Government of **Western Australia**
Department of **Health**
ABN 28 684 750 332

Pharmaceutical Services Branch

Your Ref: MPT
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Hon Kate Doust
Chair
Standing Committee on Uniform Legislation and Statutes Review
Parliament House
PERTH WA 6000

Dear Ms Doust

Medicines, Poisons and Therapeutic Goods Bill 2013

Please find attached, responses to the questions posed in your letter of 29 October 2013.

Also enclosed is a timeline for the activities which resulted in Part 6 being included in the Medicines, Poisons and Therapeutic Goods Bill 2013.

You will note the letter at Attachment 1 is the correspondence from the Commonwealth to the Western Australian Premier. The Department continues to seek a copy of the response from the Premier to the Prime Minister and, once received, will immediately forward a copy of this document to the Committee.

An electronic copy of the documents will be provided via Mark Warner, particularly as the timeline document includes a number of weblinks.

Thank you for the opportunity to provide additional information to the Committee.

Yours sincerely

Neil Keen
CHIEF PHARMACIST

4 November 2013

Enc.

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Response to Questions

of 29 October 2013

for

Standing Committee on Uniform Legislation and Statutes Review Inquiry into the Medicines, Poisons and Therapeutic Goods Bill 2013

Departmental Officers:

Neil Keen	*Chief Pharmacist*
Jane Carpenter	*Manager, Legislation & Licensing*
Robyn Daniels	*Senior Solicitor*

1. *Disallowance Provisions*

- ***How would the disallowance provisions in the Bill work in practical terms?***

Disallowance of the *Therapeutic Goods Law (WA)* regulations would follow the same procedure as present Western Australian Parliamentary legislative and policy procedures require. The Joint Standing Committee on Delegated Legislation could move to disallow regulations made to amend, modify or delete the *Therapeutic Goods Law (WA)* which would have been created to reduce the impact of the Commonwealth *Therapeutic Goods Act* 1989 on that small group of natural persons who manufacture or supply therapeutic goods exclusively within Western Australia.

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 the objectives of the Standing Committee on Uniform Legislation and Statutes Review.

As stated in oral evidence, Clause 148 along with several provisions within Part 6 provide for the Governor to amend modify or delete the Commonwealth *Therapeutic Goods Act* 1989 (Clth TGA) by regulation as it applies to the *Therapeutic Goods Law (WA).*

i) Sub-clause 78(1) identifies the text of the Clth TGA (and its associated regulations and principles) as the appropriate Act for this section of the Bill
ii) Sub-clause 78(2) defines the adopted text as the *Therapeutic Goods Law (WA)*
iii) Sub-clause 78(4) provides for the altering of the (actual) text of the Clth TGA by regulation.

This particular provision would be Western Australia's *Henry VIII clause* equivalent.

In practical terms, in adopting the actual text in the first instance, the relevant state Minister, on the authority of the Governor could regulate to amend, modify or delete specific provision or text of the *Therapeutic Goods Law (WA).*

Future amendments by the Commonwealth to the Clth TGA law could be similarly modified or amended by regulation thus allowing for the Western Australian government to quickly react to changes in Commonwealth law.

iv) Clause 93 provides for regulation to be made <u>despite</u> the existence of the *Therapeutic Goods Law (WA)* and any modifications or specific applications that exist at the time.

In practical terms, if the original text of the Clth TGA is adopted, future amendments to the Clth TGA could be amended, modified or deleted by regulation under this Bill to apply in Western Australia.

v) Sub clauses 93(2)&(3) mitigate against the immediate impact of any future amendment to the Clth TGA that becomes the Therapeutic Goods Law (WA) if the State later makes regulation to amend, modify or delete the relevant provision.

- ***Can you illustrate your answer with the steps taken for the Parliament to disallow a regulation regarding therapeutic goods law made by the Commonwealth?***

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

The Governor (at Clause 148) in association with the relevant clauses in Part 6 may make regulation that amends, modifies or "disallows" therapeutic goods law (or regulation) made by the Commonwealth as it is adopted as the Therapeutic Goods Law (WA).

As mentioned in earlier submissions, sections 6AAA-AAE, 6B & 6C of the Clth TGA provide for the adoption of Commonwealth law into the law of States and Territories for the purposes outlined in Part 6. Importantly at sec 6AAA(4), the provision within the Clth TGA that sets out the Commonwealth's consent to the conferral of functions and powers on its officers and authorities (as Part 6 of the Bill seeks to do), it states:

1. *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 officers 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*

Section 6AAE(1)&(2) provides for the authority of a corresponding State law to "override' the Clth TGA in the inclusion or exclusion of a "(therapeutic) good" for the purpose of the register of goods under the Therapeutic Goods Law (WA). Inclusion on the register means the product conforms to appropriate, quality, efficacy and safety standards.

The Joint Standing Committee on Delegated Legislation of the Western Australian Parliament may disallow the regulations made to amend, modify or delete sections or specific provisions of the Therapeutic Goods Law (WA)

Possible scenario for "disallowance":

1. The Commonwealth government commences discussions with its Advisory Committee on Complementary Medicines to institute a more stringent regime for the regulation of a particular therapeutic good – a herbal remedy produced by indigenous peoples of the north.
2. Western Australian has a different view in relation to the impact of this product - the government, the Department of Health, consumers and/or the indigenous people deriving income from manufacturing and supplying the good.

3. Despite Western Australian stakeholder input in the consultation stage, the Commonwealth progresses with the change to the Clth TGA.
4. The resultant regulation reduces access to the low risk product and decreases choice for Western Australian consumers and dramatically increases costs for the traders and threatens their livelihood.
5. The concerns of the sole trader and consumers come to the attention of the Department of Health and the Western Australian government.
6. Department officers prepare through the Regulatory Gatekeeping Unit consultation process draft regulations for the relevant Minister.
7. The regulations amending, modifying or deleting the Therapeutic Goods Law (WA) are approved by the Governor and gazetted.
8. The regulations are submitted to the Joint Standing Committee on Delegated Legislation.
9. Clause 93(2)&(3) which provides for retrospective relief comes into play for the indigenous people deriving income from manufacturing and supplying the good.
10. Department of Health officers investigate whether there is a need to implement an alternative method of control of the product quality, efficacy and safety.

- ***How will the department be advised of new regulations made by the Commonwealth?***

The department could be advised of new regulations made under the Clth TGA through a number of mechanisms:

1. Stakeholder Notification
   i) The Commonwealth has formal processes to consult with stakeholder groups before implementing legislative changes. Department of Health officers would be part of that group.
2. Mechanistic Notification
   i) Commercial legal data bases subscribed to by the Legal and Legislative Services provide systematic alerts to their clients (the Department) on changes to any legislation so tagged.
   ii) A Commonwealth Parliament site provides a regular report (each sitting week) of the work of the Senate Standing Committee on Regulation and Ordinance - that notifies the disallowance of legislative instruments.
   iii) The ComLaw site has a facility to advise on changes to Commonwealth legislation
   iv) Departmental officers (Pharmaceutical Services Branch) subscribe to a Therapeutic Goods Administration (the agency that administers the Clth TGA) alert system that advises stakeholders of any changes to regulation under the Clth TGA.

- ***How will Western Australia participate in the process of making new regulations that will have an effect on the therapeutic goods law (WA)?***

Unlike the adoption of the Commonwealth Australian Consumer Law which impacts on the life of all Western Australians, adoption of the Clth TGA as the Therapeutic Goods Law (WA) will have an extremely narrow impact on businesses in Western Australia – perhaps three or four sole traders. However, the impact on gullible members of the community could be quite profound depending on the substances and claims made by the unregulated manufacture/supplier.

The rational for adopting by reference the Clth TGA in Part 6 of the Bill is to minimise the discrepancy in the efficacy and safety of therapeutic goods manufactured and/or supply by individuals in Western Australia compared to those (corporations) who produce such goods throughout Australia.

In the circumstances however where the Western Australian Parliament or Government requires new regulation that will have an effect on the *Therapeutic Goods Law (WA),* as outlined above and in earlier documentation, clauses 78, 82, 93 and 148 allow the Governor to make the desired regulation to change the Commonwealth law as adopted.

2. What disallowance provision is there in the Bill to disallow poisons regulations?

There is no specific disallowance provision in the Bill to disallow poisons regulations. In relation to Part 6 of the Bill alternative provisions have been included to amend or modify the regulation of therapeutic goods as Therapeutic Goods Law (WA).

3. Retrospective application of the Bill. What clauses will be retrospective?

The only application of retrospectivity in the Bill occurs at Clause 93 (2) & (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 and or trading therapeutic goods exclusively within this jurisdiction.

4. What sections of the Health Act 1911 will be amended if this Bill is passed?

As mentioned in the written submission (28 October 2013) the *Health Act 1911* will be amended considerably to remove sections related to therapeutic goods that predate the enactment of the Clth TGA. It also removed provisions that were more latterly included in the *Poisons Act* 1964.

- 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 adequate and has never been used to regulate the actions of natural persons 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.

5. *Inter-relationship between Clause 152 (Reviewing the Act) and the Commonwealth*

Reference in this clause to "the Minister" refers to the relevant state minister – the Minister for Health. Part 6 of the Bill refers to the *Commonwealth Minister* and is defined to the meaning given in the Clth TGA. Reference to the Commonwealth Minister is confined to that part of the Bill.

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 Western Australian Parliament.

Chronology of Materials Available Resulting in the Insertion of Part 6

Date	Evidence	Weblink / comments
April 1995	*Intergovernmental Agreement:* COAG* Competition Principles Agreement	http://www.coag.gov.au/node/52 Relevant clauses 5(3) (6) & (7) relating to jurisdictions reviewing legislation that may restrict competition
July 1999	National Competition Policy *Review of Drugs, Poisons and Controlled Substances* announced, review conducted under COAG Competition Principles Agreement	http://www.tga.gov.au/pdf/archive/review-galbally-050628-parta.pdf (Relevant pages 1 & 2 that link the scope and issues under consideration to national competition IGA
January 2001	Final report of above review (known as the Galbally Review) presented at AHMC#	http://www.tga.gov.au/archive/review-legislation-galbally-050628.htm Relevant point is *Recommendation 23:* *"That all Commonwealth, State and Territory jurisdictions agree that all States and Territories adopt the Therapeutic Goods Act 1989 by reference into the relevant legislation."*
February 2001	Working party of AHMAC^ established to assist AHMC prepare comments on the Galbally Review for COAG	http://www.tga.gov.au/pdf/archive/review-galbally-050628-ahmac.pdf Relevant page 3 of the report which reference preparing a report for COAG
March 2001	The Commonwealth and New Zealand governments commence discussions on a Trans-Tasman joint medicines and therapeutic goods regulatory body	http://www.tga.gov.au/archive/anztpa-121127/media.htm Relevant media release which indicates parallel process of Trans - Tasman Agreement and complementary legislation by jurisdictions
April 2003	AHMAC Working Party finalises Galbally Review recommendations	http://www.tga.gov.au/pdf/archive/review-galbally-050628-ahmac.pdf Relevant page 51 at which Recommendation 23 (mentioned above) was accepted Page 7 acknowledges the potential for a Trans-Tasman regulatory authority. NSW, Tasmania and Victoria had adopted complementary legislation.

July 2004	Out of Session endorsement of Galbally Review sought by Prime Minister from Premier Gallop.	Copy of Prime Minister's letter Attachment 1
June 2005	COAG approved AHMAC Working Party response to Galbally Review (Rec 23) in an "out- of session" process.	Copy of letter cc'd to Premier Gallop from A/Prime Minister Vaile acknowledging the endorsement of the Galbally Review (including Rec 23) Attachment 2
	Precedent for – "out of session" approval for COAG papers	http://www.coag.gov.au/about_coag Relevant point quoted below: *"COAG meets as needed, usually once or twice a year, though at times it has met up to four times in a year. COAG may also settle issues out-of-session by correspondence".*
July 2007	New Zealand suspended participation in joint therapeutic products agency	http://www.tga.gov.au/newsroom/media-2007-anztpa-070716.htm
December 2007	AHMAC considers implications of suspension of joint regulatory scheme	Department of Health briefings for this meeting state: ***The withdrawal of New Zealand from the establishment of the joint agency for therapeutic goods will result in a requirement for WA to introduce complementary therapeutic goods legislation. This can be achieved by incorporating the additional requirements in the Poisons and Therapeutics Goods Bill which is in development.*** (Name of earlier versions drafted under a previous WA government)
April 2009	Approval to recommence drafting of *Medicines, Poisons and Therapeutic Goods Bill.*	Briefings included reference to complementary therapeutic goods legislation as part of the Bill.

*COAG = Council of Australian Governments
#AHMC = Australian Health Ministers' Conference
^AHMAC = Australian Health Ministers' Advisory Council
$NCCTG = National Coordinating Committee on Therapeutic Goods. A subcommittee of AHMAC. NCCTG was chaired by National Manager of the Commonwealth Therapeutic Goods Administration and also included a member from each state and territory appointed by the relevant state/territory Health Minister. The appointed members were the Chief Pharmacist of each state/territory Department of Health or equivalent position.

Attachment 1

13707

200409647

PREMIERS

PRIME MINISTER

CANBERRA

10 JUL 2004

RECEIVED
21 JUL 2004
Corporate Information
Premier & Cabinet

The Hon Dr G I Gallop MLA
Premier of Western Australia
Governor Stirling Tower
197 St George's Terrace
PERTH WA 6000

My dear Premier

You may recall that in July 1999, the Council of Australian Governments (COAG) appointed Ms Rhonda Galbally to chair a committee to undertake a review of legislation and regulation that imposes controls over access to, and supply of, drugs, poisons and controlled substances. The report of the review was presented to the Australian Health Ministers' Conference (AHMC) in January 2001. AHMC subsequently requested an Australian Health Ministers' Advisory Council (AHMAC) working party, which consulted all jurisdictions, to develop a response. In November 2003, AHMC unanimously supported the response to the review.

At the request of the Minister for Health and Ageing, the Hon Tony Abbott MP, I am writing to you to seek out-of-session endorsement by COAG of the recommendations of the response, a summary of which you will find attached. It is proposed that the final report of the Galbally Review be published together with the AHMAC working party response.

I have written to the other Premiers and Chief Ministers in similar terms and look forward to receiving your views on this matter. I have also provided a copy of the report and the response to the President of the Australian Local Government Association for his information.

Yours sincerely

(John Howard)

FOR ANY ACTION ☐ DATE REQ'D
FOR COMMENT ☐
DRAFT RESPONSE FOR PREMIER ☐
FOR INFORMATION WHITEGOOD

Attachment 2

21903

ACTING PRIME MINISTER
CANBERRA

200509594
PREMIERS

The Hon R J Carr MP
Premier of New South Wales
GPO Box 5341
SYDNEY NSW 2001

Dear Premier

Thank you for your letter of 24 June 2005 to the Prime Minister regarding out of session COAG endorsement of the proposed response to the Galbally Review of Drugs, Poisons and Controlled Substances Legislation.

COAG has now endorsed the response, as of 28 June 2005. The National Coordinating Committee on Therapeutic Goods (NCCTG) will oversee implementation of the response and will commence a consultation process on the new arrangements shortly. That process will include industry.

You raised some concerns about recommendation 16, particularly in relation to recording of pseudoephedrine sales. The NCCTG has agreed that an appendix to a new draft scheduling standard will set out the Schedule 3 substances that all jurisdictions have agreed require mandatory recording.

States and territories will be consulted regarding the legislative arrangements for the new trans-Tasman therapeutic products agency. The draft legislation will be released for comment later in 2005.

I have provided a copy of this letter to the other Premiers and Chief Ministers and to the Minister for Health and Ageing, the Hon Tony Abbott MP.

Yours sincerely

Signed

21 JUL 2005

MARK VAILE

27 JUL 2005
Premier & Cabinet