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.

Page 14

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.

Page 14

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.

Page 15

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.

Page 25

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.

Page 27

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.

Page 40

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.**