTPA treaty is ratified and the Commonwealth decides to evoke its external affairs powers with the States and Territories, it is likely to also result in considerable amendment to the *Therapeutic Goods Act 1989* (Cth) – specifically section 6AAA which acknowledges the (present) authority of the States and Territories to regulate in this area.

Page 20

Finding 9: The Committee finds that the Second Reading Speech and Explanatory Memoranda did not fully inform the Legislative Council of the history of negotiations to establish a single Australian New Zealand regulatory body, the creation of the ANZTPA and the likely repeal of the *Cth TGA 1989* in 2016.

Page 20

Recommendation 1: The Committee recommends that the Minister formally advise the Legislative Council on the implementation program of ANZTPA by 2016, Western Australia's powers and functions under the ANZTPA to amend regulations and legislation and report to the Legislative Council within two months of the tabling of this Report.

Page 22

Finding 10: The Committee finds that Australian Consumer Law (WA) also covers the regulation of sole traders.

Page 22

Recommendation 2: The Committee recommends that the Minister advise the Legislative Council whether the ACL will render the majority of the Bill invalid when it is passed into law.

Page 25

Finding 11: The Committee finds that there has been insufficient attention or explanation provided to the Legislative Council on the current proposals in the Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013 to amend the *Cth TGA 1989* introduced to the Federal Parliament in December 2013.

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Recommendation 3: The Committee recommends that the Minister confirm with the Commonwealth what the policy position of the current Government is, and if applicable, when it will be implemented and advise the Legislative Council accordingly during consideration of the Bill.

Page 25

Recommendation 4: The Committee recommends that the Minister advise the Legislative Council on the amendments to the Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013.

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Recommendation 5: The Committee recommends that the responsible Minister confirm with the Legislative Council that the repeal of the *White Phosphorous Matches Prohibition Act 1912* will not create a gap in regulation.

Page 32

Recommendation 6: The Committee recommends that the State Minister seek information and report to the Legislative Council on the Commonwealth's program of proposed amendments to the *Therapeutic Goods Act 1989* and the transition arrangements following ANZTPA's implementation in 2016.

Page 34

Finding 12: The Committee finds that there is an absence of opportunity for the Western Australian Minister for Health or the Western Australian Parliament to influence or amend Part 6 of the Bill and does not give sufficient regard to the sovereignty of the State Parliament.

Page 35

Finding 13: The Committee finds that there no legislative impediments to the operation of the ACL (WA) to regulate sole traders supplying or manufacturing therapeutic goods.

Page 36

Finding 14: The Committee finds that Clause 77 excludes the Western Australian Parliament from monitoring and oversight of Commonwealth Executive functions in Part 6 of the Bill.

Page 38

Finding 15: The Committee finds that if the Treaty with New Zealand is ratified, the State Minister for Health will not have a role in the new scheme to amend legislation, regulations or manufacturing principles, notices and orders.

Page 39

Recommendation 7: The Committee recommends that clause 78(1)(b) be amended to read "all regulations, orders and manufacturing principles in force at the time under that Act". This may be effected in the following manner:

Page 57, line 8 – to insert between 'force' and 'under' - at the time

Page 40

Finding 16: The Committee finds that Clause 78 does not provide adequate scrutiny by the Western Australian Parliament of regulations, orders and manufacturing principles introduced by the Commonwealth and is inconsistent with State Sovereignty.

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Finding 17: The Committee finds that Clause 78(4) is a Henry VIII clause and constitutionally invalid.

Page 40

Recommendation 8: The Committee recommends that Clause 78(4) be deleted.

Page 41

Finding 18: The Committee finds that Western Australian administrative law does not have an oversight function for Part 6 of the Bill.

Page 42

Recommendation 9: The Standing Committee recommends the insertion of a new clause headed "*Certain instruments to be published, and may be disallowed by Parliament"* under Part 6, Division 2. This clause shall list all the Commonwealth regulations, orders and manufacturing principles relating to this section and the requirement to place notices in the Government Gazette. This may be effected in the following manner:

Page 97, after line 5- to insert-

regulations made under the *Therapeutic Goods Act 1989* (Commonwealth);

manufacturing principles made under the *Therapeutic Goods Act 1989* (Commonwealth);

order made under the *Therapeutic Goods Act 1989* (Commonwealth);

declarations of the Secretary made under the *Therapeutic Goods Act 1989* (Commonwealth).

Page 43

Recommendation 10: The Committee recommends that clause 82(1)(b) be deleted and a new subsection be inserted. This may be effected in the following manner:

Page 59, lines 13 to 14 – to delete the lines and insert

(b) Any 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.

Page 51

Recommendation 11: The Committee recommends that Clause 148(1) of the Bill be amended to include the words *in force at the time*. This may be effected in the following manner

Page 96, line 6 – to insert after "Act" – in force at the time

Page 53

Finding 19: The Committee finds that Clause 152 limits the ability of the Western Australia Parliament to review the operation and impact of Part 6 of the Bill (if passed).

Page 56

Recommendation 12: The Committee recommends the Medicines, Poisons and Therapeutic Goods Bill 2013 be withdrawn for the following reasons:

1. **A formalised IGA for the introduction of Therapeutic Goods Law does not exist. The introduction of a uniform scheme is based on general provisions of the National Competition Principles Agreement. The Committee did not receive a signed copy of this Agreement.**

2. **The Treaty/Agreement for the ANZTPA provides that the new Australia New Zealand regulatory body will commence in 2016 and will require the repeal of the *Cth TGA 1989.***

3. **The repeal of the *Cth TGA 1989* will impact Part 6 of the Bill (if passed).**

4. **The Legislative Council was not informed of the new regulatory body (ANZTPA) and its likely impact on sole traders in Western Australia.**

5. **Part 6 of the Bill impacts the sovereignty and law making powers of the Western Australian Parliament.**

6. **The Western Australian Minister for Health does not have a review function in relation to the operation of Part 6 of the Bill.**

7. **The Commonwealth is currently amending key provisions (16 Schedules) of the *Cth TGA 1989* that includes amendments to the term 'therapeutic good'. The Committee was not able to consider the impact of the new amendments on this Bill.**

CHAPTER 1

INQUIRY REFERENCE AND PROCEDURE

1.1 On 17 October 2013, the Medicines, Poisons and Therapeutic Goods Bill 2013 (**Bill**) was referred to the Standing Committee on Uniform Legislation and Statutes Review (**Committee**).[1] On 19 November 2013, the Committee requested the Legislative Council pass a motion to extend the date by which the Committee is to report on the Bill from 3 December 2013 to 18 February 2014. The Legislative Council agreed to the Committee's request.

1.2 The Committee's function is to consider and report on Bills referred under Standing Order 126. For the purposes of the Standing Orders,

> *…a Uniform Legislation Bill is a Bill that –*
>
> *a) ratifies or gives effect to a bilateral or multilateral intergovernmental agreement to which the Government of the State is a party; or*
>
> *b) by reason of its subject matter, introduces a uniform scheme or uniform law throughout the Commonwealth.*[2]

1.3 The Parliamentary Secretary representing the Minister for Health, Hon Alyssa Hayden MLC tabled the Second Reading Speech and the Explanatory Memoranda.

> *The present regulatory regime for medicines, poisons and therapeutic goods in Western Australia is the Poisons Act 1964 and its associated Poisons Regulations 1965. This legislation is outdated, confusing and lacks the flexibility to address emerging trends and issues in the regulation, control and access to medicines and related therapeutic agents as well as domestic, agricultural and veterinary and some industrial poisons*
>
> *…*
>
> *Similarly there is inadequate regulatory support for new initiatives to reduce diversion and misuse of drugs of addiction.*[3]

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1 Hon Alyssa Hayden MLC Parliamentary Secretary representing the Minister for Health, Hon Kim Hames MLA, introduced the Bill into the Legislative Council and nominated the Bill as a Uniform Legislation Bill pursuant to Standing Order 126(1). The Bill accordingly stood referred to the Committee pursuant to Standing Order 126 (4).

2 Western Australia Legislative Council, *Standing Orders*, Standing Order 126.

3 Hon Alyssa Hayden MLC, Parliamentary Secretary, Western Australia Legislative Council, *Parliamentary Debates (Hansard)*, 17 October 2013, pp5137B-5138a.

1.4 The Bill comprises 209 clauses that propose reforms in poisons scheduling, medicines (prescriptions, authorities), regulation of health professionals and activities relating to therapeutic goods. The Commonwealth and State powers and functions in relation to the monitoring, compliance and enforcement of specific regulatory activities warrants analysis.

1.5 The Second Reading Speech stated:

> *At present, there is no regulatory framework preventing an individual from promoting an untested, ineffective or unsafe good for medical purposes within Australia. Part 6 of the Bill seeks to adopt as Western Australian law the Commonwealth legislation in this area. This will ensure that Australian consumers will have protection from substandard therapeutic goods equal to that anywhere else in Australia.*[4]

1.6 The Committee confined its inquiry to the examination of specific clauses that may impact on the sovereignty or law making powers of the Western Australian Parliament.[5]

1.7 The Committee is aware of the delicate balance of ensuring the State Parliament has adequate opportunity to scrutinise uniform legislation, with the need to introduce national legislation that provides important safeguards to protect the public.

> *Uniform Schemes and resulting legislation by their very nature have the capacity to erode or undermine the sovereignty of the Western Australian State Parliament. As elected representatives of the people of Western Australia to the State Parliament we have an obligation to protect the sovereignty of the Western Australian State Parliament. Legislation that impinges on the State's sovereignty should be passed by the Parliament only when, on balance, it is in the best interests of Western Australians to do so.*[6]

1.8 The Commonwealth signed an Agreement on 10 December 2003 with New Zealand called the *Agreement between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products*. This Agreement, commonly referred to as the *Treaty*,

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4 Hon Alyssa Hayden MLC, Parliamentary Secretary, Western Australia Legislative Council, *Parliamentary Debates (Hansard)*, 17 October 2013, pp5137B-5138a.

5 Western Australia Legislative Council, *Standing Orders* (Updated December 2013), Schedule 1. The matters raised in the submission from Dr Richard Choong, Australian Medical Association (WA) were outside the Committee's terms of reference.

6 Western Australia Parliament, Standing Committee on Uniform Legislation and Statutes Review, *Personal Property Securities (Commonwealth Laws) Bill 2011 and Personal Property Securities (Consequential Repeals and Amendments Bill 2011*, p6.

establishes an agreement with New Zealand for the creation of a single regulatory body in therapeutic goods regulation (ANZTPA). In 2007, discussions with New Zealand on ANZTPA were suspended, only to be resumed and agreed to in 2011. ANZTPA is overseeing the introduction of the Australia New Zealand therapeutic goods scheme by 2016. The Committee noted the likely repeal of the *Cth TGA 1989* with the establishment of the new regulatory body.

1.9 The Committee inquired into the status of the Treaty with both the State Minister for Health and the Commonwealth Minister for Health.

1.10 On 4 February 2014, the Committee received a letter from the Assistant Minister for Health (Commonwealth), Senator the Hon Fiona Nash providing supplementary information on the Therapeutic Goods Law (**Appendix 1**).

Inquiry Procedure

1.11 The Committee examined:

- The form (clauses) of the Intergovernmental Agreement, and evidence of discussions between the Commonwealth and the State on uniform legislation;
- The drafting of key clauses under Part 6 of the Bill and how it impacts on the Parliament's sovereignty and law making powers;
- The status of the Trans-Tasman Agreement or Treaty with New Zealand for the establishment of an Australian New Zealand regulatory body (ANZTPA) for therapeutic goods;
- The progress of the Trans-Tasman agency overseeing the implementation of a single regulatory body for therapeutic goods;
- The current Commonwealth legislative reform program to amend the *Cth TGA 1989*; and
- Other Commonwealth and Western Australian legislation that may cover the field.

1.12 **Appendix 2** lists the letters and submissions received by the Committee.

1.13 The Committee considered the following documentation:

- National Competition Policy (**NCP**) and the NCP agreement.
- *National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation* (**First Galbally Report**).

- *Final Report of the National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation* (**Final Galbally Report**) 2001.

- Australian Health Ministers Advisory Council's Working Party Response to the Galbally Review dated April 2003.

- *National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation – A Report to the Australian Health Ministers' Conference on Implementation of the Review Recommendations (as endorsed by the Council of Australian Governments*) by the National Coordinating Committee on Therapeutic Goods July 2006 (**Implementation Report**).

- ANZTPA Treaty and correspondence.[7]

- Letter from the Prime Minister to the Premier of Western Australia (dated 10 September 2004).

- The Review of Australia New Zealand Trade and Investment Relations (Parliament of the Commonwealth of Australia), Trade Sub Committee, Joint Standing Committee on Foreign Affairs Defence and Trade.

1.14 The Committee notes the considerable attention given to the regulation of therapeutic goods and the work undertaken by this State to consult with the Commonwealth on key reforms.

Intergovernmental Agreements

1.15 Decisions on uniform legislation agreed by COAG members are formalised in an Intergovernmental Agreement (**IGA**). IGAs formalise the powers, rights and obligations of the parties particularly in relation to the referral of powers from the State to the Commonwealth. Section 61 of the Commonwealth Constitution provides:

> *The executive power of the Commonwealth is vested in the Queen and is exercisable by the Governor-General as the Queen's representative, and extends to the execution and maintenance of this Constitution, and of the laws of the Commonwealth*.

1.16 The scope of the power includes the power to enter into contracts and commercial arrangements without the sanction of the Parliament.

> *There is however uncertainty about its application to agreements to subjects beyond those for which the Commonwealth has a head of substantive legislative power, which parallels the more familiar*

[7] *Australia New Zealand Therapeutic Products Agency* website, http://www.anztpa.org/ (viewed on 3 February 2014).

problems of the extent to which the Commonwealth can engage in executive schemes and enter into government contracts.[8]

1.17 **The Committee emphasises the need for a formal IGA between the Commonwealth, States and Territories that establishes the basis for the heads of power, duties and obligations of parties and formalises the validity and legal effect of the Agreement. This is particularly so, when the States and Territories are asked to agree to reforms of large and complex regulatory systems that propose to incorporate substantial legislative provisions and future amendments (as those contained in the *Cth TGA 1989*) into State law.**

1.18 Generally, IGAs have agreed recitals covering the:

- Constitutional authority for the agreement,[9]
- Overarching principles,
- Powers of the Parties,
- Referral of powers (if any) to the Commonwealth or the State/ Territories,
- Policy objectives,
- Obligations and rights of each Party,
- Review and appeal mechanisms in relation to Clauses of the IGA,
- Mechanisms to evaluate the legislation proposed,
- Sunset clauses,
- Clauses specifying mechanisms such as a Memoranda of Understanding between enforcement and administration functions,
- Mechanisms that allow for the withdrawal of a Party to the Agreement,
- Provisions that allow uniform legislation to be amended, and
- Signatures of the Parties.

1.19 In the main, IGAs are the result of a process of negotiation whereby the legal framework, outcomes, process and policy are clearly specified and agreed to by the

8 C Saunders, *Intergovernmental Agreements and the Executive Power*, Public Law Review, 2005, 16, p301.

9 Agreements must be consistent with the text and structure of the Constitution, refer C Saunders, *Intergovernmental Agreements and the Executive Power*, Public Law Review, 2005, 16, p312.

State and Territories. IGAs consider and apply constitutional/legal frameworks to uniform legislation having regard for the sovereignty of State and Territory Parliaments. Of importance is the requirement for the IGA to be signed by the Parties.

1.20 The Committee is of the view that there must be open and accountable procedures for the COAG and Ministerial Councils drawing intergovernmental agreements. Decisions made in out-of-session arrangements should be formalised in the IGA.

1.21 As the Standing Committee on Uniform Legislation and General Purposes pointed out in its Report 19:

> *It is observed that the Executive is, in effect, exercising supremacy over a State Parliament when it enters into agreements that, in practical terms, bind a State Parliament to enact legislation to give effect to national uniform schemes or an intergovernmental agreement.*
>
> *Where a State Parliament is not informed of the negotiations prior to entering the agreement and is pressured to pass uniform bills by the actions of the Executive, its superiority to the Executive can be undermined.*[10]

1.22 Whilst some States have implemented the Therapeutic Goods Law, the Committee is cognisant of the *'pressure not to amend or reject Bills for the sake of achieving national unity.*[11]

1.23 The Committee notes that in recent times, amendment Acts reference the applicable IGA. For example, the IGA between the States and Territories for the Australian Consumer Law is cited in s17 of the *Fair Trading Act 2010* (WA)).

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[10] Legislative Council, Standing Committee on Uniform Legislation and General Purposes, Report 19, Uniform Legislation and Supporting Documents, 27 August 2004, p11.

[11] Legislative Council, Standing Committee on Uniform Legislation and General Purposes, Report 19, *Uniform Legislation and Supporting Documents*, 27 August 2004, p11. Refer also to the Human Technology Amendment Bill 2007. This Uniform Bill was not passed by the Legislative Council, http://www.parliament.wa.gov.au/parliament/bills.nsf/BillProgressPopup?openForm&ParentUNID=FE8EB995A9A54CB1C82572AC0011ED67

CHAPTER 2

BACKGROUND TO THE MEDICINES, POISONS AND THERAPEUTIC GOODS BILL 2013

Background

2.1 The Bill is part of a national legislative program that regulates and controls the manufacture and supply of medicines, poisons and therapeutic goods in Western Australia. These provisions include regulation of medicines for animals.

2.2 The Committee requested from the Department of Health a copy of the signed IGA in relation to the Bill and was directed to COAG's: *Agreement to Implement the National Competition Policy and Related Reforms* of 11 April 1995 (**NCP Agreement**). The NCP Agreement is derived from the National Competition Policy (**NCP**). COAG Ministers signed the *Competition Principles Agreement - 11 April 1995 (as Amended to 13 April 2007)*(**CPA 2007**).[12] The NCP Agreement provided the basis for the Government to undertake a review of legislation on drugs, poisons and controlled substances.

2.3 The NCP Agreement provided for a series (tranche) of competition payments to the States beginning in 1997. These payments were made for a quarterly basis on a range of reforms relating to road transport, gas, and electricity arrangements. A Conduct Code Agreement formalised the basis for extending coverage of the (former) *Trade Practices Act 1974* (Cth).

2.4 The Department of Health (WA) directed the Committee to Clause 5 of the *Competition Principles Agreement*.

> *Clause 5 (1)*
>
> *The guiding principle is that legislation (including Acts, enactments, Ordinances or regulations) should not restrict competition unless it can be demonstrated that:*
>
> > *(a) The benefits of the restriction to the community as a whole outweigh the costs; and*

[12] Letter from the Minister for Health, Hon Kim Hames MLA, Attachment 3 entitled *Competition Principles Agreement 11 April 1995 (as Amended to 13 April 2007)*, 20 November 2013, p6.

> *(b) The objectives of the legislation can only be achieved by restricting competition.*[13]

2.5 This means that any Bill, Act or item of delegated legislation must be compliant with the NCP.

2.6 The Department of Health[14]referred the Committee to Clause 5 (3), (6) and (7).

> *Legislative Review*
>
> *…*
>
> *Clause 5(3)*
>
> *Subject to subclause (4), each Party will develop a timetable by June 1996 for the review, and where appropriate, reform of existing legislation that restricts competition by the year 2000.*
>
> *Clause 5(6)*
>
> *Once a Party has reviewed legislation that restricts competition under the principles set out in sub-clauses (3) and (5), the Party will systemically review the legislation at least once every ten years.*
>
> *Clause 5 (7)*
>
> *Where a review issue has a national dimension or effect on competition (or both), the Party responsible for the review will consider whether the review should be a national review. If the Party determines a national review is appropriate, before determining the terms of reference for, and the appropriate body to conduct the national review, it will consult Parties that may have an interest in those matters.*[15]

2.7 The Committee finds that the review of medicines, poisons and therapeutic goods legislation nationally had its genesis with the National Competition Policy and the

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13 Letter from the Minister for Health, Hon Kim Hames MLA, Attachment 3, *Competition Principles Agreement 11 April 1995 (As amended to 13 April 2003)*, 20 November 2013, p6.

14 Letter from the Chief Pharmacist, Department of Health (WA), Response to Questions of 29 October 2013, Attachment entitled, *Chronology of Materials Available Resulting in the Insertion of Part 6*, 4 November 2013, pp1-2.

15 Letter from the Minister for Health, Hon Kim Hames MLA, 20 November 2013, Attachment 3, *Competition Principles Agreement, 11 April 1995 (As amended to 13 April 2007)*, p6.

NCP agreement. The NCP provided funding incentives to the States to implement competition reforms across a number of portfolios.[16]

Finding 1: The Committee finds that the review of medicines, poisons and therapeutic goods legislation had its genesis with the National Competition Policy and the Competition Principles Agreement.

National Competition Policy Review of Drugs, Poisons and Controlled Substances

2.8 In 1999, COAG instigated the National Competition Policy Review of Drugs, Poisons and Controlled Substances. The review was chaired by Rhonda Galbally (**Galbally Review**) and found:

> *… that legislation that restricts access to and use of drugs and poisons may be seen as reflecting judgements being made by successive governments, at both the State and Commonwealth levels and that it was inappropriate to rely on a free market for these products. The Review confirmed that comprehensive legislation that regulates drugs and poisons is still required and that the principal objectives of the legislation were to promote and protect public health and safety by preventing accidental poisoning, deliberate poisoning, medical misadventures and diversion for abuse or manufacture of substances of abuse.*
>
> *The Review recommends that State and Commonwealth legislation needs to explicitly incorporate these objectives.*[17]

2.9 The Galbally Review produced two reports: the *National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation* (**First Galbally Report**) and the *Final Report of the National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation* (**Final Galbally Report**).

2.10 The Final Galbally Report presented in 2001 made 27 recommendations to:

> *improve efficiency, uniformity in regulation, reducing the level of control where possible, and improving the net benefit to the*

16 On 4 December 2013, Hon Bruce Billson, Federal Minister for Small Business, announced a review of the NCP after twenty years of operation. Refer to the media release at http://bfb.ministers.treasury.gov.au/media-release/014-2013/

17 Galbally Rhonda, *National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation*, 2003, p6.

> *community as a whole, of those controls which rely on professional practice to be effectual.*[18]

2.11 Recommendation 23 proposed that States and Territories '*adopt the Cth TGA 1989 by reference into the relevant State and Territory jurisdictions'*.[19] This would enable the Therapeutic Goods Administration (**TGA**) to regulate all activities and transactions of therapeutic goods across borders.

2.12 Recommendation 24 specified the work of the *National Coordinating Committee on Therapeutic Goods* (**NCCTG)** to provide advice to the AHMC through the AHMAC and to develop model legislation:

> *that includes provisions for all matters relating to the supply of medicines for therapeutic purposes and to domestic supply of household chemicals…*[20]

2.13 In March 2001, the Commonwealth entered into discussions with New Zealand on the development of a joint medicines and therapeutic goods regulatory body.[21]

2.14 The AHMC established the AHMAC Working Party[22] to consider the recommendations of the Galbally Review and assist the AHMC prepare comments on the Galbally Review for COAG. The AHMAC Working Party finalised their recommendations in April 2003 in their report, *AHMAC Working Party Response to the National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation* (**AHMAC Working Party Response**).

2.15 The AHMAC Working Party Response identified issues around the enforcement of the legislation:

> *As well as putting in place complementary legislation, legislative action is needed to ensure that all the provisions can be enforced. If the Commonwealth is to enforce the provisions of State and Territory*

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18 Letter from the Minister for Health, Hon Kim Hames MLA, Attachment 2, entitled *Response to Questions (18 November 2013),* 20 November 2013, p2.

19 Submission 1, staff of the Department of Health (WA) at the Hearing on 28 October 2013, *Response to Indicative Questions for the Standing Committee on Uniform Legislation and Statutes Review,* Attachment 2 entitled *Council of Australian Governments Review, Review of Drugs, Poisons and Controlled Substances Legislation, Final Report Part A, January 2001*, (p xxiii).

20 Letter from the Minister for Health, Hon. Kim Hames MLA, Attachment 2, entitled *Response to Questions (18 November 2013),* 20 November 2013, p2. Recommendation 24 details the provisions in full.

21 Letter from the Chief Pharmacist, Department of Health (WA), Attachment 1 entitled *Response to Indicative Questions, Chronology of Materials Available Resulting in the Insertion of Part 6*, 4 November 2013, p2.

22 The AHMAC Working Party comprised medical advisors from the Therapeutic Goods Administration, the Department of Health (NSW) and the Chief Pharmacist from the Department of Health (WA).

> *laws, all jurisdiction may need to enact provisions to deal with recent High Court case Hughes. This case casts doubt about the Commonwealth's ability to exercise powers under certain State and Territory laws. The TGA has begun the legislative process to amend the Therapeutic Goods Act to make it clear that Commonwealth officers may take action under State or Territory provisions, but do not have a duty to do so. To demonstrate that no duty exists it must be clear that other persons can take the action. If State or Territory laws do not give enforcement powers to State officials, it is mostly likely that those laws will require amending to insert provisions permitting those officials to exercise the powers and perform the functions under State legislation.*[23]

2.16 The AHMAC Working Party Response highlights the focus on attending to the constitutional constraints of the uniform legislation (recommendation 23 of the Galbally Review).

2.17 The AHMAC Working Party supported reforms on:

- licensing of sellers,
- medicine standards,
- recording and reporting of drugs,
- storage controls, handling controls,
- effectiveness of labels and improving administrative efficiencies,
- packaging,
- complementary therapeutic goods; and
- harmonising labels of medicines.

2.18 Professional standards were left to the States to amend their relevant professional practice legislation.

2.19 The AHMAC Working Party also proposed a new model of administrative oversight of standards and scheduling of medicines and poisons. The model proposed disbanding of the National Drugs and Poisons Scheduling Committee into two committees: one would be responsible for medicines (Medicines Scheduling Committee) and the other responsible for agricultural, veterinary and household

[23] Australian Health Ministers' Advisory Council Working Party, *Response to the Review of Drugs, Poisons and Controlled Substances Legislation (the Galbally Review*), April 2003, p50.

chemicals (Poisons Scheduling Committee). This was intended to expedite the entry of new products onto the market. It further recommended restrictions on sample drugs and medicinal stock with monitoring of information and standards for drugs used by humans.

2.20 The AHMAC Working Party also recommended that all State and Territory legislation on advertising be repealed in support of the adoption of the *Cth TGA 1989* as the principal legislation that controls advertising of medicines for human use. Section 51 (xx) of the Commonwealth Constitution does not provide for Commonwealth legislation in this area to capture all corporate entities (sole traders) or confer a general power of incorporation.

> *Total control over all advertising cannot be achieved by amendment to the Commonwealth Therapeutic Goods Act alone. Section 6 limits the legislation's application to things done by a natural person in interstate trade or by corporations. The constitutional limitation of the Therapeutic Goods Act means that it does not cover advertising by sole traders, such as individual pharmacists, who trade only within State borders.*[24]

2.21 Power to legislate in respect of other corporate entities and sole traders falls within the sole ambit of the State and therefore requires legislative amendment by the States.

2.22 The AHMAC Working Party supported the current prohibition on advertising Schedule 3, 4 and 8 drugs.

> *This will allow for Consumer Medicine Information to be published in its entirety without embellishment and to allow for a one-off press release about the availability of a new medicine, all such exceptions being subject to strict conditions.*[25]

The Path to Adopting Uniform Legislation

2.23 Initially, not all States agreed with the approach to adopt uniform legislation:

> *Queensland, Northern Territory and Western Australia did not support the use of model legislation to achieve uniform legislation*

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[24] *Australian Health Ministers' Advisory Council Working Party Response to the Review of Drugs, Poisons and Controlled Substances Legislation (the Galbally Review),* April 2003, p6.

[25] *Australian Health Ministers' Advisory Council Working Party Response to the Review of Drugs, Poisons and Controlled Substances Legislation (the Galbally Review),* April 2003, p27.

> *(and) have proposed alternative strategies to achieve the same outcome.*[26]

2.24 Queensland is not a participant of the uniform legislation program.[27]

2.25 In July 2006, the (former) National Coordinating Committee on Therapeutic Goods tabled the report to COAG entitled '*A Report to the Australian Health Ministers' Conference on Implementation of the Review Recommendations (as endorsed by the Council of Australian Governments)*' (**Implementation Report**).

2.26 The Implementation Report updated the AHMC on the progress of implementing Recommendation 23 (proposing uniform legislation). It concluded:

> ***It will be unnecessary for the States and Territories to adopt the new therapeutic products legislation to be administered by the Authority as the Australian Government will be able to regulate all individuals who supply (and/or manufacture for supply) therapeutic products only within a State or Territory (sole traders), through the use of the external affairs powers of the Treaty between Australia and New Zealand when that Treaty enters into force.*** [28]

2.27 The Department of Health (WA) explained that:

> *The Committee at that stage appears to have believed with the advent of the agreement being reached and discussion commencing on the establishment of a joint agency, it was no longer necessary for States and Territories to adopt state-based legislation. The assertion "it will be unnecessary" would appear to have been made not fully understanding the intricacies of constitutional law and international relations.*[29]

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26 *Australian Health Ministers' Advisory Council Working Party Response to the Review of Drugs, Poisons and Controlled Substances Legislation (the Galbally Review)*, April 2003, p5.

27 Other State and Territory legislation that applies the *Cth TGA 1989* are as follows: *Medicines, Poisons and Therapeutic Goods Act 2008 (ACT), Poisons and Therapeutic Goods Act 1966, (NSW), Therapeutic Goods (Victoria) Act 2010 (Vic), Therapeutic Goods and Cosmetics Act (NT), Part 2A of the Controlled Substances Act 1984 (SA) (as amended by the Controlled Substances (Therapeutic Goods and Other Matters) Amendment Act 2011 (SA).*

28 Commonwealth, National Coordinating Committee on Therapeutic Goods Report, *A Report to the Australian Health Ministers' Conference on Implementation of the Review Recommendations (as endorsed by the Council of Australian Governments)*, July 2006, p45.

29 Letter from the Minister for Health, Hon Kim Hames MLA, Department of Health, Attachment 2 entitled, *Response to Questions (18 November 2013)*, 20 November 2013, p3.

Supporting Documentation on the Uniform Legislation

2.28 The Committee finds that recommendation 23 (of the Galbally Review) is a key driver for Therapeutic Goods Law, however documentary evidence of a signed *Competition Principles Agreement* could not be located. The Committee was not provided with a 'stand-alone' IGA for Therapeutic Goods Law.

Finding 2: The Committee finds that recommendation 23 (of the Galbally Review) is a key driver for Therapeutic Goods Law, however documentary evidence of a signed IGA (*Competition Principles Agreement*) could not be located.

2.29 The Department of Health (WA) provided the Committee with a copy of a letter to then Prime Minister Rt Hon. John Howard, from the then Premier of Western Australia, Dr Geoff Gallop (dated 2004) that agreed with the publication of the AHMAC Working Party response to the Galbally Review[30] (**Appendix 3**). The letter approves the release of the Working Party response with the release of the Final Galbally Report.

Finding 3: The Committee finds that the letter to the then Prime Minister Rt Hon. John Howard from the then Premier of Western Australia, Dr Geoff Gallop (dated 2004) agreed with the recommendations of and the publication of the AHMAC Working Party response to the Galbally Review.

2.30 The Committee was advised by the Minister for Health (WA) that COAG approved the recommendations of the Galbally Review in an out of session process on 28 June 2005 (for which there are no minutes).

2.31 The Committee received the response from the Assistant Minister for Health, Senator Hon Fiona Nash who confirmed that:

> *The Department of Health has confirmed with the COAG secretariat in the Department of the Prime Minister and Cabinet that the Galbally Review Recommendations were agreed by COAG out-of-session by an exchange of letters.*[31]

30 Letter from the then Western Australian Premier, Hon Geoff Gallop to the then Prime Minister, Hon John Howard, 13 September 2004, p1.

31 Letter from the Assistant Minister for Health (Cth), Hon Fiona Nash, received by the Committee on 4 February 2014, p1.

Finding 4: The Committee finds that COAG approved the recommendations of the Galbally Review in an out-of-session process by an exchange of letters.

Finding 5: The Committee finds that COAG did not draft an Intergovernmental Agreement for uniform legislation on the Therapeutic Goods Law.

2.32 The Department of Health (WA) informed the Committee that the State Minister for Health approved (31 October 2010) the adoption by reference of the *Cth TGA 1989* into the Bill.[32]

The Treaty

2.33 Information on the Treaty and the national project to develop a new, single regulatory body with New Zealand by 2016 was not addressed in the Explanatory Memoranda or the Second Reading Speech.

2.34 The Committee considered whether a Treaty had been ratified, and the operational effect of the arrangement between the Commonwealth and New Zealand on Australian jurisdictions.

2.35 The Treaty is entitled *The Agreement between the Government of Australia and the Government of New Zealand for the establishment of a joint scheme for the regulation of therapeutic products.*[33] The Treaty is not ratified and is commonly referred to as the Trans-Tasman Treaty or simply, the Agreement. The Treaty is available on the internet[34] and is a substantial document containing 23 Articles.

2.36 The Committee requested updated information on the establishment of the transitional agency, ANZTPA.[35] The Commonwealth Minister referred the Committee to the ANZTPA website.[36] The background to the ANZTPA on the website is contained in **Appendix 4**.

2.37 The letter from the Assistant Minister for Health (Cth) is an unhelpful and unsatisfactory response and highlights the reluctance of the Commonwealth to provide

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32 Submission No 1 from staff of the Department of Health (WA) tabled at the Committee hearing, 28 October 2013, p2.

33 Australia New Zealand Therapeutic Products Agency website, http://www.anztpa.org/about/treaty.htm, viewed on 6 February 2014.

34 Australia New Zealand Therapeutic Products Agency website, http://www.anztpa.org/about/treaty.htm, viewed on 6 February 2014.

35 Trans Tasman negotiations were suspended in 2007, and recommenced in 2011. ANZTPA was established to implement the agreement.

36 Letter from the Assistant Minister for Health (Cth), Hon Fiona Nash, 4 February 2014, p1.

full and detailed information on the uniform scheme that the Western Australia Parliament is required to accept.

2.38 With regard to the Treaty and the possible exercise of external affairs powers, the Committee was advised that:

> *[WA] Departmental officers had no information that the Commonwealth was or is intent on exercising its external affairs powers in relation to regulating therapeutic goods for this small group of traders/and or manufacturers in the near future.*[37]

2.39 The Committee was advised that:

> 1. *The State Minister is not privy to the recently elected Commonwealth Government's program of legislative reform in relation to:*
>
>   - *the ANZTPA ceasing to be a transitional agency*
>
>   - *what will occur in relation to reforming/amending the TGA, and/or*
>
>   - *a commitment to pursuing a Treaty with New Zealand in relation to therapeutic goods.*[38]
>
> 2. *The Regulatory Gatekeeping Unit was not notified of the Commonwealth's Government's agreement to establish the ANZTPA at the permission to print stage. The Commonwealth's intention to recommence discussions with New Zealand was announced (in June 2011) prior to the issuing of the Compliance Statement*.[39]
>
> 3. *The drafters of the Bill were not (and remain) of the view that the recommencement of formal discussions between Australia and New Zealand to proceed with the establishment of the ANZTPA was not (and is not) likely to have a significant impact on the Medicines, Poisons and Therapeutic Goods Bill 2013.*[40]

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37 Letter from the Minister for Health, Hon Kim Hames MLA, Attachment 2 entitled *Response to Questions (18 November 2013)*, 20 November 2013, p7.

38 Letter from the Minister for Health, Hon Kim Hames MLA, Attachment 1 entitled *Response to Questions (11 December 2013)*, 10 January 2014, p2.

39 Letter from the Minister for Health, Hon Kim Hames MLA, with Attachment 1 entitled *Response to Questions (11 December 2013)*, 10 January 2014, p3.

40 Letter from the Minister for Health, Hon Kim Hames MLA, with Attachment 1 entitled *Response to Questions (11 December 2013)*, 10 January 2014, p3.

4. *The intention to develop a Trans Tasman agreement has been under discussion for 13 years.*[41]

5. *The amending legislation associated with the Cth TGA 1989 had not (and has not) been commenced.*[42]

2.40 The Minister for Health (WA) advised that:

> *The most recent information suggests that the joint agency will be established and functioning by mid 2016. However, no legislative drafting or discussion on the ratifying of the Treaty has occurred.*[43]

2.41 It is arguable that the Treaty is an Agreement. What is known is that the ANZPTA has been established (whether under an agreement or a treaty)[44] to transition to a single regulatory model. ANZTPA is now operational as a transitional agency to effect the change by 2016. This will most likely require the repeal of the *Cth TGA 1989*.

2.42 It is also arguable whether ratification is required.

> *So far as Australia is concerned, ratification of bilateral treaties is the exception rather than the rule; signature alone is generally sufficient, with ratification being used only in the case of treaties which are politically sensitive or which call from implementing legislation.*
>
> *…*
>
> *In the case of Australia, the process of ratification may involve asking the Houses of the Commonwealth Parliament to 'approve' the treaty. But, because the Crown is constitutionally autonomous in treaty making, parliamentary approval has no domestic or international legal significance: ratification is an executive act and, where it is required by the terms of a treaty, it is performed by the Minister for*

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41 Letter from the Minister for Health, Hon Kim Hames MLA, with Attachment 1 entitled *Response to Questions (11 December 2013)*, 10 January 2014, p3.

42 Letter from the Minister for Health, Hon Kim Hames MLA, with Attachment 1 entitled *Response to Questions (11 December 2013)*, 10 January 2014, p3.

43 Letter from the Minister for Health, Hon Kim Hames MLA, with Attachment 2 entitled *Response to Questions (18 November 2013)*, 20 November 2013, p3.

44 On 17 May 2006, Dr Ian Watt, the former Secretary for the Department of Finance and Administration wrote to the Commonwealth Parliament, Chairman of the Trade Sub Committee of the Joint Standing Committee on Foreign Affairs, Defence and Trade looking into the Inquiry into Australia and New Zealand Closer Economic Ties and reported that the *'Australian and New Zealand governments signed a Treaty to establish a joint scheme, and ANZTPA, will replace the Therapeutic Goods Administration (TGA) in Australia and Medsafe in NZ, representing a unique approach to trans-Tasman regulation*'. This information contrasts with the TGA website that refers to the Treaty as an Agreement.

> *Foreign affairs, after formal approval by the Federal Executive Council.* [45]

2.43 The Committee notes that a Regulatory Impact Statement and National Interest Analysis were prepared for the Treaty.

2.44 The Minister for Health (WA) advised:

> *Until the formal establishment and operation of a joint therapeutic products agency with New Zealand and the evoking by the Commonwealth of its powers under section 51 (xxix) of the Constitution (Cth) Commonwealth Therapeutic Goods Law cannot be applied to sole traders operating entirely within a single jurisdiction.*[46]

2.45 The status of the Treaty becomes relevant to the Western Australia Parliament's law making powers if the Commonwealth decides to exercise its external affairs power to implement the scheme in all Australian jurisdictions. The Committee was not informed by the Department of Health (State or Commonwealth) whether the States are still required to agree to introduce uniform legislation or if the States' incorporation of applied law is indeed part of the transition to a single regulatory body.

2.46 Sections 6AAA – AAE, 6B and 6C of the *Cth TGA 1989* (refer to **Appendix 5**) provide for the adoption of Commonwealth law into the law of States and Territories for the purposes outlined in Part 6 of the Bill.

2.47 The adoption of the Trans-Tasman Treaty and its likely impact on the Bill, was described in correspondence to the Committee (November 2013) in the following terms:

> *Adoption of a Trans Tasman Treaty would require amendment to the Medicines Poisons and Therapeutic Goods Act (Bill) to the extent of removing any reference to the Therapeutic Goods Act 1989 (Cth) and the repeal of Part 6 of the Act/ Bill.*
>
> *…*
>
> *If and/or when the Treaty is ratified, and the Commonwealth decides to evoke its external affairs powers with the States and Territories, it*

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45 ND Campbell, Australian Treaty Practice and Procedure, *International Law in Australia* 1984, cited in , P Hanks, F Gordon, G Hill, *Constitutional Law in Australia*, Lexis Nexis, New South Wales, 2012, pp476-477.

46 Letter from the Minister for Health, Hon Kim Hames MLA, with Attachment 2 entitled *Response to Questions (18 November 2013)*, 20 November 2013, p4.

> *is likely to also result in considerable amendment to the Therapeutic Goods Act 1989 – see section 6AAA which acknowledges the (present) authority of the States and territories to regulate in this area.*[47]

2.48 However, in January 2014, the Committee was advised:

> *The drafters of the Bill were not (and remain) of the view that the recommencement of formal discussions between Australia and New Zealand to proceed with the establishment of the ANZTPA was not (and is not) likely to have a significant impact on the Medicines, Poisons and Therapeutic Goods Bill 2013.*[48]

2.49 Amending the Bill to the extent indicated in paragraph 2.47 will involve the removal of the *Cth TGA 1989*, regulations, manufacturing principles and orders from the Act and the repeal of Part 6. The Committee does not agree that the amendments to the *Cth TGA 1989* are not likely to have a significant impact on the Bill.

2.50 If the Commonwealth were to validly legislate to implement the Treaty and there was an inconsistency between that Commonwealth legislation and State legislation, then the State legislation would be inoperative to the extent of the inconsistency in accordance with section 109 of the Commonwealth Constitution.[49]

2.51 The Committee did not receive direct answers to a number of questions put to the Commonwealth Minister for Health. The Committee viewed the Commonwealth's referral to the ANZTPA website for information on the Treaty as unhelpful. Similarly, the letter referring the Committee to the Commonwealth Parliament website for detail on the Therapeutic Goods Amendment (2013 Measures No.1) did not explain the reform program currently amending the *Cth TGA 1989*. The approach taken by the Assistant Minister for Health (Cth) to the Committee's questions was unsatisfactory. The Western Australia Parliament is being asked to pass a Bill for uniform legislation that will be impacted by current amendments before the Commonwealth Parliament.

Finding 6: The Committee finds that substantial discussions have occurred between the Commonwealth and New Zealand for the implementation of a joint Australian New Zealand Therapeutic Products Agency by 2016.

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47 Letter from the Minister for Health, Hon Kim Hames MLA, Attachment 2 entitled, *Response to Questions (18 November 2013)*, 20 November 2013, p6.

48 Letter from the Minister for Health, Hon Kim Hames MLA, with Attachment 1 entitled *Response to Questions (11 December 2013)*, 10 January 2014, p3.

49 P.Hanks, F Gordon, G Hill, *Constitutional Law in Australia*, 3rd Edition, Lexis Nexis, News South Wales, 2012, p289.

Finding 7: The Committee finds that the adoption and ratification of the ANZTPA Treaty would require significant amendment to the Medicines, Poisons and Therapeutic Goods Act (the current Bill) to the extent of removing any reference to the *Therapeutic Goods Act 1989* (Cth) and the repeal of Part 6.

Finding 8: The Committee finds that if and when the ANZTPA treaty is ratified and the Commonwealth decides to evoke its external affairs powers with the States and Territories, it is likely to also result in considerable amendment to the *Therapeutic Goods Act 1989* (Cth) – specifically section 6AAA which acknowledges the (present) authority of the States and Territories to regulate in this area.

Finding 9: The Committee finds that the Second Reading Speech and Explanatory Memoranda did not fully inform the Legislative Council of the history of negotiations to establish a single Australian New Zealand regulatory body, the creation of the ANZTPA and the likely repeal of the *Cth TGA 1989* in 2016.

Recommendation 1: The Committee recommends that the Minister formally advise the Legislative Council on the implementation program of ANZTPA by 2016, Western Australia's powers and functions under the ANZTPA to amend regulations and legislation and report to the Legislative Council within two months of the tabling of this Report.

Closing the Sole Trader Loophole in Regulation

2.52 The Department of Health (WA) advised that the options available to Western Australia to close the loophole (in respect of the regulation of sole traders) were:

- *leave this group of manufacturers and/ or suppliers unregulated;*
- *adopt the Commonwealth Therapeutic Goods Law, as agreed to under COAG; or*
- *develop a regulatory regime and associated infrastructure and expertise that mirrors the Therapeutic Goods Administration (TGA).*[50]

2.53 The Committee also identified a legislative overlap of Australian Consumer Law (WA) with the Therapeutic Goods Law. On 1 January 2011 the Australian Consumer

[50] Letter from the Minister for Health, Hon Kim Hames MLA, Attachment 2 entitled *Response to Questions (18 November 2013)*, 20 November 2013, p4.

Law (ACL) commenced. The ACL is a cooperative reform of the Australian Government and the States and Territories, through the Ministerial Council on Consumer Affairs (MCCA).

> *The ACL replaced the following fair trading and consumer protection laws in WA:*
>
> *Fair Trading Act 1987 (WA)*
>
> *Consumer Affairs Act 1971 (WA)*
>
> *Door to Door Trading Act 1987 (WA)*
>
> *Trade Practices Act 1974 (Cth): Parts IVA, V, VA and VC* [51]

2.54 The ACL also covers product safety (health and cosmetic products), investigating potential chemical hazards in consumer products, developing bans and mandatory standards where evidence shows a consumer product has or could cause injury, illness or death.

2.55 The Department of Health (WA) explained:

- *the Commonwealth Therapeutic Goods Law and the Australian Consumer Law already coexist and complement each other,*
- *the Commonwealth Therapeutic Goods Law:*
  - *is prospective law, regulating goods before the product is available to the consumer;*
  - *requires minimum compliance with a set of standards in relation to raw material quality, manufacturing quality, labelling requirements;*
  - *requires evidence of efficacy and safety for the claimed therapeutic purpose;*
  - *requires an assessment of safety and efficacy for prescription medicines prior to approval for marketing across Australia.*
- *the Consumer Law is "post fact" complaints based law;*

Therapeutic goods are:

[51] Australian Consumer Law, website http://www.consumerlaw.gov.au/content/Content.aspx?doc=current_laws/wa.htm (viewed on 6 February 2014).

- *not considered to be the ordinary items of commerce covered by Australian Consumer Law (WA)*

- *required to be included on a Register either through a notification process or via an approval process.*[52]

2.56 The Committee notes the ACCC prosecutions in recent years relating to unsubstantiated cancer cure claims and notes the overlap of the two regulatory bodies. The submission by the ACCC to the AHMAC (for its inquiry looking at unregulated health practitioners) details the comprehensive regulatory oversight of the ACCC. The ACCC submission to the AHMAC inquiry is located at **Appendix 6.**

Finding 10: The Committee finds that Australian Consumer Law (WA) also covers the regulation of sole traders.

Recommendation 2: The Committee recommends that the Minister advise the Legislative Council whether the ACL will render the majority of the Bill invalid when it is passed into law.

The Therapeutic Goods Administration and its reform program

2.57 The Therapeutic Goods Administration is the principal agency regulating therapeutic goods in Australia.

> *In addition to the TG Act and the Charges Act, the TGA is also responsible for administering the Therapeutic Goods Regulations 1990, the Therapeutic Goods (Charges) Regulations 1990 and the Therapeutic Goods (Medical Devices) Regulations 2002. Delegates of the Minister or the Secretary within the TGA also from time to time make or amend a range of legislative instruments, such as Therapeutic Goods Orders which set out standards for therapeutic goods, and Listing Notices which require that specified therapeutic goods be included in the part of the Australian Register of Therapeutic Goods for listed goods.*[53]

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52 Letter from the Minister for Health, Hon Kim Hames MLA, Attachment 2 entitled *Response to Questions (18 November 2013)*, 20 November 2013, p4.

53 Therapeutic Goods Administration, http://www.tga.gov.au/about/tga-regulatory-change-03-delegated.htm (viewed on 31 January 2014).

2.58 There are a wide range of legislative instruments that comprise the Therapeutic Goods Law that diminishes the Western Australia parliamentary sovereignty:

> *First, there is the primary Act [Cth TGA 1989], and secondly, there is subordinate legislation that theoretically runs the risk of disallowance in either chamber of the Parliament. Immediately beneath those two levels, however, are the guidelines that the TGA itself has promulgated; these are not legislative instruments subject to disallowance in either House. Fourthly, there are international standards that aim for an international harmonisation of standards, and for recognition of testing processes pursuant to mutual recognition agreements with Europe, Switzerland, North America and Singapore.*[54]

2.59 The Committee notes the process of amending Commonwealth regulations:

> *Regulations, including regulations that amend other regulations, are approved by the Governor-General at a meeting of the Federal Executive Council, and are tabled in Parliament.*
>
> *Meetings of the Executive Council are scheduled throughout the year. Proposed amendment regulations are prepared ahead of such meetings, so that the amendment regulation can be provided for the Governor-General's consideration and approval.*[55]

2.60 The *Cth TGA 1989* provides for a range of legislative instruments to be developed (without recourse to the Commonwealth Parliament):

> *… that may be made by the Minister or Secretary (or a respective delegate), such as manufacturing principles or the Therapeutic Goods Advertising Code.*
>
> *Such instruments will, in most cases, be prepared by TGA officers, once all of the necessary consultations, policy approvals and regulatory impact assessments have been satisfactorily completed. TGA officers will also prepare an ES [Explanatory Statement] to accompany the instrument, and a Statement of Compatibility with Human Rights.*

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54 Aronson, M., Subordinate Legislation: Lively Scrutiny or Politics in Seclusion, *Australasian Parliamentary Review*, Spring, 2011, Vol. 26 (2), p7.

55 Therapeutic Goods Administration, http://www.tga.gov.au/about/tga-regulatory-change-03-delegated.htm (viewed on 31 January 2014).

> *As with regulations, the TGA's legislative instruments must be registered on FRLI [Federal Register of Legislative Instruments] to have legal effect.*[56]

2.61 This Bill is directly impacted by any amendments to the principal Act, regulations and legislative instruments passed by the Commonwealth Parliament or the Commonwealth Executive.

2.62 The Therapeutic Goods Administration is implementing the *TGA reforms: A blueprint for TGA's future*.[57]

2.63 The Committee notes that key provisions of the *Cth TGA 1989* are undergoing amendment. The letter from the Assistant Minister for Health (Cth) did not provide sufficient detail on the amendments before the Federal Parliament. Prior to the Federal Parliament being prorogued in September 2013, the Senate Standing Committee for the Scrutiny of Bills[58] scrutinised the Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013. This Bill proposes to introduce 16 schedules into the Act that includes goods that are not therapeutic goods. Of a range of matters, the Senate Standing Committee considered the proposed new section 7AA – excluding goods for public policy reasons that would enable the (Commonwealth) Minister to determine by legislative instrument that specified products are not therapeutic goods for the purposes of the *Cth TGA 1989* or are not therapeutic goods when used, advertised or presented in a specified way.

2.64 On 12 December 2013, the Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013[59] was again introduced into the House of Representatives. As the letter from the Assistant Minister for Health (Cth) did not provide any details on the amendments, the Committee considered the Minister for Health (Cth) Second Reading Speech in December 2013 (refer to **Appendix 7)**.

2.65 **Amendments to the *Cth TGA 1989* will impact Western Australia. The Bill does not provide a mechanism for the Western Australian Parliament to scrutinise or disallow Commonwealth regulations before they are passed by the Commonwealth. Insufficient attention is given to explaining the Commonwealth's reform program in regard to the Therapeutic Goods Law. The**

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56 Therapeutic Goods Administration http://www.tga.gov.au/about/tga-regulatory-change-03-delegated.htm (viewed on 31 January 2014).

57 Therapeutic Goods Administration, http://www.tga.gov.au/about/tga-reforms-blueprint-progress-130630.htm (viewed on 31 January 2014).

58 Commonwealth Parliament, Senate Standing Committee for the Scrutiny of Bills, Sixth Report of 2013, 19 June 2013, p236.

59 Commonwealth of Australia, http://www.aph.gov.au/Parliamentary_Business/Bills_Legislation/Bills_Search_Results/Result?bId=r5156 (viewed on 3 February 2014).

State Parliament therefore is being asked to pass a law for the State when the text of the law is not known.

Finding 11: The Committee finds that there has been insufficient attention or explanation provided to the Legislative Council on the current proposals in the Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013 to amend the *Cth TGA 1989* introduced to the Federal Parliament in December 2013.

Recommendation 3: The Committee recommends that the Minister confirm with the Commonwealth what the policy position of the current Government is, and if applicable, when it will be implemented and advise the Legislative Council accordingly during consideration of the Bill.

Recommendation 4: The Committee recommends that the Minister advise the Legislative Council on the amendments to the Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013.

CHAPTER 3

SUMMARY OF THE BILL

3.1 The Western Australian Bill comprises 12 parts and proposes 209 clauses. Some provisions come under the authority of the Western Australian Minister for Health (poisons schedules) and his/her delegates. Decisions made by the delegate may be reviewable by the State Administrative Tribunal. Other provisions in the Bill (such as Parts 6 and 7) cover the application of Commonwealth administrative laws to the Therapeutic Goods Law, the powers of the Commonwealth Minister, the Commonwealth Secretary and confer powers on Commonwealth officers and authorities.

3.2 The Bill proposes to repeal the *Poisons Act 1964*, the *White Phosphorus Matches Prohibition Act 1912* and *Poisons Regulations 1965*. The Committee notes that a Parliamentary Committee had considered the repeal of the *White Phosphorus Matches Prohibition Act 1912.* In 2009, the *Standing Committee on Uniform Legislation and Statutes Review* in their Report (Report No 39) into the Statutes (Repeals and Minor Amendments) Bill 2009 found that there were insufficient legislative safeguards to protect the public if the *White Phosphorus Matches Prohibition Act 1912* was repealed. The Committee is concerned with the repeal of the Act if it is likely to leave a gap in regulation of the manufacture and sale of yellow/white phosphorus.

Recommendation 5: The Committee recommends that the responsible Minister confirm with the Legislative Council that the repeal of the *White Phosphorous Matches Prohibition Act 1912* will not create a gap in regulation.

3.3 Part 1 of the Bill outlines the definitions and terms used. Clause 1 sets out the short title. This clause is a formality. Clause 2 of the Bill provides for sections 1 and 2 to come into operation on the day which it receives Royal Assent and for the rest "*on a day or days fixed by proclamation and different days may be fixed for different provisions*". Some Clauses of the Bill require the application of Commonwealth legislation, manufacturing principles and orders as it exists *from time to time*.

3.4 Part 1 includes the classification of substances as poisons under nine Schedules. Clause 4 states the Governor may on the recommendation of the Minister make regulations classifying a substance as a poison included in the Schedule. The Minister has proposed powers under Part 1, Clause 4(2) to recommend that a substance be identified in the regulations in any way the Minister thinks fit. Clause 4(3) lists seven considerations when classifying a substance.

3.5 Definitions under Part 1 include the scheduled controlled drugs and supply, the range of professionals (authorised health professionals, investigators) and the interaction with the *Misuse of Drugs Act 1981*. If a provision in the proposed Act is inconsistent with a provision in the *Misuse of Drugs Act 1981* the provision of the Act (if passed) prevails.

3.6 Part 2 sets out the offences and penalty provisions for manufacture and supply for various scheduled drugs, licensing offences including third parties, recording and reporting and restrictions on vending machines. There are a number of strict liability offences and penalties. Regulations will cover the circumstances in which prescribed poisons will be supplied from a vending machine and the premises where vending machines can be located.

3.7 Parts 3, 4 and 5 provide a high level framework of controls over medicines and poisons designed to protect public health and safety. The finer detail of the controls in the manufacture, use, sale or supply of medicines and poisons will be developed in subsidiary legislation.[60] These parts cover health professionals with authority to prescribe and manufacture medicines, as well as the grounds for suspension and cancellation of the permit and the Chief Executive Officer's powers in relation to this (Part 5). These decisions will be reviewable and a notice must be published in the *Government Gazette*.

3.8 Part 6 covers the Application of Commonwealth Therapeutic Goods Law to Western Australia and the application of Commonwealth Administrative Law to the Therapeutic Goods Law (WA).

3.9 Part 7 deals with drugs of addiction, the oversupply of drugs and the recording and disclosure of information. These clauses are designed to restrict 'doctor shopping'. There are provisions for review of decisions by the State Administrative Tribunal.

3.10 Part 8 deals with enforcement and investigations, evidentiary matters and Part 9 deals with regulations and the general power to make regulations.

3.11 Part 10 is headed '*Miscellaneous*' and covers confidential information and the review of the Act. There is a review provision (clause 152(1) and (2)) whereby the Minister is to carry out a review of the operation and effectiveness of the Bill after the fifth anniversary and the expiry of each five yearly interval after that anniversary. The Minister is to prepare a report and cause it to be laid before each House of Parliament.

3.12 Part 11 deals with repeals and transitional provisions and Part 12 deals with consequential amendments.

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[60] Western Australian Parliament, Legislative Council, Hon Alyssa Hayden MLC Parliamentary Secretary representing the Minister for Health, Medicines, Poison and Therapeutic Goods Bill 2013, Second Reading Speech,17 October 2013, p2.

3.13 The Second Reading speech provided information on the control of substances:

> *The Bill retains the majority of the controls associated with the present Act. Substances controlled through the current Poisons legislation are classified into a set of nine 'schedules'. A substance is included in a particular schedule based on its risk to human health and need for expert oversight. These schedules are consistent with the national approach to regulating medicines and poisons under the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). The controls that are applied to a particular substance are related to the schedule it resides in. These controls vary, commensurate with the risk posed. For example, some medicines are available 'over the counter' at pharmacies (Schedules 2 and 3) whilst other medicines must be prescribed (Schedule 4). The new Bill will retain these schedules.*[61]

3.14 The Department informed the Committee:

> *The Bill as a whole also handles veterinary medicines where they contain a substance in the poison schedules. That would currently be already handled under the Agvet Code, which is already adopted by reference into agricultural legislation.*[62]

3.15 The Second Reading speech stated:

> *The main controls for handling medicines and poisons will continue to be through the authority afforded to defined groups of health practitioners, the issuing of licences and permits to supply or use, and controls on the labelling, packaging, storage and recording of such substances.*[63]

3.16 The Committee notes that existing provisions that regulate therapeutic goods in WA under State law will be removed:

> *…the Health Act 1911, will be amended considerably to remove sections related to therapeutic goods that predate the enactment of*

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61 Western Australian Parliament, Legislative Council, Hon Alyssa Hayden MLC Parliamentary Secretary, Second Reading Speech, Medicines, Poisons and Therapeutic Goods Bill 2013, 17 October 2013, p2.

62 Ms Jane Carpenter, Manager, Legislation and Licensing Pharmaceutical Services Branch, Department of Health, *Transcript of Evidence*, 28 October 2013, p8.

63 Western Australian Parliament, Legislative Council, Hon Alyssa Hayden MLC Parliamentary Secretary, Second Reading Speech, Medicines, Poisons and Therapeutic Goods Bill 2013, 17 October 2013, p2.

the Cth TGA. It also removed provisions that were more latterly included in the Poisons Act 1964.[64]

3.17 The Department of Health (WA) informed the Committee that the amendments are:

- *Part VIIA is headed 'Drugs, medicines, disinfectants, therapeutic substances and pesticides'. The consequential amendments replace this heading with the term "Part VIIA – Pesticides'". The Part is divided into six divisions.*
- *Division 5 headed "Drugs" will be deleted. The contents of this division were largely superseded by the Poisons Act (and not amended at that time – 1964). The provisions deal with the mixing, sale and labelling of substances.*
- *Division 6 headed "Medicines and disinfectants" will be deleted. The contents of this division were largely by the Poisons Act, the Commonwealth Therapeutic Goods Act in that it deals with sales and false statements in publications and trade.*
- *Division 7 headed "Manufacture of therapeutic goods" will be deleted. This division has been superseded by the Commonwealth Therapeutic Goods Act for corporations. Retention of this Division as a substitute for the adoption of the Commonwealth law would not [be] adequate and has never been used to regulate the actions of natural person manufacturing or supplying therapeutic goods within the State.*
- *Division 9 headed "Regulations" will be deleted. This division becomes redundant with the removal of most of the divisions associated with this Part. Pesticides which is the remaining division in the Part has its own regulation making provision.*[65]

3.18 It is apparent that the proposed amendments are intended to update and consolidate the legislation.

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64 Letter from Chief Pharmacist, Department of Health (WA), Attachment 1 entitled *Response to Questions of 29 October 2013,* 4 November 2013, p5.

65 Letter from Chief Pharmacist, Department of Health (WA), Attachment 1 entitled *Response to Questions of 29 October 2013,* 4 November 2013, p6.

CHAPTER 4

SPECIFIC PROVISIONS OF THE BILL

4.1 The Committee considered a number of clauses in the Bill that challenged the sovereignty and law making powers of this Parliament. The Committee's concerns with several clauses of the Bill are outlined below.

4.2 Clause 2 is reads as:

> *Clause 2 Commencement*
>
> *This Act comes into operation as follows —*
>
> *(a) sections 1 and 2— on the day on which this Act receives the Royal Assent;*
>
> *(b) the rest of the Act — on a day fixed by proclamation and different days may be fixed for different provisions.*

4.3 This clause means that there is no certainty when different Parts of the Act will have effect. The Bill has a number of Parts covering different provisions that are decided by the State Minister or Executive officers of either the Commonwealth or the State Departments. This is a sub-delegation of legislative power from the Western Australian Parliament to the Executive and the Commonwealth and hence directly impacts on the law making powers of the Western Australian Parliament.

4.4 The impact of different commencement mechanisms for specific clauses on the Parliament's law making power is raised as a concern.

> *The proclamation method of commencement involves a Minister exercising the ultimate discretion, that is, whether or not to prepare a proclamation for consideration by the Executive.*
>
> *The proclamation method mean the Parliament gives the Executive discretion to indefinitely suspend the operation of laws passed by the Parliament.*
>
> *…where unfettered control is given to the Executive to decide the commencement of particular Act, this can usurp the power that lies at the heart of the role of the Western Australian Parliament.*[66]

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66 Western Australian Parliament, Legislative Council, Standing Committee on Uniform Legislation and Statutes Review, Report 35, *National Gas Access (WA) Bill 2008*, 10 March, 2009, p22.

4.5 The Veterinary Surgeons' Board of Western Australia identified a need for the public and stakeholders to receive sufficient notice and explanation of some provisions before they are passed. The Committee holds the view that the public requires sufficient notice to be informed about the new arrangements proposed in the Bill.

4.6 It is clear that a policy decision supports the Commonwealth Executive to exercise considerable powers in the regulation of Therapeutic Law until 2016. After that date, the Committee is unclear as to whether there is a mechanism by which the State Minister, the Executive or the Parliament of Western Australia will be able to scrutinise proposed or future amendments to manufacturing orders, notices or other legislative instruments before they are passed by the Commonwealth Parliament or the Commonwealth Executive.

Recommendation 6: The Committee recommends that the State Minister seek information and report to the Legislative Council on the Commonwealth's program of proposed amendments to the *Therapeutic Goods Act 1989* and the transition arrangements following ANZTPA's implementation in 2016.

Part 6 – Therapeutic Goods Law

4.7 The Bill proposes to '*close a loophole in the law*'.[67] The application of the text of *Cth TGA 1989* and regulations is proposed as a solution to potentially regulate the activities of three to four Western Australian individuals and/or sole traders a year. The *Cth TGA 1989* text is approximately 577 pages of principal legislation and delegated legislation (plus executive orders and manufacturing principles).

> *At present there is no regulatory framework preventing an individual from promoting an untested, ineffective or unsafe good for medical purposes within Western Australia. The Bill, at Part Six seeks to adopt as Western Australian law the Commonwealth legislation in this area. This will ensure that Western Australian consumers will have equal protection from substandard therapeutic goods, compared to anywhere else in Australia.*[68]

4.8 The Committee does not agree with this contention. In 2013, the Western Australian Parliament passed legislation that incorporated Schedules of the Australian Consumer Law into the Western Australian *Fair Trading Act 2010*. This Act covers sole traders who provide goods and services and does not specifically exclude therapeutic goods or services. The Australian Competition and Consumer Commission (**ACCC**), the

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67 Department of Health (WA), *Transcript of Evidence*, 28 October 2013, p3.

68 Hon Alyssa Hayden MLC, Parliamentary Secretary, Second Reading Speech, 2013, 17 October 2013, p4.

Australian Securities and Investment Commission and State and Territory consumer agencies enforce the ACL. There is overlap between the two legislative regimes.[69]

4.9 Part 6 (Division 1) of the Bill deals with the application of Commonwealth law text (Therapeutic Goods Law). This will ensure that natural persons or manufacturers trading therapeutic goods exclusively within this jurisdiction are subject to the same regulatory framework as corporations.

> *Sections 6AAA-AAE, 6B and 6C of the Cth TGA provide for the adoption of the Commonwealth law into the law of States and Territories for the purposes outlined in Part 6. Section 7A provides for the Secretary (of the Commonwealth department) to authorise officers of a Department of State to exercise powers under the Clth TGA.*[70]

4.10 As raised at paragraph 2.20, the AHMAC Working Party Response identified the constitutional challenges posed by the High Court *R v Hughes* case in relation to the States adopting uniform legislation. The Department of Health (WA) advised the Committee that:

> *…provisions within the TGA (at 6AAAA-AAE) that make allowances for the States to adopt the TGA and importantly at sec 6AAE(1) & (2) provides for the authority of the corresponding State law to "override" the TGA.*[71]

4.11 The Committee notes however, that the law in *R v Hughes* is still unsettled.[72] The Committee holds the view that the operation of sections 6AAA-AAE, 6B and 6 C of the *Cth TGA 1989* lacks a mechanism by which the Parliament of Western Australia is able to scrutinise new regulations or subsequent amendments passed by the Commonwealth.

4.12 The Western Australian Minister for Health has no powers or direct functions in relation to Part 6 of the Bill.[73] The Committee notes that where matters are currently

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69 The ACCC and the TGA jointly developed consumer safety alerts on the therapeutic and non therapeutic uses of some goods. Refer to *AccCount – A Report of the Australian Competition and Consumer Commission/s and Australian Energy Regulator's Activities 1 April to 30 June 2013*, Commonwealth of Australia, 2013.

70 Submission No 1, *Response to Indicative Questions*, Department of Health (WA), tabled at the Committee's Hearing, 28 October 2013, p4.

71 Letter from the Minister for Health, Hon Kim Hames MLA, Attachment entitled *Response to Questions (11 December 2013)*, 10 January 2014, p5.

72 The majority judges said that where there is an imposition by federal law upon Commonwealth officers of duties to perform functions or exercise powers created and conferred by State law, the Federal law must be supported by a head of power. *R v Hughes*, (2000), 171 ALR, 155 at 164.

73 Submission No 1, Department of Health (WA), *Response to Indicative Questions*, tabled at the Hearing, 28 October 2013, p4.

regulated under State law, the text of the provision will reflect the Commonwealth provisions. Some State laws will be repealed and the Commonwealth assumes the functions and powers under Part 6. The Commonwealth provisions delegate powers to Commonwealth officers. State Officers may be authorised officers under the *Cth TGA 1989* to carry out functions under Part 6.

4.13 The Commonwealth administrative law framework will apply for all matters where the Commonwealth has a function. The administrative framework will have the general characteristics of Commonwealth rather than State laws.

4.14 Executive officers of the Commonwealth Government will be able to exercise substantial discretion in the creation of regulations and legislative and procedural instruments without any input from the State.

Finding 12: The Committee finds that there is an absence of opportunity for the Western Australian Minister for Health or the Western Australian Parliament to influence or amend Part 6 of the Bill and does not give sufficient regard to the sovereignty of the State Parliament.

Proportionality

4.15 The Bill will regulate the activities of a small number of traders a year. The Department said:

> *the failing of this national law within an individual state means that Western Australians are potentially not protected from harmful therapeutic goods. Each year, there [are] a small number of therapeutic goods identified and produced within WA that make unsubstantiated claims. The government and the department have no specific powers to make a supplier rescind misleading claims or to cease trading of a dangerous good. These are usually traditional or complementary medicines that contain scheduled poisons or unscheduled chemical substances*.[74]

4.16 The Committee considered existing 'legislative regimes' to regulate sole traders. The question in the Committee's mind is one of proportionality and whether the adoption of over 577 pages of *Cth TGA 1989* is a necessary or only protection available. The Department illustrated the need for such legislation by referring to the lack of legislative protections to regulate sole traders (natural persons) who promote unsafe cancer cures or treatments.

[74] Department of Health (WA), *Transcript of Evidence*, 28 October 2013, pp2-3.

4.17 As stated earlier in the report and at paragraph 4.8, the Western Australian Parliament passed amendments[75] to the *Fair Trading Act 2010* (WA) incorporating the legislative reforms of the Commonwealth Australian Consumer Law as part of WA law. These amendments provide a mechanism to prosecute sole traders who make false or misleading representations in relation to (manufactured) goods or services to the public. The Committee notes that prior to the enactment of the ACL, the ACCC prosecuted companies making claims in relation to cancer treatment cures.[76] Witnesses for the Department of Health (WA) were unable to fully explain the operation of the ACL (WA) to regulate sole traders who manufacture goods or provided services. The Committee notes the submission to the AHMAC (at **Appendix 6**) identifying the regulatory work of the ACCC.[77]

Finding 13: The Committee finds that there no legislative impediments to the operation of the ACL (WA) to regulate sole traders supplying or manufacturing therapeutic goods.

Clause 77 Terms Used

4.18 Clause 77 reads as:

> ***77. Terms used***
>
> *In this Part —*
>
> **Commonwealth administrative laws** *means —*
>
> *(a) the following Acts —*
>
> *(i) the Administrative Appeals Tribunal Act 1975 (Commonwealth);*
>
> *(ii) the Freedom of Information Act 1982 (Commonwealth);*
>
> *(iii) the Ombudsman Act 1976 (Commonwealth);*
>
> *(iv) the Privacy Act 1988 (Commonwealth);*

75 *Fair Trading Amendment Act 2013*.

76 (Refer http://www.accc.gov.au/media-release/accc-takes-criminal-proceedings-against-discredited-cancer-therapist), viewed on 13 November 2013.

77 Australian Competition and Consumer Commission's Submission to the AHMAC on options for the regulation of unregistered Health Practitioners 2011 details the role of the ACCC in investigations, refer to http://www.ahmac.gov.au/cms_documents/pdf/No%20150%20-%20Australian%20Competition%20and%20Consumer%20Commission.pdf

and

(b) the regulations in force under those Acts;

Commonwealth authority *has the meaning given in the Therapeutic Goods Act 1989 (Commonwealth) section 3;*

Commonwealth Minister *means the Minister under the Therapeutic Goods Act 1989 (Commonwealth);*

Commonwealth officer *has the meaning given in the Therapeutic Goods Act 1989 (Commonwealth) section 3;*

Commonwealth Secretary *means the Secretary as defined in the Therapeutic Goods Act 1989 (Commonwealth) section 3;*

confer *includes impose.*

4.19 The Commonwealth's *Acts Interpretation Act 1901* (refer to Clause 80) applies for the purposes of interpreting Part 6 of the Bill only. The *Interpretation Act 1984* (WA) therefore has no application to the clauses in Part 6 of the Bill.

4.20 Clause 77 effectively excludes the Western Australia Parliament from monitoring and oversight of Commonwealth Executive functions in Part 6. Bearing in mind that State Public Sector employees will be implementing the provisions, the arrangements will provide two masters – the Commonwealth and the State. The constitutional ambiguity this creates is unacceptable. It also raises a further question – which Minister is accountable to which Parliament and for what functions?

Finding 14: The Committee finds that Clause 77 excludes the Western Australian Parliament from monitoring and oversight of Commonwealth Executive functions in Part 6 of the Bill.

4.21 The Departmental witnesses expressed the view that disallowance provisions are contained in Clause 78 of the Bill.

Clause 78 Application of Therapeutic Goods Law

4.22 Clause 78 reads as follows:

78. Application of Therapeutic Goods Law

(1) For the purposes of this section, the Therapeutic Goods Law (Commonwealth) text consists of —

(a) the Therapeutic Goods Act 1989 (Commonwealth); and

(b) all regulations, orders and manufacturing principles in force under that Act.

(2) The Therapeutic Goods Law (Commonwealth) text, as in force from time to time and as modified under this Part —

(a) applies as a law of this jurisdiction; and

(b) as so applying may be referred to as the Therapeutic Goods Law (WA); and

(c) as so applying, is part of this Act.

(3) The Therapeutic Goods Law (Commonwealth) text so applies as if it extended to —

(a) things done or omitted to be done by persons who are not corporations; and

(b) things done or omitted to be done in the course of trade or commerce within the limits of Western Australia.

(4) Regulations made under section 148[78] *may modify the Therapeutic Goods Law (Commonwealth) text for the purposes of this section.*

4.23 The Committee considered the construction of the Clause 78 as discussed below.

4.24 Clause 78(1)(b) includes all *regulations, orders and manufacturing principles in force under that Act*. Regulations are subject to tabling and therefore subject to scrutiny and disallowance provisions by Parliamentary committees. In this regard, the Commonwealth Parliament has the power to scrutinise Commonwealth regulations - not the Western Australian Parliament. Orders and manufacturing principles are characterised as Executive decisions and are not instruments for scrutiny under disallowance provisions.[79]

[78] Clause 148 refers to the general power of the Governor to make regulations.

[79] However, Clause 80(b) allows '*regulations, orders and manufacturing principles in the Therapeutic Goods Law (WA, whether or not modified by the regulations, are to be taken to be regulations, orders or manufacturing principles under a Commonwealth Act*.'

4.25 The Western Australian Parliament is denied oversight or scrutiny of any amendments to Commonwealth regulations, orders or manufacturing principles. It also highlights the accountability deficits inherent in the Bill.

4.26 When asked what role the State Minister for Health will have to amend legislation, regulations, orders or manufacturing principles (of a single Trans-Tasman regulatory model), the Department stated:

> *It is assumed that if the Commonwealth Government proceeded to pursue (and ratify) a formal Treaty with New Zealand, the State Minister for Health would have no role in the new Scheme to amend legislation, regulations or manufacturing [principles] notices and orders.*[80]

Finding 15: The Committee finds that if the Treaty with New Zealand is ratified, the State Minister for Health will not have a role in the new scheme to amend legislation, regulations or manufacturing principles, notices and orders.

4.27 Clause 78 (1) (b) and (2) specify the date of the regulations, orders and manufacturing principles in force *from time to time*. This would allow the Commonwealth Executive to make amendments without the views or input of the Western Australian Parliament.

4.28 Currently, amendments to manufacturing principles are made by the delegate of the Commonwealth Minister for Health who is authorised to make determinations and publish these determinations relating to the Therapeutic Goods Manufacturing Principles on the Therapeutic Goods Authority website. This means that a delegate of the Commonwealth Executive or a delegate of the State may make determinations that may impact this State without the Western Australian Parliament having any mechanism to scrutinise future or proposed amendments to these 'instruments'.

4.29 The Committee holds the view that the Western Australian Parliament would have greater scrutiny if all *instruments* cited in the provision had the words '*in force at the time'* be inserted into the clause. This approach is consistent with the general approach or protocols for drafting legislation (as recommended by Parliamentary Counsel):

> *Western Australia has taken a policy decision that it will not generally adopt the legislation of other jurisdictions as in force from time to time (other jurisdictions make similar decisions on particular legislative projects). When applied laws legislation used for national*

[80] Letter from the Minister for Health, Hon Kim Hames MLA, Attachment 1 from the Department of Health (WA), 10 January 2014, p2.

> *uniform legislation, Western Australia (and those other jurisdictions) will enact consistent legislation and keep it up to date by subsequent amending legislation when the template legislation is amended.*[81]

4.30 Amending the Clause would allow the Western Australian Parliament to consider new Commonwealth amendments at the time they are passed by the Commonwealth.

Recommendation 7: The Committee recommends that clause 78(1)(b) be amended to read "all regulations, orders and manufacturing principles in force at the time under that Act". This may be effected in the following manner:

Page 57, line 8 – to insert between 'force' and 'under' - at the time

4.31 Under Clause 78(3), the Department informed the Committee:

> *the Bill confers powers to the extent it adopts the Cth TGA [1989] to apply to things done or omitted to be done by persons who are not corporations and things done or omitted to be done in the course of trade or commerce within the limits of Western Australia.*[82]

4.32 This means the Commonwealth, Minister, Commonwealth Secretary or their delegates will be empowered to undertake activities associated with the regulation of the Therapeutic Goods Law in Western Australia. Again, the State Minister for Health will not have a function and the Western Australian Parliament will not be able to scrutinise amendments before they are passed by the Commonwealth.

4.33 The Department identified Clause 78 (4) as a way to modify the text of Commonwealth law.

> *Sub clause 78 (4) provides for the altering of the (actual) text of the Cth TGA by regulation. This particular provision would be Western Australia's Henry VIII clause equivalent.*
>
> *If disallowance were to occur, this would result in Commonwealth law as the Therapeutic Goods Law (WA) being adopted in its original form. Disallowance of Western Australian made regulations to override Commonwealth law would appear to be counter intuitive to*

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81 Parliamentary Counsels' Committee, *Protocol on Drafting National Uniform Legislation*, 2008, Third Edition, p2.

82 Submission No 1, Department of Health (WA), *Response to Indicative Questions*, tabled at the Committee's Hearing, 28 October 2013, p9.

> *the objectives of the Standing Committee on Uniform Legislation and Statutes Review.*
>
> *In practical terms, in adopting the actual text in the first instance, the relevant State Minister, on the authority of the Governor would regulate to amend, modify or delete specific provision of the Therapeutic Goods Law (WA).* [83]

4.34 Clause 78(4) is a Henry VIII clause. Henry VIII clauses are regulations that alter the effect or modify the principal Act:

> *Henry VIII clause is a generic clause for a section in an Act of Parliament that enables the Act or another Act to be amended by subordinate legislation made by the Executive. It is the power given to the executive to override the intention of parliament expressed in an Act that causes consternation over the use of Henry VIII clauses.*[84]

4.35 This response from the Department of Health (WA) infers that the State Minister should simply adopt the actual text even if it is a Henry VIII clause. The Parliament of Western Australia is opposed to the inclusion of Henry VIII clauses, which extend, narrow, amend or evade an Act. As a general premise, the Committee does not support the adoption of Henry VIII clauses.

Finding 16: The Committee finds that Clause 78 does not provide adequate scrutiny by the Western Australian Parliament of regulations, orders and manufacturing principles introduced by the Commonwealth and is inconsistent with State Sovereignty.

Finding 17: The Committee finds that Clause 78(4) is a Henry VIII clause and constitutionally invalid.

Recommendation 8: The Committee recommends that Clause 78(4) be deleted.

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83 Letter from the Chief Pharmacist, Department of Health (WA), Attachment 1 entitled *Response to Questions of 29 October 2013*, 4 November 2013, p2.

84 Western Australia, Standing Committee on Public Administration and Finance Report tabled March 2002 on the *Planning Appeals Amendment Bill 2001*.

Clause 79 Exclusion of legislation of this jurisdiction

4.36 Clause 79 excludes the oversight function of key State legislation. The utility of Commonwealth internal oversight is brought into question.

4.37 Clause 79 reads as:

> ***79. Exclusion of legislation of this jurisdiction***
>
> *The following Acts of this jurisdiction do not apply to the Therapeutic Goods Law (WA) —*
>
> *(a) the Auditor General Act 2006;*
>
> *(b) the Financial Management Act 2006;*
>
> *(c) the Freedom of Information Act 1992;*
>
> *(d) the Interpretation Act 1984;*
>
> *(e) the Parliamentary Commissioner Act 1971;*
>
> *(f) the Public Sector Management Act 1994;*
>
> *(g) the State Records Act 2000.*

4.38 This provision effectively voids any scrutiny by, accountability to, monitoring or oversight by the Western Australian Parliament. There is no effective mechanism in this provision in Part 6 for the State to scrutinise the operations of the Therapeutic Goods Law. This provision directly undermines the sovereignty of the Western Australian Parliament.

Finding 18: The Committee finds that Western Australian administrative law does not have an oversight function for Part 6 of the Bill.

Clause 80 Interpretation of Therapeutic Goods Law (WA)

4.39 Clause 80 reads as:

> ***80. Interpretation of Therapeutic Goods Law (WA)***
>
> *The Acts Interpretation Act 1901 (Commonwealth) applies as a law of this jurisdiction in relation to the interpretation of the Therapeutic Goods Law (WA) and for that purpose —*

> *(a) the statutory provisions in the Therapeutic Goods Law (WA), whether or not modified by the regulations, are to be taken to be a Commonwealth Act; and*
>
> *(b) the regulations, orders and manufacturing principles in the Therapeutic Goods Law (WA), whether or not modified by the regulations, are to be taken to be regulations, orders or manufacturing principles under a Commonwealth Act.*

4.40 The Committee notes that orders and manufacturing principles are Executive decisions and not ordinarily subject to procedures for scrutiny and disallowance by the Commonwealth Parliament.

4.41 In accordance with the treatment taken to incorporate ACL law into Western Australian law, the Committee further recommends certain legislative instruments be cited in a new Clause in the Bill.

4.42 In this way, the Bill may have a mechanism to consider and disallow instruments made by the Commonwealth.

Recommendation 9: The Standing Committee recommends the insertion of a new clause headed "*Certain instruments to be published, and may be disallowed by Parliament*" under Part 6, Division 2. This clause shall list all the Commonwealth regulations, orders and manufacturing principles relating to this section and the requirement to place notices in the Government Gazette. This may be effected in the following manner:

Page 97, after line 5- to insert-

regulations made under the *Therapeutic Goods Act 1989* (Commonwealth);

manufacturing principles made under the *Therapeutic Goods Act 1989* (Commonwealth);

order made under the *Therapeutic Goods Act 1989* (Commonwealth);

declarations of the Secretary made under the *Therapeutic Goods Act 1989* (Commonwealth).

Clause 82 Application of Commonwealth Administrative Laws to the Therapeutic Goods Law (WA)

4.43 Clause 82 reads as:

> ***82. Application of Commonwealth administrative laws in relation to Therapeutic Goods Law (WA)***
>
> *(1) The Commonwealth administrative laws apply as laws of this jurisdiction to any matter arising in relation to the Therapeutic Goods Law (WA) and for that purpose a matter arising in relation to the Therapeutic Goods Law (WA) —*
>
> *(a) is to be taken to be a matter arising in relation to a law of the Commonwealth in the same way as if the Therapeutic Goods Law (WA) were a law of the Commonwealth; and*
>
> *(b) is to be taken not to be a matter arising in relation to a law of this jurisdiction.*
>
> *(2) Subsection (1) has effect except as prescribed by the regulations.*

4.44 The wording of Clause 82(1)(b) is confusing. The Committee recommends the wording as drafted by New South Wales at s33E(4) of their Act:

> ***33 E Application of Commonwealth Administrative Law to Applied provisions***
>
> *(4) Any 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.*[85]

Recommendation 10: The Committee recommends that clause 82(1)(b) be deleted and a new subsection be inserted. This may be effected in the following manner:

Page 59, lines 13 to 14 – to delete the lines and insert

(b) Any 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.

[85] Refer to s33E of the NSW *Poisons and Therapeutic Goods Act 1966* (NSW).

Clause 83 Functions and Powers conferred on Commonwealth officers and authorities

4.45 Clause 83 is read as:

> ***83 Functions and powers conferred on Commonwealth officers and authorities***
>
> *(1) A Commonwealth administrative law that confers on a Commonwealth officer or Commonwealth authority a function or power is to be taken to confer on the officer or authority the same function or power for the purposes of a matter arising in relation to the Therapeutic Goods Law (WA).*
>
> *(2) In performing a function or exercising a power conferred by subsection (1), the Commonwealth officer or authority must act as nearly as practicable as the officer or authority would act in performing or exercising the same function or power for the purposes of a matter arising in relation to a Commonwealth Act.*

4.46 This clause delegates functions and powers to an officer or authority. The Committee is unclear on the operation of the clause and notes that the State Minister would not be accountable for the delegated activities of Commonwealth officers and authorities.

Clause 86 Functions and Powers of Commonwealth Minister

4.47 Clause 86 reads as:

> ***86 Functions and powers of Commonwealth Minister***
>
> *The Commonwealth Minister has, for the purposes of a matter arising in relation to the Therapeutic Goods Law (WA), the same functions and powers as that Minister has under the Therapeutic Goods Act 1989 (Commonwealth) and the regulations, orders and manufacturing principles in force under that Act.*

4.48 The Committee noted that the State Minister for Health does not have powers and functions under Part 6 of the Bill.

Clause 87 Functions and Powers of Commonwealth Secretary

4.49 Clause 87 reads as:

> ***87. Functions and powers of Commonwealth Secretary***

> *(1) The Commonwealth Secretary has, for the purposes of a matter arising in relation to the Therapeutic Goods Law (WA), the same functions and powers as that Secretary has under the Therapeutic Goods Act 1989 (Commonwealth) and the regulations, orders and manufacturing principles in force under that Act.*
>
> *(2) Without limiting subsection (1), the Commonwealth Secretary has the function of including goods in the Australian Register of Therapeutic Goods kept under the Therapeutic Goods Law (WA) and is authorised to cancel the inclusion of goods in the Register in accordance with those provisions.*

4.50 Clause 87 prescribes the function of the Commonwealth Secretary to include goods in the Australian Register of Therapeutic Goods (**ARTG**) kept under the Therapeutic Goods Law (WA).

4.51 The Secretary is also authorised to cancel the inclusion of goods in the Register in accordance with those provisions. The State Minister does not have this function in the Bill. The Commonwealth Secretary will be able to cancel a good manufactured or provided by a sole trader or a corporation in Western Australia.

4.52 Rights of review of ARTG decisions are made through the Commonwealth. The Committee holds the view that the Western Australian Parliament would have diminished sovereignty in relation to decisions made regarding goods on the ARTG. The Committee was unable to identify a mechanism by which the State Minister for Health could include a product or good on the ARTG or approval for a good not to be included on the ARTG.

4.53 The Committee notes that the Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013 proposes changes to the *Cth TGA 1989* that extends the powers of the Commonwealth Secretary in relation to therapeutic goods on the ARTG.

Clause 88 Functions and Powers of other persons

4.54 Clause 88 states:

> ***88. Functions and powers of other persons***
>
> *(1) In this section —*
>
> **authorised person** *has the meaning given in the Therapeutic Goods Act 1989 (Commonwealth) section 3.*

> *(2) An authorised person has, for the purposes of a matter arising in relation to the Therapeutic Goods Law (WA), the same functions and powers as the person has under the Therapeutic Goods Act 1989 (Commonwealth) and the regulations, orders and manufacturing principles in force under that Act.*

4.55 Clause 88 allows authorised persons to carry out functions. Clause 88(1) defines an *authorised person* as that described in s3 of *Cth TGA 1989*.

4.56 Section 3 of the *Cth TGA 1989* reads as:

> *s3*
>
> *"**authorised person**" means:*
>
> *(a) in relation to any provision of this Act, a person authorised by the Secretary to exercise powers under that provision; or*
>
> *(b) in relation to a provision of Part 6-2, a member of the Australian Federal Police, or a Customs officer exercising powers in a Customs place (within the meaning of section 183UA of* the *Customs Act 1901).*

4.57 The effect of these provisions under Clause 88 means that Commonwealth officers have delegated authority to exercise specific powers to conduct investigations and inspect premises.

4.58 The Committee is unclear on the role (if any) of State officers carrying out specific functions.

Clause 92 Conferral of functions on Commonwealth Director of Public Prosecutions

4.59 Clause 92 reads as:

> ***92. Conferral of functions on Commonwealth Director of Public Prosecutions***
>
> *The Director of Public Prosecutions for the Commonwealth (the* **Commonwealth Director***) may —*
>
> *(a) institute prosecutions on indictment for indictable offences under the Therapeutic Goods Law (WA); and*

(b) carry on prosecutions of the kind referred to in paragraph (a) (except prosecutions instituted by the Attorney General or the Director of Public Prosecutions of this jurisdiction), whether or not instituted by the Commonwealth Director; and

(c) if the Attorney General or the Director of Public Prosecutions of the State requests the Commonwealth Director in writing to carry on a prosecution of the kind referred to in paragraph (a) that was instituted by the Attorney General or the Director of Public Prosecutions of this jurisdiction — carry on the prosecution; and

(d) institute proceedings for the summary conviction of persons in relation to offences under the Therapeutic Goods Law (WA); and

(e) carry on proceedings of a kind referred to in paragraph(d) (whether or not instituted by the Commonwealth Director); and

(f) do anything incidental or conducive to the performance of any of the functions referred to in paragraphs (a) to (e).

4.60 Clause 92 empowers and prescribes a process by which the Commonwealth Director of Public Prosecutions (**Cth DPP**) may institute prosecution of individuals under the *Therapeutic Goods Law* (WA). The State Attorney General or State Director of Public Prosecutions may on written request to the Cth DPP carry on a prosecution.

4.61 The Committee noted that this is a legislative drafting option that is intended to maintain the Constitutional powers of the State, but still allows referral to the Commonwealth to prosecute.

Clause 93 Relationship with other State laws

4.62 Clause 93 reads as:

93. Relationship with other State laws

(1) Despite any other provision of this Part or the Therapeutic Goods Law (WA), the regulations may provide —

(a) that a specified enactment has effect despite the Therapeutic Goods Law (WA), or a specified provision of the Therapeutic Goods Law (WA); or

(b) that the Therapeutic Goods Law (WA), or a specified provision of the Therapeutic Goods Law (WA), applies as a law of Western Australia with modifications prescribed by the regulations; or

(c) that a specified provision of the Therapeutic Goods Law (WA) that would otherwise apply by virtue of Division 2 does not apply as a law of Western Australia.

(2) Subject to subsection (3), regulations under subsection (1) (b) or (c) may, if the regulations so provide, have retrospective effect on or from the day on which the relevant provision of the Therapeutic Goods Law (WA) applied (or would otherwise have applied) as a law of this jurisdiction.

(3) To the extent that regulations take effect under subsection (2) on or from a date that is earlier than the date of their publication in the Gazette, the regulations do not operate so as —

(a) to 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 the date of publication; or

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

4.63 The Explanatory Memoranda[86] states that Clause 93 provides that the State may make regulations that may counter or modify the impact or application of the Therapeutic Goods Law (WA). This is a *Henry VIII* Clause.

4.64 As identified earlier at paragraph 4.34, Henry VIII clauses affect the sovereignty and function of a parliament to legislate and to scrutinise legislation.

[86] Explanatory Memoranda, 17 October 2013,p29.

> *... A Henry VIII clause is the term given to a provision in a primary Act which gives the power for secondary legislation (regulations) to include provisions which amend, repeal or are inconsistent with the primary legislation. The effect of a Henry VIII clause is that whoever makes the regulations has been delegated legislative power by the Parliament. In other words, the executive arm of government would have the power to make regulations which can modify the application of the primary statute.*[87]

4.65 The Committee also expressed concern as to whether the regulations (at Clause 93(2)) would authorise the making of delegated legislation by the Commonwealth that over-rides or alters the scope or application of the primary legislation. This is an unsatisfactory position and one that is not supported by the Committee.

4.66 The Department of Health (WA) identified Clause 93(2) as applying retrospectivity:

> *The only application of retrospectivity in the Bill occurs at Clause 93(2) and (4). These two sub-clauses provide for the State to retrospectively modify, amend or delete certain provisions within the Therapeutic Goods Law (WA) by way of regulation in order to modify, minimise or eliminate the impact on natural persons manufacturing.*[88]

4.67 The Committee is opposed to any provision that introduces law to be applied retrospectively.

4.68 The Department's answer also created confusion about the drafting of the Bill and whether a sub clause was inadvertently left out as the Bill does not contain Clause 93 (4).

4.69 The Committee notes that Clause 93(3)(a) and (b) is a *boiler plate* provision expressed similar to that found in other legislation previously before the House.

Clause 148 General power to make regulations

4.70 Clause 148 reads as:

> ***148. General power to make regulations***

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87 *Rule of Law* Institute of Australia http://lsa.net.au/wcb-content/uploads/lsa/files/2011/Henry%20VIII%20clauses.pdf viewed on 22 October 2013.

88 Letter from the Chief Pharmacist, Department of Health (WA), Attachment 2, *Response to Questions of 29 October 2013*, 4 November 2013, p5.

> *(1) The Governor may make regulations prescribing all matters that are required or permitted by this Act to be prescribed, or are necessary or convenient to be prescribed for giving effect to the purposes of this Act.*
>
> *(2) The regulations may —*
>
> *(a) provide that a contravention of a regulation is an offence; and*
>
> *(b) prescribe for such an offence a penalty not exceeding a fine of $15,000.*

4.71 The intent of the provision is to make regulations that are to give effect to the purposes of the Act.

4.72 The Committee considered the principles and conventions of statutory interpretation on the use of different words such as *provide* and *prescribe* in Clause 148 to convey different meanings.

4.73 The word '*provide*' is not defined in the Commonwealth *Acts Interpretation Act 1901*. The ordinary meaning of '*provide*' suggests a wider ambit than does '*prescribe*'. By way of contrast, under the *Interpretation Act 1984* (WA) all State regulations are disallowable instruments. The use of the term '*prescribe*' will usually guarantee that any State delegated legislation subsequently made under the provision will be a disallowable instrument and come before the Western Australia Joint Standing Committee on Delegated Legislation for scrutiny. This process of scrutiny and disallowance is not triggered if the regulations are Commonwealth regulations and if there is no mechanism in the Bill to allow scrutiny of every new amendment or instrument passed by the Commonwealth.

4.74 The Department of Health (WA) confirmed:

> *The Western Australian Parliament is unable to directly disallow a regulation regarding therapeutic goods law made by the Commonwealth.*[89]

4.75 To strengthen the mechanism for this Parliament to scrutinise and disallow regulations in the Bill when the regulation is first made and tabled, the Committee recommends the words '*in force at the time'* be included in Clause 148.

4.76 It is proposed that Clause 148(1) is amended to read as:

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[89] Letter from the Chief Pharmacist, Department of Health (WA), Attachment 1 entitled *Response to Questions of 29 October 2013*, 4 November 2013, p3.

The Governor may make regulations prescribing all matters that are required or permitted by this Act to be prescribed or convenient to be prescribed for effect to the purposes of the Act <u>in force at the time</u>.

4.77 This amendment may assist scrutiny of regulations made for provisions outside Part 6 of the Bill.

Recommendation 11: The Committee recommends that Clause 148(1) of the Bill be amended to include the words *in force at the time*. This may be effected in the following manner

Page 96, line 6 – to insert after "Act" – in force at the time

Clause 152 Review of the Act

4.78 Clause 152 reads as:

152. Review of Act

(1) The Minister is to carry out a review of the operation and effectiveness of this Act as soon as is practicable after —

(a) the fifth anniversary of its commencement; and

(b) the expiry of each 5 yearly interval after that anniversary.

(2) The Minister is to prepare a report based on the review and, as soon as is practicable after the report is prepared, cause it to be laid before each House of Parliament.

4.79 The Explanatory Memoranda provided to the Committee stated: *Review of the Act – Self explanatory.*[90] The Committee found this comment unhelpful and of limited utility to explain the operation of the review clause.

4.80 Review clauses are a mechanism for parliamentary accountability. Important consequences of a review clause are:

…parliament is not permitted to lose sight of its creation.

…it does not attempt to speculate on the years ahead on the likely state of affairs.[91]

[90] Explanatory Memoranda, 17 October 2013,p43.

4.81 The Committee is unclear, however on the parameters of the review given the different dates of proclamation and commencement of some sections of the Bill. The Committee requested information from the Department on:

- what clauses or provisions of the Bill would be reviewable by the State Minister,
- whether the State Minister had access to Commonwealth Secretary held information on therapeutic goods activities in WA, and
- the process by which the State Minister or the Commonwealth Secretary is able to report to their respective jurisdictions on matters that are scoped in the entire Bill.

4.82 The Department stated:

> *The practical application of this provision, with regard to Part 6 would be the evaluation of the effectiveness of the Therapeutic Goods Law (WA) in regulating the actions of this small group of individuals and in protecting vulnerable consumers. In undertaking this review, the assistance of the Commonwealth may be sought, however the Therapeutic Goods Administration could not be compelled to assist.*
>
> *The report would be laid before each House of the West Australian Parliament.*[92]

4.83 The Committee notes that the State Minister can only report on matters about which he or she has powers or functions. The State Minister does not have powers to report on Commonwealth activities even though they are occurring within this State if the information is not provided to the State Minister. The Commonwealth Minister is not compelled to do so, but may provide information that the State Minister may incorporate in his report. This is an unsatisfactory situation. The Committee finds that the provision limits the ability for the Parliament to receive information on the operation and impact of Part 6 of the Bill. In the absence of an IGA, there is no other mechanism to discuss any form of review of specific provisions in the uniform scheme.

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91 Thornton, GC, *Legislative Drafting*, 4th Edition, (1996), Butterworths, London, p216.

92 Letter from the Chief Pharmacist, Department of Health (WA), Attachment 1 entitled *Response to Questions of 29 October 2013*, 4 November 2013, p6.

Finding 19: The Committee finds that Clause 152 limits the ability of the Western Australia Parliament to review the operation and impact of Part 6 of the Bill (if passed).

Clause 163 Minister may exempt certain therapeutic goods from requirements of Therapeutic Goods Law (WA)

4.84 Clause 163 reads as:

> ***163 Minister may exempt certain therapeutic goods from requirements of Therapeutic Goods Law (WA)***
>
> *(1) The Minister may, by notice published in the Gazette, exempt a therapeutic good from a requirement of the Therapeutic Goods Law (WA) if the Minister is satisfied that —*
>
> *(a) the therapeutic good was being manufactured in Western Australia before commencement day; and*
>
> *(b) the continued manufacture and use of the therapeutic good will not pose a risk to the health, safety and welfare of a person or of the public.*
>
> *(2) A notice under subsection (1) must —*
>
> *(a) describe with reasonable particularity the therapeutic good to which it applies; and*
>
> *(b) specify the requirements of the Therapeutic Goods Law (WA) that do not apply in respect of the therapeutic good; and*
>
> *(c) specify the period for which the exemption applies; and*
>
> *(d) specify any conditions to be complied with in respect of the manufacture, supply or use of the therapeutic good.*

4.85 This provision is a saving and transitional provision and has no application in terms of modifying regulations relating to Part 6 of the Bill. This provision applies to goods manufactured in WA before commencement day and where the continued manufacture and use of the therapeutic good will not pose a risk to health, safety or welfare of a person or of the public.

4.86 The Committee holds the view that this provision does not modify the operation of the Commonwealth Therapeutic Goods Law and any future amendments by the Commonwealth should the Bill be passed.

Other Matters Raised in Submissions

4.87 The Committee received a submission from the Veterinary Surgeons' Board raising concerns in relation to Clause 143. Whilst this submission fell outside the Committee's Terms of Reference, the Committee notes the concerns expressed by the Board. **Appendix 8** considers the issues of averment clauses.

CONCLUSION

4.88 The Committee addressed a number of threshold issues:

1. Whether the State of Western Australia entered into and signed an Intergovernmental Agreement for the Bill;

2. Whether the Intergovernmental Agreement specifies the powers and functions of the State in relation to Therapeutic Goods Law;

3. The extent to which clauses of the Intergovernmental Agreement are reflected in the Bill;

4. The extent to which the Explanatory Memoranda and the Second Reading Speech provide sufficient explanation and detail to the House and the Committee on the Therapeutic Goods Law and the Bill;

5. The extent to which other regulatory schemes cover the field;

6. Whether clauses of the Bill impact the sovereignty and law making powers of the Parliament; and,

7. Whether there are sufficient protections and/or mechanisms in the Bill to allow for the Western Australian Parliament to scrutinise future amendments proposed by the Commonwealth.

4.89 The Committee did not receive documentary evidence of a signed formal IGA for this Bill. This is an unsatisfactory finding of the inquiry. Discussions occurred at COAG and AHMC to adopt Therapeutic Goods Law in an out-of-session process. COAG also endorsed the development of a Trans-Tasman Treaty or Agreement with New Zealand for a single regulatory body (ANZTPA).

4.90 At the time the Bill was tabled, the House was not informed of the considerable work to establish ANZTPA. The Second Reading Speech and Explanatory Memoranda

were silent on the ANZTPA and the substantial reforms of the *Cth TGA 1989* currently underway. This raised a concern for the Committee.

4.91 The current timetable for the ANTZPA implementation is 2016 (and if the Treaty is ratified) will mostly likely require the repeal of the *Cth TGA 1989*. It is insufficient to say that the Treaty is not ratified – thereby implying that no action is being taken. The arrangement for a joint regulatory body with New Zealand is well underway.

4.92 The Commonwealth has a legislative reform program for the *Cth TGA 1989* that has not been fully explained to the Committee. The repeal of the *Cth TGA 1989* in two years has implications for the current Bill being proposed.

4.93 As it stands, the Bill proposes that the Commonwealth Minister and delegates will have responsibility for the Therapeutic Goods Law. The State Minister will not have any powers or functions under Part 6 to scrutinise amendments to regulations, orders and manufacturing principles (and other legislative instruments) made by the Commonwealth Minister or their delegate.

4.94 The Committee considered matters of proportionality and whether the applied law was necessary as other legislation (ACL (WA)) appears to cover the field. The incorporation of over 577 pages of *Cth TGA 1989* (including regulations, orders and manufacturing principles) into Western Australian law is a disproportionate remedy to the protection sought for consumers from the activities of a handful of sole traders.

4.95 The Committee found there was insufficient explanation given to the interaction of the Australian Consumer Law with the proposed Therapeutic Goods Law. The Committee holds the view that there is no impediment to the operation of the ACL (WA) to regulate sole traders. The Committee is satisfied that if the Bill is not passed, that the ACL (WA) operates as a sufficient regulatory mechanism to cover sole traders.

4.96 Western Australia will have little oversight, scrutiny or parliamentary review of any of the administrative matters in Part 6. Bearing in mind that State Public Sector employees will be implementing the provisions, the arrangements will provide two masters – the Commonwealth and the State. The constitutional ambiguity this creates is unacceptable.

4.97 The review function of the State Minister to report to the Western Australian Parliament is limited and does not cover Part 6 of the Bill.

4.98 It is the Committee's view that provisions contained in Part 6 of the Bill challenge the law making powers and sovereignty of the Western Australian Parliament. There are few mechanisms within Part 6 of the Bill that enable this Parliament to scrutinise a range of legislative instruments.

4.99 The Committee therefore proposes amendments to strengthen opportunities for the Western Australian Parliament to scrutinise Commonwealth amendments.

4.100 Without a formal IGA, the State is not bound to incorporate all clauses of the Bill. There is scope to amend the Bill without triggering a breach of the terms of an IGA.

4.101 The Committee is of the view that the Bill does not do what it purports to do - that the only way to achieve the stated aims of the Bill is for the Bill to be withdrawn for the purpose of amendment.

Recommendation 12: The Committee recommends the Medicines, Poisons and Therapeutic Goods Bill 2013 be withdrawn for the following reasons:

1. **A formalised IGA for the introduction of Therapeutic Goods Law does not exist. The introduction of a uniform scheme is based on general provisions of the National Competition Principles Agreement. The Committee did not receive a signed copy of this Agreement.**

2. **The Treaty/Agreement for the ANZTPA provides that the new Australia New Zealand regulatory body will commence in 2016 and will require the repeal of the *Cth TGA 1989*.**

3. **The repeal of the *Cth TGA 1989* will impact Part 6 of the Bill (if passed).**

4. **The Legislative Council was not informed of the new regulatory body (ANZTPA) and its likely impact on sole traders in Western Australia.**

5. **Part 6 of the Bill impacts the sovereignty and law making powers of the Western Australian Parliament.**

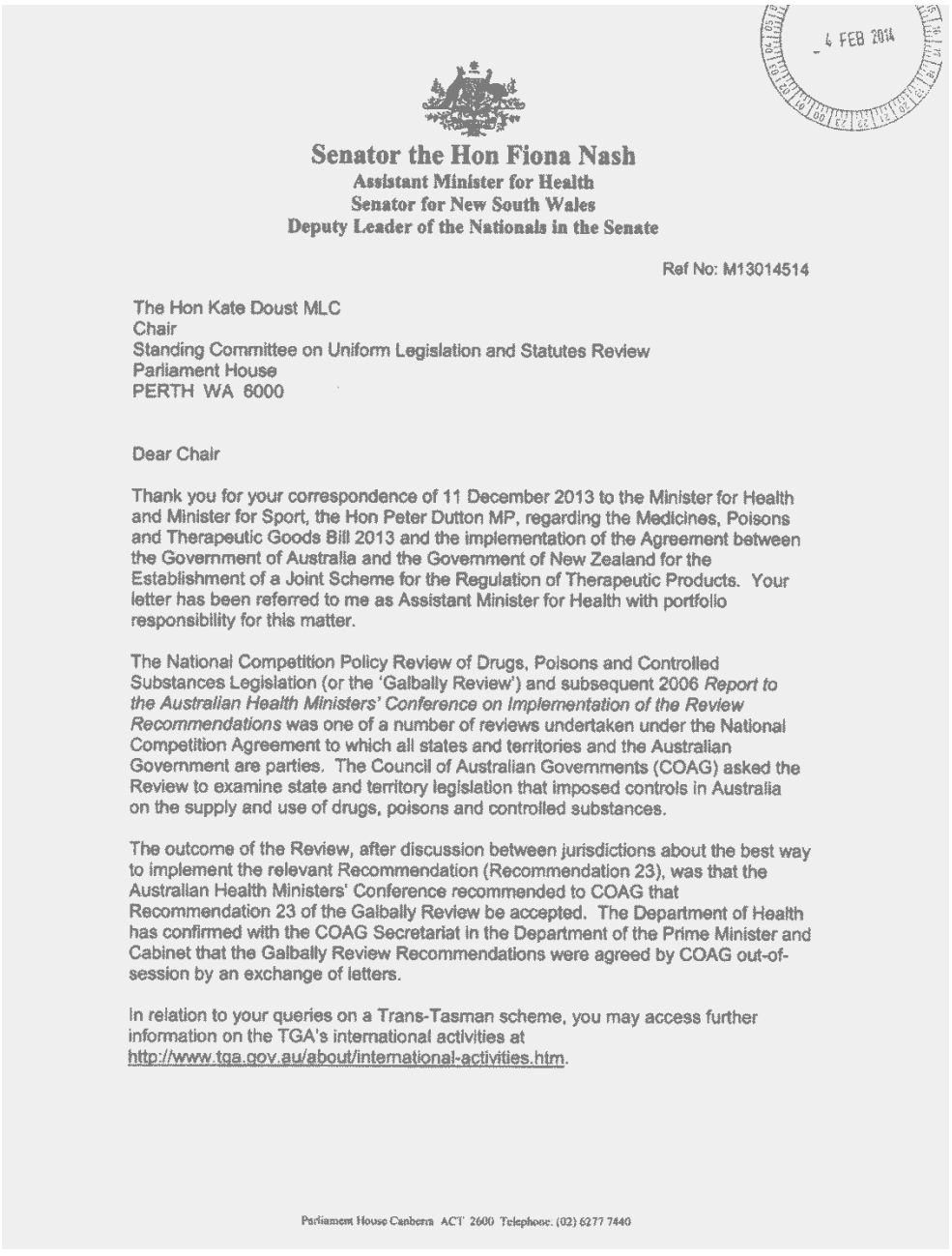
6. **The Western Australian Minister for Health does not have a review function in relation to the operation of Part 6 of the Bill.**

7. **The Commonwealth is currently amending key provisions (16 Schedules) of the *Cth TGA 1989* that includes amendments to the term 'therapeutic good'. The Committee was not able to consider the impact of the new amendments on this Bill.**

Hon Kate Doust MLC
Chair
18 February 2014

APPENDIX 1

LETTER FROM COMMONWEALTH ASSISTANT MINISTER FOR HEALTH 4/2/2014



4 FEB 2014

Senator the Hon Fiona Nash
Assistant Minister for Health
Senator for New South Wales
Deputy Leader of the Nationals in the Senate

Ref No: M13014514

The Hon Kate Doust MLC
Chair
Standing Committee on Uniform Legislation and Statutes Review
Parliament House
PERTH WA 6000

Dear Chair

Thank you for your correspondence of 11 December 2013 to the Minister for Health and Minister for Sport, the Hon Peter Dutton MP, regarding the Medicines, Poisons and Therapeutic Goods Bill 2013 and the implementation of the Agreement between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products. Your letter has been referred to me as Assistant Minister for Health with portfolio responsibility for this matter.

The National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation (or the 'Galbally Review') and subsequent 2006 *Report to the Australian Health Ministers' Conference on Implementation of the Review Recommendations* was one of a number of reviews undertaken under the National Competition Agreement to which all states and territories and the Australian Government are parties. The Council of Australian Governments (COAG) asked the Review to examine state and territory legislation that imposed controls in Australia on the supply and use of drugs, poisons and controlled substances.

The outcome of the Review, after discussion between jurisdictions about the best way to implement the relevant Recommendation (Recommendation 23), was that the Australian Health Ministers' Conference recommended to COAG that Recommendation 23 of the Galbally Review be accepted. The Department of Health has confirmed with the COAG Secretariat in the Department of the Prime Minister and Cabinet that the Galbally Review Recommendations were agreed by COAG out-of-session by an exchange of letters.

In relation to your queries on a Trans-Tasman scheme, you may access further information on the TGA's international activities at http://www.tga.gov.au/about/international-activities.htm.

Parliament House Canberra ACT 2600 Telephone: (02) 6277 7440

You also inquired about the Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013 (the Bill) which was introduced into the House of Representatives on 12 December 2013. A copy of the Bill, including the Explanatory Memorandum and first and second reading speeches explaining each of the amendments is available on www.aph.gov.au.

I trust this information is of assistance.

Yours sincerely

FIONA NASH

APPENDIX 2

LIST OF SUBMISSIONS

No	Name	Date
1	Letter from the Minister for Health, Hon Kim Hames, MLA	4 September 2013
2	Submission 1, Staff from the Department of Health (WA) tabled at the Committee's hearing on 28 October 2013.	28 October 2013
3	Letter from the Chief Pharmacist, Department of Health	4 November 2013
4	Letter from the Veterinary Surgeons' Board of WA	7 November 2013
5	Letter from Dr Richard Choong, President, Australian Medical Association, Western Australia	12 November 2013
6	Letter from the Minister for Health, Hon Kim Hames, MLA	18 November 2013
7	Letter from the Minister for Health, Hon Kim Hames, MLA	20 November 2013
8	Letter from the Minister for Health, Hon Kim Hames, MLA	21 November 2013
9	Letter from the Minister for Health, Hon Kim Hames, MLA	10 January 2014
10	Letter from the Assistant Minister for Health (Cth), Hon Fiona Nash	4 February 2014

APPENDIX 3

LETTER TO THE PRIME MINISTER 13/9/2004

Premier of Western Australia

JH37992

Our Ref: 200409647

The Hon John Howard MP
Prime Minister of Australia
House of Representatives
Parliament House
CANBERRA ACT 2600

Dear Prime Minister

RESPONSE TO THE GALBALLY REVIEW – ENDORSEMENT BY COAG OUT OF SESSION

Thank you for your letter dated 10 July 2004, seeking out of session endorsement by the Council of Australian Governments (COAG), of the Australian Health Ministers' Conference working party response to the Galbally review of drugs, poisons and controlled substances legislation.

I endorse the working party response and your proposal to publish the response along with the final report of the Galbally Review.

I note that the area of drugs, poisons and controlled substances legislation was included in the Commonwealth Treasurer's 2003 competition payments suspension pool for outstanding review and reform obligations, not only for Western Australia but also for all States and Territories except New South Wales.

It is expected that the current delay in COAG consideration of the working party's response to the Galbally review will mean that the issue will not be included as a competition payments penalty in the Commonwealth Treasurer's decisions on competition payments for 2004.

Yours sincerely

DR GEOFF GALLOP MLA
PREMIER

13 SEP 2004

197 St George's Terrace, Perth, Western Australia 6000
Telephone (08) 9222 9888 Facsimile (08) 9322 1213 Email: wa-government@dpc.wa.gov.au
www.premier.wa.gov.au

APPENDIX 4

AUSTRALIA NEW ZEALAND THERAPEUTIC PRODUCTS AGENCY (ANZTPA)

Extract from the ANZTPA website.[93]

THE ANZTPA PROJECT

About the trans Tasman therapeutic products agency project

Related information

- Milestones of the ANZTPA project

On 10 December 2003, the Australian and New Zealand Governments signed an agreement to establish a joint regulatory scheme for therapeutic products.

The joint scheme will regulate medicines (including complementary medicines) and medical devices and is expected to come into force on the passage of legislation and ratification of the treaty.

On this page

What is the project about?

The trans Tasman therapeutic products agency project has involved New Zealand and Australia giving consideration to establishing a joint agency to regulate therapeutic products (medicines, medical devices and complementary medicines/dietary supplements that have therapeutic uses) in both countries.

The decisions of the Australian and New Zealand Governments to establish a trans Tasman agency to regulate therapeutic products have moved the project into a new phase. This phase of the project sees the development of the final details of the regulatory framework and the legislation underpinning the joint agency, the treaty between Australia and New Zealand, and the transitional arrangements to create a new agency.

[93] ANZTPA website, http://www.anztpa.org/about/anztpa_project.htm (viewed on 13 February 2013).

- **Text of the treaty:** Agreement between the Government of Australia and the Government of New Zealand for the establishment of a joint scheme for the regulation of therapeutic products

- Other documents relating to the treaty

Why are we establishing a trans Tasman therapeutic products agency?

The key objectives in establishing the Agency are to:

- Establish a trans Tasman regulatory scheme for therapeutic products that will safeguard public health and safety in Australia and New Zealand by regulating therapeutic products and maintain an effective and sustainable regulatory capacity in both countries; and

- Resolve the special exemption for therapeutic products under the Trans Tasman Mutual Recognition Arrangement (TTMRA) in a manner that facilitates trans Tasman trade and enhances Closer Economic Relations between Australia and New Zealand.

The establishment of a trans Tasman agency is also likely to lead to closer cooperation between countries and regulators in the Asia-Pacific region.

1.1.1. Trans Tasman Mutual Recognition Arrangement

The TTMRA is an arrangement between the Australian Commonwealth, State and Territory governments and the government of New Zealand. The TTMRA seeks to remove regulatory barriers and facilitate trade between Australia and New Zealand.

The differences between the New Zealand and Australian systems for regulating therapeutic products were sufficient to necessitate a special exemption to the TTMRA that allowed officials time to assess options to resolve the need for a special exemption.

The options identified for resolving the special exemption were mutual recognition, permanent exemption and harmonisation of regulatory systems.

Australian and New Zealand Health Ministers agreed that harmonisation of regulatory systems was likely to be the best option. The establishment of a trans Tasman therapeutic products agency will deliver a harmonised approach with the flow on benefits of lowering trade barriers between Australia and New Zealand and enhancing CER.

1.1.2. Regulatory capacity

Regulatory Impact Assessments undertaken by the New Zealand Institute of Economic Research (NZIER) in 2000 and 2002 confirmed that New Zealand's current system for regulating therapeutic products is not sustainable. New Zealand does not have sufficient capacity in terms of technical expertise to continue to evaluate the risks and benefits of increasingly complex high risk products (such as medicines of biological origin). Such expertise is in demand internationally and is scarce in some disciplines. Australia may face a similar challenge to its regulatory capacity in the longer term.

- National Interest Analysis on the Agreement Between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products (March 2004)

- New Zealand Regulatory Impact Statement (September 2003)
- New Zealand Regulatory Impact Statement on a proposal for a trans Tasman agency to regulate therapeutic products (November 2002)
- Assessment of regulatory options for therapeutic products - report to the trans-Tasman working group (October 2002)

What will form the basis of the new agency?

The new Agency will replace the Australian Therapeutic Goods Administration (TGA) and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe), and be accountable to the Australian and New Zealand Governments. It will be recognised in law in both Australia and New Zealand and assume responsibility for the regulatory functions currently undertaken in both countries.

What will the agency do?

The role of the Agency will be to safeguard public health and safety through regulation of the quality, safety and efficacy or performance of therapeutic products in both Australia and New Zealand.

The regulatory activities of the agency will include:

- pre-market evaluation and assessment;
- product licensing;
- controls on manufacture;
- post-market monitoring and surveillance; and
- setting standards.

A risk-based approach will be taken so that the level of regulation is commensurate with the level of risk associated with the products.

What are the advantages of having a trans Tasman therapeutic products agency?

The Agency has a number of benefits for both countries. The Agency will:

- assist in creation of a single market for therapeutic products;
- facilitate trade and reduce compliance costs by replacing dual regulatory processes with harmonised regulatory requirements;
- strengthen each country's regulatory capacity to meet a new wave of innovative therapeutic products which are being driven by emerging technologies and globalisation; and
- ensure consumers have early access to new products entering the market, while maintaining confidence in public health and safety.

How will the agency be set up?

The Agency will:

- have a distinct legal identity and be recognised in the legislation of both countries;
- be established, and operate, in accordance with key principles set out in a Treaty between the two countries;
- be directly accountable to both Ministers and to both Parliaments;
- deliver common regulatory outcomes and have the authority to implement and enforce laws in both countries;
- operate subject to the ability of either country to depart from the joint regulatory scheme. This will apply in extraordinary circumstances, under agreed criteria and within agreed timeframes and will include a process for the future resolution of issues that have led to a separate decision; and
- be subject to common regulatory review and appeal mechanisms that are suitable for therapeutic products and provide access for industry in both countries.

The Agency will be overseen by a two-member Ministerial Council comprising the New Zealand Minister of Health and the Australian Health Minister. The Agency will also have a five member Board. A Treaty will establish the Ministerial Council and the Board of the agency. The Board will be responsible for the strategic direction and financial management of the Agency. One of the Board members, the Managing Director, will be responsible for regulatory decisions about therapeutic products and for the day to day management of the Agency. The Board and the Managing Director will be appointed by the Ministerial Council.

The framework for the regulatory scheme administered by the Agency will be set up under the Treaty and implemented through Acts of Parliament in both countries, a single set of Rules made by the Ministerial Council, and technical Orders made by the Managing Director.

1.1.3. Accountability arrangements

It has been agreed that a fundamental requirement for the joint agency must be that the Agency has no lesser accountability to Ministers, Parliaments, industry and the public than is currently the case for Medsafe and the TGA. Work continues on further defining accountability requirements for the Agency, such as:

- procedures for appropriate stakeholder input into, and parliamentary scrutiny of, initial and subsequent legislation, including Rules and Orders;
- review of regulatory decisions;
- annual, corporate and financial planning;
- access to official information;
- privacy requirements; and
- human rights/anti-discrimination regimes.

Stakeholder consultation

Since 1998 there has been extensive consultation with industry, health professionals and consumer groups on the proposal to establish a joint therapeutic products agency.

Consultation will continue with key stakeholders, especially on the final proposals for the establishment and implementation of a joint regulatory scheme.

Discussion documents and other reports and documents designed to keep stakeholders informed on developments towards the establishment of a joint agency can be found on this website. Stakeholders should regularly check the website for new information and updates on progress towards establishing the trans Tasman agency.

APPENDIX 5

EXTRACT FROM THE COMMONWEALTH THERAPEUTIC GOODS ACT 1989

6AAA Commonwealth consent to conferral of functions etc. on its officers and authorities by corresponding State laws

(1) A corresponding State law may confer functions or powers, or impose duties, on:

(a) a Commonwealth officer; or

(b) a Commonwealth authority.

(2) Subsection (1) does not authorise the conferral of a function or power, or the imposition of a duty, by a corresponding State law to the extent to which:

(a) the conferral or imposition, or the authorisation, would contravene any constitutional doctrines restricting the duties that may be imposed on Commonwealth officers or Commonwealth authorities; or

(b) the authorisation would otherwise exceed the legislative power of the Commonwealth.

(3) Subsection (1) does not extend to a function, power or duty of a kind specified in regulations made for the purposes of this subsection.

(4) This Act is not intended to exclude or limit the operation of a corresponding State law that confers any functions or powers, or imposes any duties, on a Commonwealth officer or Commonwealth authority to the extent to which that law:

(a) is consistent with subsections (1) to (3); and

(b) is capable of operating concurrently with this Act.

6AAB When duty imposed

Application

(1) This section applies if a corresponding State law purports to impose a duty on a Commonwealth officer or Commonwealth authority.

State legislative power sufficient to support duty

(2) The duty is taken not to be imposed by this Act (or any other law of the Commonwealth) to the extent to which:

(a) imposing the duty is within the legislative powers of the State concerned; and

(c) imposing the duty by the corresponding State law is consistent with the constitutional doctrines restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority.

Note: If this subsection applies, the duty will be taken to be imposed by force of the corresponding State law (the Commonwealth having consented under section 6AAA to the imposition of the duty by the corresponding State law).

Commonwealth legislative power sufficient to support duty but State legislative powers are not

(3) If, to ensure the validity of the purported imposition of the duty, it is necessary that the duty be imposed by a law of the Commonwealth (rather than by force of the corresponding State law), the duty is taken to be imposed by this Act to the extent necessary to ensure that validity.

If, because of subsection (3), this Act is taken to impose the duty, it is the intention of the Parliament to rely on all powers available to it under the Constitution to support the imposition of the duty by this Act.

(5) The duty is taken to be imposed by this Act in accordance with subsection (3) only to the extent to which imposing the duty:

(a) is within the legislative powers of the Commonwealth; and

(b) is consistent with the constitutional doctrines restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority.

(6) To avoid doubt, neither this Act (nor any other law of the Commonwealth) imposes a duty on the Commonwealth officer or Commonwealth authority to the extent to which imposing such a duty would:

(a) contravene any constitutional doctrine restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority; or

(b) otherwise exceed the legislative power of the Commonwealth.

(7) Subsections (1) to (6) do not limit section 6AAA.

6AAC Imposing duty under State law

(1) This section:

(a) applies only for the purposes of the application of the provisions of this Act or another law of the Commonwealth (with or without modification) as a law of a State by a provision of a corresponding State law; and

(b) does not apply for those purposes if the corresponding State law otherwise provides.

(2) If the corresponding State law purports to impose a duty on a Commonwealth officer or Commonwealth authority to do a particular thing, the duty is taken to be imposed by the corresponding State law to the extent to which imposing the duty:

(a) is within the legislative powers of the State; and

(c) is consistent with the constitutional doctrines restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority.

(3) To avoid doubt, the corresponding State law does not impose the duty on the Commonwealth officer or Commonwealth authority to the extent to which imposing the duty would:

(a) contravene any constitutional doctrine restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority; or

(b) otherwise exceed the legislative powers of the State.

(4) If imposing on the Commonwealth officer or Commonwealth authority the duty to do that thing would:

(a) contravene any constitutional doctrine restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority; or

(b) otherwise exceed the legislative powers of both the State and the Commonwealth;

the corresponding State law is taken instead to confer on the officer or authority a power to do that thing at the discretion of the officer or authority.

6AAD Conferral of jurisdiction on federal courts

If:

(a) a provision of a corresponding State law purports to apply a provision of a law of the Commonwealth (the ***applied provision***) as a law of the State; and

(b) the applied provision purports to confer jurisdiction in relation to a matter on a federal court;

the jurisdiction in relation to that matter is taken to be conferred on the court by this section.

6AAE Consequences of State law conferring duty, function or power on Commonwealth officer or Commonwealth authority

(1) If a corresponding State law confers on a Commonwealth officer or Commonwealth authority:

(a) the function of including goods in the Register; or

(b) the power to include goods in the Register;

the officer or authority may include the goods in the Register in accordance with the corresponding State law.

(2) If a corresponding State law authorises or requires a Commonwealth officer or Commonwealth authority to cancel the inclusion of goods in the Register, the officer or authority may cancel the inclusion of the goods in the Register in accordance with the corresponding State law.

(3) The inclusion of goods in the Register under subsection (1) does not subject any person to any liability whatever under this Act, except a liability under Part 6-1.

(4) A Commonwealth officer or Commonwealth authority may make any notations in the Register that the officer or authority considers necessary to identify entries that relate to goods included in the Register under subsection (1).

(5) Goods may be included in the Register under subsection (1) even though the same goods have already been included in the Register under another provision of this Act.

(6) A reference in this section to the inclusion of goods in the Register is a reference to the inclusion of the goods:

(a) in the part of the Register for goods known as registered goods; or

(b) in the part of the Register for goods known as listed goods; or

(ba) in the part of the Register for biologicals included under Part 3-2A; or

(c) in the part of the Register for medical devices included under Chapter 4.

6B Review of certain decisions under State laws

(1) Application may be made to the Administrative Appeals Tribunal for review of a reviewable State decision.

(2) A decision made by the Secretary in the performance of a function, or the exercise of a power, conferred by a corresponding State law is a reviewable State decision for the purpose of this section if:

(a) the law under which the decision was made provides for review by the Administrative Appeals Tribunal; and

(b) the decision is declared by the regulations to be a reviewable decision for the purposes of this section.

(3) For the purposes of subsection (1), the *Administrative Appeals Tribunal Act 1975* has effect as if a corresponding State law were an enactment.

6C Fees payable to Commonwealth under State laws

(1) This section applies to fees payable to the Commonwealth under a State law in respect of the performance or exercise of functions or powers conferred by that law on the Secretary.

(2) The Secretary may make arrangements with the appropriate authority of a State, of the Australian Capital Territory or of the Northern Territory in relation to the payment to the Commonwealth of fees to which this section applies.

7A Authorised persons

The Secretary may, in writing, authorise any of the following persons to exercise powers under a specified provision of this Act:

(a) an officer of the Department, of another Department or of an authority of the Commonwealth;

(b) an officer of:

(i) a Department of State of a State; or

(ii) a Department or administrative unit of the Public Service of a Territory; or

(iii) an authority of a State or of a Territory;

being a Department, unit or authority that has functions relating to health matters or law enforcement matters.

APPENDIX 6

ACCC SUBMISSION TO AHMAC

ACCC submission to Australian Health Ministers' Advisory Council's (AHMAC) Consultation on options for regulation of unregistered health practitioners 2011

Executive Summary

While a fundamental tenet of AHMAC's current consideration is the difference in powers/ambit/roles of various regulators and private citizens when it comes to registered health practitioners (RHP) and unregistered health practitioners (UHP), the ACCC does not face similar constraints in exercising its enforcement powers under the *Competition and Consumer Act 2010* (the Act) (formerly the *Trade Practices Act 1974* (TPA)) and the Australian Consumer Law (ACL) which is a schedule to the Act.[1]

The ACCC has a long history of targeting those who could be considered 'rogues' such as those identified in the consultation paper as well as those practitioners who may be well-intentioned but ultimately ill-informed. The ACCC has done so through its enforcement and compliance powers in line with its policies and priorities, often resulting in valuable health messages being passed on to the Australian community.

This submission outlines the functions of the ACCC, its role and experience with industry codes of conduct and outlines its compliance and enforcement activities in the health sector.

Role of the ACCC

The ACCC is an independent statutory authority established to enforce and encourage compliance with the Act. The purpose of the Act is to enhance the welfare of Australians by promoting competition among businesses and fair trading by businesses and providing for the protection of consumers in their dealings with business, including against misleading and deceptive conduct and anti-competitive conduct.

In the administering the Act, the ACCC has a dual role as:

- a national enforcement agency, and;
- a provider of education and information for business (including the professions) and consumers in relation to compliance with the Act.

To achieve compliance with the Act the ACCC takes a flexible and integrated strategic approach, from education and liaison work through to enforcement action. In deciding what sort of action to take, the ACCC's overarching consideration is what will provide the greatest overall benefit to consumers and business – those suffering or likely to suffer harm as a result of any offending conduct.

A large component of the ACCC's work is directed towards preventing breaches from occurring. This is done by educating industry, the professions and consumers about their rights and obligations under the Act. The ACCC's education work can take the form of publications, as well as speeches, presentations and submissions.

[1] See www.consumerlaw.gov.au and www.accc.gov.au/acl for further information on the ACL.

For example, the ACCC has several publications directed towards the medical profession including the *Infokit for the medical profession 2004* which is currently under review and *Professional Associations and the Act* and *Industry Associations and the CCA* available on the ACCC's website: www.accc.gov.au

The ACCC's education work also includes hosting a Heath Services Consultative Committee (HSCC) to promote consultation and the exchange of information between the ACCC and health professionals on matters relevant to the effective administration of trade practices.

In cases, where the ACCC assesses potential risk flowing from conduct as low, the ACCC may accept an administrative resolution. Depending on the circumstances, administrative resolutions can range from a commitment by a business in correspondence to a signed agreement between the ACCC and a business setting out detailed terms and conditions of the resolution.

The ACCC also undertakes enforcement action where appropriate and necessary to underpin its compliance objectives. The ACCC has varied and extensive enforcement powers, recently enhanced by amendments to the Act. These powers are detailed in the ACCC's publication *Business snapshot: ACCC powers to issue notices* and include powers to issue infringement, substantiation and public warning notices.

Legal action is taken where, having regard to all the circumstances, the ACCC considers litigation is the most appropriate way to achieve its enforcement and compliance objectives. The ACCC is more likely to proceed to litigation in circumstances where the conduct is particularly egregious, where there is reason to be concerned about future behaviour or where the party involved is unwilling to provide a satisfactory resolution.

As the national enforcement agency tasked with ensuring compliance with and taking action against breaches of the national competition and consumer laws, the ACCC is guided by its *Compliance and enforcement policy* which takes account of such factors as widespread consumer detriment, market failure and blatant disregard for the law in selecting which matters to pursue and how.

Consumer protection issues

Misleading and deceptive conduct and misleading representations

Section 18 of the ACL requires that in operating a professional practice, health practitioners, like other business people, have an obligation not to make representations which mislead or deceive consumers. This includes patients, as consumers of medical products and services.

Broadly speaking, conduct will be considered misleading if specific representations are inaccurate, or the overall impression conveyed is likely to mislead the people at whom it is directed. This may include intentionally misleading patients, leading them to a wrong conclusion, creating a false impression, leaving out important information, hiding or omitting to raise important information such as fine print disclaimers and making false or inaccurate claims.

As well as the general rule against misleading conduct, the ACL also creates obligations in relation to representations practitioners make about their services and in respect of any goods

they may sell as part of their medical practice. The ACL prohibits practitioners from falsely representing, amongst other things:

- that services or goods are of a particular standard, quality, value, grade, composition, style or model, or have had a particular history or particular previous use
- that a particular person has agreed to acquire services or goods
- testimonials by any person relating to goods or services
- consumer guarantees applicable to the purchase of goods and services
- that services or goods have sponsorship, approval, performance characteristics, accessories, uses or benefits
- that a company has sponsorship, approval or affiliation
- the price or services or goods
- the need for any services or goods

The provisions of the ACL that relate to misleading and deceptive conduct are relevant to all means of promoting medical services and products, including electronic and print media advertising, information brochures, direct mail, internet promotions and outdoor advertising. Care must be taken to ensure that all statements made are honest and accurate.

Companies which seek to make claims about the efficacy of their treatments must ensure that they have a reasonable basis for making such claims. The ACCC will take appropriate action, including legal action, against any company which make misleading and deceptive medical claims.

The ACCC is particularly concerned that consumers with serious diseases and might be immediately attracted to products and services that are advertised as a quick and effective cure-all for a wide range of ailments or for an undiagnosed pain. It is a real risk that a consumer may stop conventional medical treatment in place of products and services offering cures of such diseases, when in fact those claims are false, irrelevant or misleading.

ACCC messaging around potential health scams is consistent: if it sounds too good to be true, it probably is. The ACCC warns consumers to beware of such products or treatments. Phrases which may cause concern include "scientific breakthrough", "miraculous cure", "exclusive product", and "secret ingredient". Further, consumers should be cautious of testimonials claiming amazing results.

Last month (March 2011), proceedings initiated by the ACCC concluded when the court found three companies and two individuals made false claims and misled consumers about their ability to test for and treat allergies. Each claimed they could diagnose, treat and/or cure allergies using "Nambudripad's allergy elimination technique" (NAET) or similar techniques. A previous ACCC action in 2009 saw the Federal Court find Allergy Pathway Pty Ltd, had misled consumers about their ability to identify and cure allergies.

In 2009, ACCC investigations revealed that some hypnotherapists and laser clinics were making unproven and misleading claims about the success rate of their smoking addiction treatments when hypnotherapists Angelo and Susan Sette, trading as Stop Smoking in One Hour, admitted they could not substantiate advertised claims that 100 per cent of smokers successfully gave up after attending a maximum of four treatment sessions. A number of 'stop smoking' laser therapy clinics around the country also amended their advertising after the ACCC raised concerns about claims that the laser technology.

In 2006, the Menopause Institute of Australia admitted misleading and deceiving its patients and potential customers about the safety and effectiveness of its Natural Hormone Replacement Therapy Program for the treatment of menopause, as part of a court settlement.

These representations included that NHRT: reduced the risk of cancer, heart disease, Alzheimer's disease and senility; was without dangerous, unwanted, reported or any side effects; treated osteoporosis, premenstrual syndrome and loss of libido; had a reduced risk of breast cancer and stroke in comparison to conventional; was proving to be much safer than conventional HRT; and was just as effective as conventional HRT.

Testimonials

Testimonials are statements from previous customers about their experience with a product or service. These can give consumers confidence in a product or service on the basis that another person, particularly a celebrity or well-known person, is satisfied with the goods or services. It is unlawful for a business to make a misleading testimonial.

In March 2010, misleading advertising claims about an alleged anti-snoring ring were withdrawn by the manufacturer and supplier after ACCC intervention. More than 200,000 consumers worldwide are understood to have sought relief from the Anti Snore Therapeutic Ring, The company's website claimed the ring had a 'proven history of successful drug free treatment of snoring' and was 'Tested and recommended by a Physician'. The ACCC raised concerns that these claims were likely to mislead consumers to believe that the product had proven medical outcomes in treating snoring, sinus, restless sleep and insomnia when this was not so.

In 2004, the ACCC instituted legal proceedings against Advanced Medical Institute Pty Ltd (AMI), Mr Philip Somerset of Colby Co Media, and Mr Ian Turpie alleging misleading and deceptive conduct in relation to the advertising and promotion of the nasal spray form of treatments for erectile dysfunction (impotence).

The ACCC alleged that AMI breached the TPA in an advertisement that represented Mr Turpie had undertaken an interview during which he disclosed, in the presence of his wife, that he was losing his sexual potency, and the AMI nasal delivery system had cured Mr Turpie of the effects of impotence or erectile dysfunction and improved his sexual potency.

Consumer guarantees

The ACL imposes certain consumer guarantees upon suppliers of consumer goods (including medical devices) and services (including health and wellbeing services) supplied to consumers .

The consumer guarantees require that goods must be of acceptable quality, fit for any disclosed purpose and match any description given, sample or demonstration model shown to the consumer prior to purchase. Repair facilities and spare parts must be reasonably available for a reasonable time, and any extra warranty made about goods must be honoured.

Services must be provided with care and skill and achieve any purpose specified by the consumer or the service provider. Services must also be provided within a reasonable timeframe if the contract for services does not specify one.

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If a consumer guarantee is not met the consumer has a right to a remedy. The appropriate remedy depends on whether the failure to comply with the guarantee is major or minor. A major failure is one where the failure was so severe that a reasonable consumer would not have purchased the goods or services had they known of the full extent of the problem, the goods differ significantly from any description, sample or demonstration model, the goods are not of acceptable quality because they are unsafe or the services create an unsafe situation.

Where the failure to comply with the guarantee is major, or cannot be fixed in a reasonable time, the consumer is entitled to choose the appropriate remedy. If the failure to comply is minor, the supplier or service provider can choose to fix the problem.

Extensive further information on rights and remedies under the consumer guarantees regime is available from the ACCC's website at www.accc.gov.au/acl

Unconscionable conduct

The ACCC notes that a key aspect of modern medical practices is conducting business transactions, negotiations and transactions which may be undertaken with larger and stronger parties including suppliers for goods or services. Conversely, the inherent information asymmetry between practitioner and patient leads to special concerns and responsibilities.

Unconscionable conduct involves the harsh or oppressive exploitation of a weaker party by a stronger one that goes beyond normal hard commercial or professional dealings and offends good conscience. The provisions contained in Part 2-2 of the Act relating to unconscionable conduct cover: commercial and professional dealings between business; and consumer transactions

When deciding a case involving unconscionable conduct involving consumer transactions for example, the court may take into account a range of circumstances in determining whether a health practitioner has been involved in unconscionable conduct. It may consider:

- the relative bargaining strengths of the parties;
- whether undue influence, pressure or unfair tactics were used;
- whether there was the imposition of conditions not reasonably necessary to protect the doctors legitimate interests;
- whether the consumer understood any documentation used
- how much the consumer would have had to pay and under what circumstances, to buy equivalent goods or services from another doctor.

The judicial meaning of unconscionable conduct is dependent of the circumstances of the case but the courts, in considering the issue, have described unconscionable conduct as: something being clearly unfair and unreasonable; conduct which shows no regard for conscience; and conduct which is irreconcilable with what is right or reasonable.

In December 2010, the ACCC commenced proceedings against AMI, AMI Australia Holdings Pty Ltd, James Vandeleur, Jacov Vaisman and Brian Lonergan for alleged unconscionable conduct in the promotion and supply of medical services and medications for men suffering from erectile dysfunction. The case remains before the court.

In 2007, the Federal Court declared that cancer cure and other claims promoted by several NuEra companies under The RANA System breached the TPA. The RANA System was described as "*an alternative approach to cancer care which offers HOPE to cancer sufferers*". Representations of concern were to the effect that the RANA System and/or the NuEra Products could cure cancer, or reverse, stop or slow its progress.

It was of particular concern to the ACCC that the case involved unconscionable conduct towards persons suffering from terminal cancer and that significant sums of money were extracted from these persons and their families on the basis of false hopes that the sufferers could be cured or their lives prolonged.

Competition issues

Industry codes of conduct

An association can make rules regarding the behaviour of individual practitioners and impose sanctions if these standards are not met. Many professional bodies choose to do this by requiring their members to comply with a code of conduct and/or ethics that is usually drafted and enforced by that association.

The ACCC has considerable experience in the use of codes of conduct to regulate market behaviour. Effective codes can potentially assist in achieving compliance with the Act; deliver increased consumer protection and reduce regulatory burdens for business. In contrast, ineffective codes may place compliance burdens on business without any realisable benefits and potentially make signatories to it less competitive.

Effective voluntary codes of conduct must be well designed, effectively implemented, administered and properly enforced. The ACCC publication *Guidelines for developing effective voluntary codes of conduct* provides guidance to assist industries and professional associations develop and implement effective voluntary codes of conduct.

Codes of conduct developed by professional associations can benefit members not only by assisting with broader compliance but also by giving their services added credibility through accreditation and an affiliation with the association. The regulation and enforcement of standards also ensures that the profession's reputation remains intact and creates greater confidence in the services provided by members of that profession. For example, it is common for association rules to regulate the dealings of professionals with their clients where their conduct may reflect on the profession (and association) more broadly. Associations also provide benefits to consumers by providing a trusted and reputable name and an avenue for recourse in the first instance should a dispute arise with a member. The ACCC is generally supportive of professional association rules that can be shown to have a benefit to consumers.

However, professional associations should ensure that the rules are transparent, that they do not relate to pricing policies and that any disciplinary procedures are not exclusionary in any way (such as restricting and reducing competition in an industry). Associations should not make rules that contravene the Act, and the ACCC has previously taken action against professional bodies that do so.

It should be noted that while the ACCC is pleased to provide guidance and assist professional associations in developing codes of conduct, it does not have powers to endorse or otherwise sign off on the effectiveness of a particular code. The ACCC is unable to provide prescriptive

comment on the status of the code or prescribe elements of the code. Associations are encouraged to seek professional advice about possible competition or consumer law issues arising out of their codes' operation as the ACCC is unable to provide legal advice.

Availability of limited immunity from ACCC action

The ACCC may authorise or allow notifications of proposed conduct to stand, where businesses seek to engage in arrangements or conduct that would otherwise breach the competition provisions of the Act when it is satisfied that the public benefit from the arrangements or conduct outweighs any public detriment.

Authorisation

The ACCC may authorise businesses to engage in certain arrangements or conduct that would otherwise breach the competition provisions of the Act when it is satisfied that the public benefit from the arrangements or conduct outweighs any public detriment.

The authorisation provides protection from legal action under the Act for the arrangement or conduct. Authorisation can be sought for a range of conduct, including that which might constitute cartel provisions, primary or secondary boycotts, and other forms of anti-competitive agreement, exclusive dealing or resale price maintenance.

It is not uncommon for associations, or groups of professionals, to lodge applications for authorisation or notification of collective bargaining arrangements, or other conduct, with the ACCC. In some cases, associations will engage in collective negotiations with relevant suppliers or businesses on their members' behalf.

An example of ACCC authorisation, with conditions, of an industry code of conduct is where Medicines Australia sought ACCC authorisation for a code of conduct to govern the activities of drug companies when they promote prescription medicines to doctors in 2007.

Notifications

Notification is a process through which parties proposing to engage in collective bargaining or exclusive dealing conduct may, by lodging a notification with the ACCC, obtain protection from legal action under the Act for the proposed conduct. The notification process differs slightly according to the conduct being notified.

Further information on authorisations and notifications is available at www.accc.gov.au

Certified Trade Marks

It is worth noting the ACCC's role in approving Certification Trade Marks (CTMs). CTMs exist under the *Trade Marks Act 1995*. Registration under the Trade Marks Act gives the owner rights and protections, including the exclusive right to use and to allow other parties to use the CTM. CTMs indicate to consumers that a product or service meets a particular standard and are usually licensed by a CTM owner for others to use in their promotions.

To be registered, CTMs require the ACCC's approval. CTMs cannot be assigned and their rules cannot be varied without ACCC approval, to stay properly registered under the Trade Marks Act.

A CTM may raise consumer protection concerns if it is apparent that the processes for testing whether goods or services meet the standards claimed are flawed. A CTM may raise a competition concern if, for example, the accreditation is a valuable attribute in the marketplace and it's possible for its owners to deny, inappropriately, objectively eligible parties a licence.

In addition to the CTM guide on the ACCC's website information is also available at IP Australia's website on its role in the CTM approval process[2].

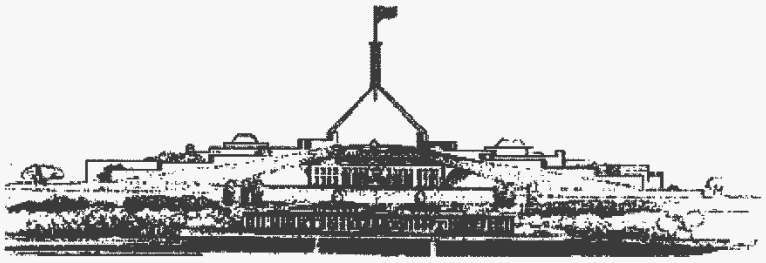
[2] http://www.ipaustralia.gov.au/resources/forms_trademarks_certrules_govern.shtml

APPENDIX 7

CTH SECOND READING SPEECH ON THE THERAPEUTIC GOODS AMENDMENT (2013 MEASURES NO. 1) 2013

COMMONWEALTH OF AUSTRALIA

PARLIAMENTARY DEBATES



HOUSE OF REPRESENTATIVES

BILLS

Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013

Second Reading

SPEECH

Thursday, 12 December 2013

BY AUTHORITY OF THE HOUSE OF REPRESENTATIVES

SPEECH

Date Thursday, 12 December 2013 **Source** House
Page 2585 **Proof** No
Questioner **Responder**
Speaker Dutton, Peter, MP **Question No.**

Mr DUTTON (Dickson—Minister for Health and Minister for Sport) (12:38): I move:

That this bill be now read a second time.

I am pleased to introduce the Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013, which amends the Therapeutic Goods Act 1989.

The purpose of this bill is to make a number of changes that will contribute to a reduction in regulation or in potential health risks to the public, improving the transparency of the regulatory scheme or providing greater clarity and certainty about the operation of the act.

An important measure included in the bill, which is the power of the minister to remove products from the operation of the Therapeutic Goods Act in appropriate circumstances, will provide a basis to address the growing trend of therapeutic claims being made for all manner of products to appeal to health conscious consumers. Jewellery, bedding and even clothing may be marketed for their claimed health or wellbeing benefits, and because of such claims, may draw those products within the regulatory scheme for therapeutic goods, a scheme which is primarily directed at the regulation of goods designed specifically to, amongst other things, ameliorate, prevent, treat or influence ailments, diseases or injuries.

This has come about because the definition of 'therapeutic goods' in the act is very wide, and may capture goods in respect of which any claim is made that it could, for example, influence or modify a physiological process in persons. Claims made that a good will influence a person's wellbeing, physical attributes or mood could well bring those products within the description of 'therapeutic goods' and attract regulation under the act.

New section 7AA will allow the minister to remove such products from the regulatory scheme for therapeutic goods, and reduce unnecessary or inappropriate regulation of goods that are caught by the act only because of claims made about them, particularly where any concerns about the nature and extent of those claims may be more appropriately dealt with under other existing regulatory schemes, such as the consumer protection laws.

In making decisions to remove products from the operation of the act, the minister must consider a number of factors, including whether it is likely that the goods in question—if not regulated under the act—might harm the health of members of the public, whether it is appropriate in all the circumstances for the goods to be regulated under the act, and whether the goods could be more appropriately dealt with under another regulatory scheme. The new section will provide the first opportunity for particular goods to be removed from the regulatory constraints of the act where those goods, for instance, do not represent a health risk, or where there may be other sound reasons for not regulating the products under therapeutic goods legislation. The Australian public should be assured that there is no intention to use this power to remove from the regulatory oversight of the TGA medicines and medical devices in relation to which standards, level of assessment for marketing approval and post market monitoring and compliance under the act is appropriate.

Any decision to exclude particular goods from the operation of the act will be by way of a legislative instrument, and will be subject to parliamentary scrutiny and where appropriate will involve industry and public consultation.

Consistent with this approach of ensuring that the focus of regulation under the act remains directed at products that have a genuine public health focus, the bill also includes a power for the secretary to remove goods from the Australian Register of Therapeutic Goods where they are not, in fact, therapeutic goods.

Such goods can find their way into the register where sponsors of low-risk products, such as complementary medicines, include goods that may be, for instance foods, into the register by means of electronic listing without pre scrutiny by the TGA.

A new power will allow the secretary to remove those products from the register but only after the sponsor has been afforded an opportunity to make submissions and any decision is subject to internal and, indeed, external review by the Administrative Appeals Tribunal.

Another measure that will have the effect of reducing regulation is the removal of the offence provisions directed at applicants seeking marketing approval for

their therapeutic goods who fail to provide information required by the TGA about their goods. The application of these offence provisions to such applicants is unnecessary because if an applicant fails to respond to a requirement to provide information this could lead to a refusal to grant marketing approval for the applicant's goods, and this will mean that the goods may not be lawfully manufactured or supplied.

Other measures that reduce regulation include expanding the scope of the definition of a 'kit' which will allow a greater range of products to be subject to a simpler regulatory approval process, and amendments to allow the reversal of cancellation decisions done at the request of sponsors and holders of licences thus avoiding review procedures or the need to seek new marketing approval or licences.

To assist industry with complying with current regulatory requirements, a number of changes have been made to clarify the operation of existing provisions in the act.

One of those is the reference to the obligation to comply with requirements relating to advertising applicable under the act and regulations. An amendment has been included to clarify that these advertising requirements include complying with applicable provisions of the Therapeutic Goods Advertising Code, a document that sets out rules for the advertising of therapeutic goods. Among other things, this requirement to comply with 'advertising requirement' forms one of the criteria for determining whether goods should be included in the register and whether goods should be removed from the register because of non-compliance with this requirement. Information about compliance with advertising requirements may also be required from sponsors of therapeutic goods applying to include their goods in the register or who have goods already included in the register.

The process by which higher risk medicines are registered in the register has been made clearer, with changes to the act that clarify under which provisions of the act decisions to approve product information, and decisions to approve an application to register medicines, are made. Both decisions are interrelated, and the amendments clarify that, where a decision to approve an application and a decision on product information have both been made, additional administrative steps that are already required under the act must be followed before the medicine may actually be included in the register, from which time the sponsor of that medicine may then lawfully market it.

To assist with clarity and provide greater consistency, amendments have been included to address a legal anomaly to ensure that the offence for publishing or broadcasting an advertisement about therapeutic goods to the public containing a prohibited representation for a low-risk medicine (for example, a reference to the treatment of cancer) does not apply where the sponsor of the goods has been given the TGA's permission under the act to use the representation in particular circumstances. This will ensure that a sponsor with such permission will be able to use the representation in accordance with the permission without fear of committing an offence.

To reduce potential health risks to the public, two new grounds for cancelling goods from the register have been included in the bill. One of these grounds enables the TGA to cancel products from the register where the presentation of therapeutic goods is no longer acceptable. Presentation includes how the goods are named, how they are labelled and packaged, and any advertising or other informational material associated with the goods. Presentation is one of the matters that is relevant to a decision whether to include medicines and biologicals in the register. The effect of the new ground of cancellation is to ensure that this important pre-condition to the inclusion of goods in the register continues to apply while they remain in the register but will not increase the regulatory burden on compliant sponsors and is aimed solely at safeguarding public health. It should be noted in this context that the TGA already has the power under the act to cancel medicines from the register that do not comply with applicable standards such as the standard on medicine labelling and packaging.

The second ground of cancellation of goods from the register relates to a failure by a sponsor to comply with a request to provide information about its medicines after the medicine has been included in the register. This information may be required to inform the TGA about whether the medicine in question should remain in the register, or whether regulatory action should be taken in relation to that medicine because of any concerns about its safety, efficacy or quality. Again, this measure would not increase regulatory burden for compliant sponsors who respond to requests for information about their products within the required time.

Sponsors have a right to both internal and external review about decisions the TGA makes to cancel products from the register.

Currently, it is an offence or a breach of a civil penalty provision for a sponsor of complementary medicines to give false or misleading information in response to a request by the secretary for information about their goods. An amendment has been included in the bill to extend this offence to also cover all sponsors of

registered goods and other persons such as applicants for registration or listing to whom such requests for information can be made.

The bill also introduces offences and a civil penalty provision where sponsors of therapeutic goods give information that is false or misleading in a material particular in a request for approval of changes to their goods. The kinds of information that may accompany such requests can include complex and extensive scientific data about the goods, for example clinical trial results or the incidence of adverse reactions to prescription medicines. This information will often only be known to the sponsor, and can be critical to determining the quality, safety or efficacy of the goods. It is therefore important that the act contains an effective deterrence against providing false or misleading information to the TGA about goods that are being used by the Australian public.

These measures will not increase the regulatory burden on compliant sponsors but are, rather, aimed solely at safeguarding public health.

An amendment has become necessary to support the current transition arrangement for the reclassification of hip, knee and shoulder joint implants from class IIb medical devices to class III. These products were reclassified following the November 2011 inquiry by the Senate Standing Committee on Community Affairs on regulatory standards for the approval of medical devices. The proposed amendment will allow for an alternative number of days (to be prescribed in the regulations) to the current 20 working days for the secretary to decide whether to audit an application for marketing approval for a class IIb device seeking up-classification to class III and what information is required from the applicant for the purposes of undertaking that audit.

A large number of these transitional applications are expected in the lead-up to the end of the transition period on 30 June 2014. Allowing more time to determine whether an application should be audited will help ensure that the TGA can manage all the applications efficiently but will not adversely affect sponsors because their class IIb devices will remain on the register, allowing these to continue to be marketed, until their application for up-classification has been processed, providing their application is lodged before 30 June 2014. It will also help ensure that resources are not diverted from consideration of applications for other kinds of medical devices during that period.

Finally, measures that will require the TGA to publish details of cancellations of medicines on the TGA's website or in the gazette, and measures to allow the publication of decisions currently required to be published in the gazette to be published on the TGA's website, plus a new requirement for TGA to publish the outcomes of any internal review decision where the effect is to overturn a decision to suspend or cancel a product from the register, will improve transparency of the regulatory scheme established under the act.

In conclusion, the measures contained in this bill will make improvements to the regulatory scheme by making a contribution to reduction in regulation where appropriate and in potential health risks to the public, create greater transparency about decisions made under the act and assist industry by providing greater clarity, certainty and consistency in relation to the operation of the act.

Debate adjourned.

CHAMBER

APPENDIX 8

CLAUSE 143 – AVERMENT PROVISIONS

Medicines Poisons and Therapeutic Goods Bill 2013

143. Evidence of various matters

An allegation in a prosecution notice of any of the following matters is to be taken to be proved —

(a) that the prosecutor is authorised to commence the prosecution;

(b) that something is a specified substance;

(c) that at a specified time a specified substance was a poison included in a specified Schedule;

(d) that an act done in relation to a poison was done as part of the process of producing the poison or bringing it to its final state;

(e) that a document is or is not a prescription;

(f) that at a specified time a specified person was or was not any of the following —

(i) a registered health practitioner;

(ii) a veterinary surgeon;

(iii) a member of a class of person prescribed for the purposes of the definition of ***health professional*** in section 3;

(iv) a member of a class of person prescribed for the purposes of section 25;

(v) the holder of a licence of a specified kind;

(vi) the holder of a permit of a specified kind;

(vii) a corporate officer of a body corporate;

(viii) an employee or agent of another specified person;

(ix) a patient of another specified person;

(x) an investigator;

(xi) the holder of a specified office;

(g) that at a specified time a licence, permit or professional authority —

(i) did or did not authorise a specified person to manufacture, supply, use or prescribe a specified poison; or

(ii) was subject to a specified condition; or

(iii) was cancelled, suspended or for any other reason of no effect;

(h) that at a specified time —

(i) a poison was or was not packaged in a specified manner; or

(ii) a container containing a poison was or was not labelled in a particular manner;

(i) that at a specified time the name of a specified person was or was not included on the drugs of addiction record as —

(i) a drug dependent person; or

(ii) an oversupplied person.

Committee comment

Clause 143 provides when an allegation in a prosecution notice is taken to be proved. This clause is commonly known as an averment provision.

In its submission to the inquiry, the Veterinary Surgeons' Board (**Board**) [94] stated:

> *It was not clear to the Board what the intent of this section is. Some explanation would be of benefit as currently this section states that an allegation is taken to be proved which seems to negate the presumption of innocence.*

The Clause provides for a reversal of the onus of proof. At common law, it is clearly established that the burden or onus of proving every element of an offence rests with the prosecution[95]. Under the Criminal Code of Western Australia, it is accepted that the

94 Refer to Submission No 4 from Veterinary Surgeons' Board, 7 November 2013, p2.

95 Refer example *DPP v United Telecasters* (1990) 91 ALR, 5 citing *Woolmington v Director of Public Prosecutions* [1935] AC 462, pp481-482.

Woolmington rule applies. Clause 143 allows statements of fact made by the prosecution to be accepted as proved unless the defendant brings evidence before the Court to rebut them.[96]

Clause 143 specifies the list of items whereby the onus of proof is on the defendant to refute (on the balance of probabilities) that the item is as listed. In the context of Commonwealth legislation, the courts have concluded that averment provisions do not place the legal burden of proof on the defendant because the prosecution still must prove each element of the offence to establish that the offence was committed beyond reasonable doubt.

If there is evidence to cast doubt on the averment and the whole of the case is not established beyond reasonable doubt, the defendant must be acquitted.[97] The Committee notes the substantial debate regarding averment provisions. The House of Representatives Standing Committee on Legal and Constitutional Affairs in 2004 noted that there is considerable potential for abuse of these provisions as they go against fundamental principles requiring the prosecution to prove every element of its case to the appropriate standard.[98]

The Committee agrees with the Board's submission that the public and stakeholders should be informed of the operation of the Clause.

96 Commonwealth Parliament, House of Representatives, Standing Committee on Legal and Constitutional Affairs, *Modern Day Usage of Averments in Customs Prosecutions*, May 2004, pp1-2.

97 J.D. Heydon, C*ross of Evidence*, Seventh Australian Edition, Butterworths, Australia, 2004, p255.

98 Commonwealth Parliament, House of Representatives, Standing Committee on Legal and Constitutional Affairs, *Modern Day Usage of Averments in Customs Prosecutions*, May 2004, pp1-2.