



THIRTY-EIGHTH PARLIAMENT

REPORT 53

**STANDING COMMITTEE ON UNIFORM
LEGISLATION AND STATUTES REVIEW**

PHARMACY BILL 2010

Presented by Hon Adele Farina MLC (Chairman)

June 2010

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:

“8. Uniform Legislation and Statutes Review Committee

- 8.1 A *Uniform Legislation and Statutes Review Committee* is established.
- 8.2 The Committee consists of 4 Members.
- 8.3 The functions of the Committee are -
- (a) to consider and report on Bills referred under SO 230A;
 - (b) of its own motion or on a reference from a Minister, to consider or review the development and formulation of any proposal or agreement whose implementation would require the enactment of legislation made subject to SO 230A;
 - (c) to examine the provisions of any instrument that the Commonwealth has acceded to, or proposes to accede to, that imposes an obligation on the Commonwealth to give effect to the provisions of the instrument as part of the municipal law of Australia;
 - (d) to review the form and content of the statute book;
 - (e) to inquire into and report on any proposal to reform existing law that may be referred by the House or a Minister; and
 - (f) to consider and report on any matter referred by the House or under SO 125A.
- 8.4 For a purpose relating to the performance of its functions, the Committee may consult with a like committee of a House of the Parliament of the Commonwealth, a state or a territory, and New Zealand and similarly, may participate in any conference or other meeting.”

Members as at the time of this inquiry:

Hon Adele Farina MLC (Chairman)	Hon Liz Behjat MLC
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CONTENTS

RECOMMENDATIONS	i
1 REFERENCE AND INTRODUCTION	1
Reference	1
Introduction - Bill partially replaces <i>Pharmacy Act 1964</i>	1
2 INQUIRY PROCEDURE	2
3 UNIFORM LEGISLATION.....	2
Supporting documents identified by the Committee.....	3
4 BACKGROUND TO THE BILL.....	4
Overlap of State and Commonwealth jurisdiction	4
National Competition Policy review of pharmacy	6
National Competition Policy	6
National review of pharmacy legislation.....	7
COAG Agreement on co-ordinated regulation of pharmacy.....	8
Subsequent intergovernmental agreement as to the number of pharmacies that may be owned	9
Continuation of NCP legislative reform under National Reform Agenda	10
Relationship to Health Practitioner Regulation National Law.....	11
5 OVERVIEW OF THE BILL	12
Purpose.....	12
Provisions.....	12
Registration of pharmacy premises	12
Ownership of pharmacy limited	14
Limitation on commercial interest in pharmacy business	16
The Board.....	19
6 CONSISTENCY WITH SUPPORTING DOCUMENTS.....	22
Clause 43(e) - supermarkets.....	22
7 SOVEREIGNTY.....	23
8 PARTICULAR PROVISIONS OF THE BILL	23
Henry VIII clauses - where administrative decisions may override legislative provision.....	23
Pharmacy businesses may be exempted from premises registration requirement by Executive	23
Clauses 47 and 48.....	24
Other issues	25
Right of inspection and powers on inspection.....	26
Regulations may prohibit sale of prescribed goods.....	26
Removal of presumption of innocence.....	27
APPENDIX 1 IDENTIFIED STRUCTURES FOR UNIFORM LEGISLATION	31
APPENDIX 2 EXTRACT FROM THE COAG WORKING GROUP COMMENTARY .	35
APPENDIX 3 INVESTIGATION PROVISIONS OF THE <i>PHARMACY ACT 1964</i>.....	47

EXECUTIVE SUMMARY AND RECOMMENDATIONS FOR THE
REPORT OF THE STANDING COMMITTEE ON UNIFORM LEGISLATION AND STATUTES
REVIEW

IN RELATION TO THE

PHARMACY BILL 2010

RECOMMENDATIONS

1 Recommendations are grouped as they appear in the text at the page number indicated:

Page 15

Recommendation 1: The Committee recommends that the responsible Minister explain to the Legislative Council how the Bill expands “*ownership structures*” in respect of pharmacies in the context of sections 28 and 36 of the *Pharmacy Act 1964*.

Page 19

Recommendation 2: The Committee recommends that the responsible Minister:

- explain to the Legislative Council the rationale for the definition of “*proprietary interest*” proposed by clause 3 of the Bill in light of the recommendations of the COAG Senior Officials Working Group Commentary;
- advise the Legislative Council whether the definition of “*proprietary interest*” proposed by clause 3 of the Bill is consistent with equivalent definitions in other jurisdictions; and
- if not, advise the Legislative Council whether the definition of “*proprietary interest*” proposed by clause 3 of the Bill results in a greater limitation of ownership of pharmacies in Western Australia than in other jurisdictions.

Page 19

Recommendation 3: The Committee recommends that the responsible Minister advise the Legislative Council of the type of “*arrangements*” that it is contemplated will be prescribed under clause 3(2)(a) of the Bill.

Page 20

Recommendation 4: The Committee recommends that the definition of “*commencement day*” proposed by clause 77 of the Bill be amended to reflect the renumbering of the clauses of the Health Practitioner Regulation National Law (WA) Bill 2010. This can be effected in the following manner:

Page 44, line 17 - To delete “15(j)” and insert -

14(j)

Page 21

Recommendation 5: The Committee recommends that the responsible Minister explain to the Legislative Council:

- the purpose of, and necessity for, clause 11 of the Bill;
- the purpose of, and necessity for, clause 28(2) of the Bill;
- the purpose of, and necessity for, clause 29 of the Bill; and
- whether or not it is intended that the Board be independent of the Minister and, if so, the role of clauses 11, 28(2) and 29 in maintaining that independence.

Page 24

Recommendation 6: The Committee recommends that the responsible Minister explain to the Legislative Council the shift from prescription of conditions on registration of pharmacy premises in subsidiary legislation to conditions determined by the regulator.

Page 25

Recommendation 7: The Committee recommends that the responsible Minister explain to the Legislative Council the purpose of clause 48 of the Bill and what it is intended will constitute “*public interest*” for the purposes of that clause.

Page 25

Recommendation 8: The Committee recommends that the responsible Minister identify for the Legislative Council the provision/s of the Bill empowering the Board to:

- inspect a pharmacy for the purpose of ensuring that conditions imposed under clause 47 of the Bill are met; and
- cancel registration of a pharmacy for failure to meet conditions imposed under clause 47 of the Bill;

or, in the event there are no such provisions, explain to the Legislative Council why such provisions are not required.

Page 26

Recommendation 9: The Committee recommends that the responsible Minister explain to the Legislative Council:

- the reasons for the different inspection regime proposed by the Bill from the regime existing under the *Pharmacy Act 1964*;
- whether the regulations will prescribe any of the matters prescribed in section 31A to 31I of the *Pharmacy Act 1964* and; if so, which matters; and
- how the inspection regime proposed by the Bill will work in the absence of prescription of any matters prescribed by sections 31A to 31I of the *Pharmacy Act 1964*.

Page 27

Recommendation 10: The Committee recommends that the responsible Minister provide the House with advice as to whether clause 63(2)(b) of the Bill is restricted in its operation to prescription of pharmacy goods and services and:

- if so, identify the relevant clause/s imposing that restriction;
- if not, provide the House with the rationale for the need to regulate the sale or supply of non-pharmaceutical goods and services at a registered pharmacy in association with the practice of pharmacy; and
- if not, explain to the House the wide ambit of the delegated legislation-making power.

Page 29

Recommendation 11: The Committee recommends that the responsible Minister advise the Legislative Council of:

- the response of the courts and legal professional bodies to the removal of the presumption of innocence inherent in clauses 71(2) and 71(4) of the Bill;
- the process by which, and by whom, it will be determined that a corporation “*commit[ted] the offence*” for the purposes of clause 71(3); and
- the basis on which a court will determine that an offence is “*proved*” against a corporation for the purposes of clause 71(4).

Page 29

Recommendation 12: The Committee recommends that the responsible Minister provide the Legislative Council with the reasons for the removal of the presumption of innocence inherent in clauses 71(2), (3) and (4) of the Bill.

Page 30

Recommendation 13: The Committee recommends that, subject to a cogent explanation being provided by the responsible Minister in respect of recommendation 12, the Legislative Council amend clause 71(3) of the Bill, to remove the assumption of committal of an offence by the corporation, and not enact clause 71(4) of the Bill. This can be effected in the following manner:

Page 41, line 5 - To delete “body corporate commits an offence” and insert -

body corporate is suspected, on reasonable grounds, to have committed an offence

Page 41, line 8 - To delete “the offence was committed” and insert -

the suspected offence is believed, on reasonable grounds, to have been committed

Page 41, lines 10 to 13 - To delete the lines

Page 41, line 14 - To delete “(5)” and insert -

(4)

**REPORT OF THE STANDING COMMITTEE ON UNIFORM LEGISLATION AND STATUTES
REVIEW**

IN RELATION TO THE

PHARMACY BILL 2010

1 REFERENCE AND INTRODUCTION

Reference

- 1.1 The Pharmacy Bill 2010 (**Bill**) was introduced to the Legislative Council on 25 May 2010 by Hon Simon O'Brien MLC, Minister for Transport.¹
- 1.2 Following its Second Reading Speech, the Pharmacy Bill 2010 was referred to the Standing Committee on Uniform Legislation and Statutes Review pursuant to Standing Order 230A, which requires the Committee to report to the Legislative Council within 30 days of referral. The reporting date for the Pharmacy Bill 2010 is 24 June 2010.

Introduction - Bill partially replaces *Pharmacy Act 1964*

- 1.3 The *Pharmacy Act 1964* currently regulates the practice of pharmacy in the State by requiring registration of “*pharmaceutical chemists*” and pharmacies (premises), and licensing of pharmacy businesses. It also specifies who may own a pharmacy business and the number of such businesses that may be owned by a person. The Pharmaceutical Society of Western Australia, managed by the Pharmaceutical Council of Western Australia, is established by the *Pharmacy Act 1964* for regulatory purposes.
- 1.4 The Health Practitioner Regulation National Law (WA) Bill 2010 proposes that regulation of “*pharmacists*” occur under a national scheme (see the Committee’s Report 52) and, in clause 14(j), that the *Pharmacy Act 1964* be repealed in its entirety.
- 1.5 The Bill proposes new regulation of pharmacy businesses by means of requiring registration of pharmacy premises, rather than licensing of businesses, and proposes new ownership structures and an increased number of businesses that may be owned by a person.
- 1.6 The Bill also proposes to establish the Pharmacy Registration Board of Western Australia to continue the functions of the Pharmaceutical Council of Western

¹ Hon Simon O'Brien MLC, Western Australia, Legislative Council, *Parliamentary Debates (Hansard)*, 25 May 2010, p3200.

Australia (established under the *Pharmacy Act 1964*) in respect of regulation of pharmacy premises and ownership of pharmacy businesses.

2 INQUIRY PROCEDURE

- 2.1 The inquiry was published on the Committee's website and the Committee wrote to the Minister for Health on 1 June 2010 requiring provision of the usual supporting documents.
- 2.2 The Committee has previously reported on the difficulties it experiences in reporting within its 30 day deadline when faced with multiple referrals of bills. As explained above, the Bill is consequent to the proposed repeal of the whole of the *Pharmacy Act 1964* by clause 14(j) of the Health Practitioner Regulation National Law (WA) Bill 2010, reinstating the regulation of pharmacy premises and ownership of pharmacy businesses that will lapse on repeal of that Act.
- 2.3 The terms of the Health Practitioner Regulation National Law (WA) Bill 2010, therefore, necessitate consideration of the Bill prior to clause 14(j) of the former bill coming into effect. The Second Reading Speech to the Bill advises:

It is proposed that the pharmacy bill and the national law bill will commence operation at the same time.²

- 2.4 Bearing this in mind, the nature of the questions arising in respect of the Bill, the Committee decided to proceed without holding a hearing (which might require an extension of time for reporting) but to recommend provision of further information by the responsible Minister for the consideration of the House at the time of debate of the Bill.

3 UNIFORM LEGISLATION

- 3.1 National legislative schemes, to the extent that they may introduce a uniform scheme or uniform laws throughout the Commonwealth, can take a number of forms. **Appendix 1** summarises nine different categories of legislative structures promoting uniformity in legislation, each with a varying degree of emphasis on national consistency or uniformity of laws. As most recently emphasised in the Committee's Report 44 - *Criminal Code Amendment (Identity Crime) Bill 2009*, Appendix 1 is a useful guide, not an exhaustive list.
- 3.2 Appendix 1 is most useful in identifying bills to which Standing Order 230A(1)(b) applies, although its structures - in particular Structure 7 - also acknowledge that intergovernmental agreements may bind jurisdictions to giving effect to legislative principles, rather than exact terms of model legislation. The Bill reflects "*Structure 7 - Unilateralism. Each jurisdiction goes its own way*".

² Ibid, p3201.

3.3 The Bill also falls within: “*Structure 1 - Complementary Commonwealth-State or Co-operative Legislation. The Commonwealth passes legislation, and each State or Territory passes legislation which interlocks within and which is restricted in its operation to matters not falling within the Commonwealth’s constitutional powers*” and “*Structure 2 - Complementary or Mirror Legislation. For matters which involve dual, overlapping, or uncertain division of constitutional powers, essentially identical legislation is passed in each jurisdiction*”.

3.4 The inter-relationship of Commonwealth and State jurisdictions was summarised in the National Competition Policy Review of Pharmacy, *Final Report, 2000 (Wilkinson Review)* as follows:

*In accordance with commitments under the 1995 Competition Principles Agreement, a review has been commissioned by State, Territory and Commonwealth governments to examine State and Territory legislation relating to pharmacy ownership and registration of pharmacists, together with Commonwealth legislation relating to regulation of the location of the premises of pharmacists approved to supply pharmaceutical benefits.*³

Supporting documents identified by the Committee

3.5 The Minister for Health provided the following documents on 9 June 2010:

- Agreement to Implement the National Competition Policy and Related Reforms Intergovernmental Agreement 1995 (**NCP Implementation IGA**);
- Competition Principles Agreement 1995, as amended in April 2007 (**CPA**); and
- Terms of Reference of the National Competition Policy Review of Pharmacy.

3.6 The Committee identified the following additional, supporting documents:

- the **Wilkinson Review**;
- Council of Australian Governments (**COAG**) Senior Officials Working Group *Commentary on the National Competition Policy Review of Pharmacy*, August 2002 (**COAG Working Group Commentary**);
- National Competition Council, *Assessment of Governments’ progress in implementing the national competition policy and related reforms: 2004 (2004 NCP Assessment)*;

³ National Competition Policy Review of Pharmacy, *Final Report, 2000*, Appendix 1 - *The Review’s Terms of Reference*, p1.

- National Competition Council, *Assessment of Governments' progress in implementing the national competition policy and related reforms: 2005 (2005 NCP Assessment)*;
 - COAG *Background Paper: COAG National Competition Policy Review*, February 2006 (**COAG NCP Background Paper**);
 - COAG Communiqué, 10 February 2006; and
 - COAG National Reform Agenda, *COAG Regulatory Reform Plan*, April 2007 (**COAG Regulatory Reform Plan**).
- 3.7 On request from Committee staff, the Department of Health provided the Committee with a copy of the COAG Working Group Commentary on 10 June 2010.

4 BACKGROUND TO THE BILL

Overlap of State and Commonwealth jurisdiction

- 4.1 The States and Territories regulate the sale and distribution of drugs and poisons on a uniform scheduling basis, the national standard for which regulation is set in Commonwealth legislation.
- 4.2 The States and Territories have also traditionally regulated who might practise as a pharmacist, run or own a pharmacy business and the inter-relationship of the professional and commercial practice of pharmacy. This has been effected by a process of State and Territory registration or licensing of pharmacists, pharmacy premises and pharmacy businesses.
- 4.3 The Commonwealth relies on State and Territory regulation of persons practising as pharmacists, and carrying on pharmacy businesses, to underpin its pharmaceutical benefits scheme (**PBS**). By sections 4 and 90(1) of the *National Health Act 1953* (Cwlth), a person registered as a pharmacist under the law of a State or Territory, or carrying on a pharmacy business, may be approved to supply pharmaceutical benefits at “*particular premises*”.⁴ The Commonwealth regulates where a pharmacy business may operate through the *National Health (Australian Community Pharmacy Authority Rules) Determination 2006* (Cwlth) (**Pharmacy Location Rules**), made under section 99L of the *National Health Act 1953* (Cwlth). The Pharmacy Location Rules, for example provide that a pharmacy may relocate within a rural area in the following circumstances:

⁴ Section 90(1) of the *National Health Act 1953* (Cwlth) allows a “pharmacist” to apply for approval to supply pharmaceutical benefits at particular premises and section 4 of that Act defines “*pharmacist*” to be: “*a person registered as a pharmacist or pharmaceutical chemist under a law of a State or Territory providing for the registration of pharmacists or pharmaceutical chemists, and includes a friendly society or other body of persons (whether corporate or unincorporate) carrying on business as a pharmacist*”.

1. The proposed premises are in the same rural locality as the existing premises.

2. The proposed premises are at least 10 km, by the shortest lawful access route, from the nearest approved premises other than the existing premises.⁵

4.4 The Pharmacy Location Rules reflect the terms of the current Australian Community Pharmacy Agreement negotiated between the Commonwealth and the Pharmacy Guild of Australia. Such agreements have been negotiated from time to time since 1990. The Australian Community Pharmacy Agreement sets out the remuneration that a pharmacist may receive under the PBS and outlines the criteria for approval of a pharmacy premises. These criteria include location of the premises.

4.5 The latest Australian Community Pharmacy Agreement (the fifth) includes provisions relating to the regulation of pharmacy businesses by providing, for example, a programme for pharmacy accreditation:

Enhancements to the pharmacy accreditation system through standards development and processes: This funding will support the revision of standards for the accreditation of pharmacies in order to ensure they are focused on clinical and patient issues; and to support pharmacies to adjust to the new quality system of accreditation.⁶

(Original emphasis)

4.6 The importance of this overlap in the State and Commonwealth regulation of pharmacy businesses and premises was noted in the Wilkinson Review, which reported:

The greater part of community pharmacies' income (about two dollars in every three in turnover) is underpinned by government-funded remuneration and the fixed retail prices of subsidised medicines dispensed on the PBS.⁷

⁵ Clause 102 of *National Health (Australian Community Pharmacy Authority Rules) Determination 2006* (Cwlth).

⁶ Australian Government, Department of Health and Ageing, *Fifth Community Pharmacy Agreement Fact Sheet*, p5. (Available World Wide Web URL [http://www.health.gov.au/internet/main/publishing.nsf/Content/C3DB799DB360AFOCCA25772000249FA8/\\$File/FACTSHEET.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/C3DB799DB360AFOCCA25772000249FA8/$File/FACTSHEET.pdf) (viewed 20 June 2010).

⁷ National Competition Policy Review of Pharmacy, *Final Report*, 2000, p5.

National Competition Policy review of pharmacy

National Competition Policy

4.7 On 19 August 1994, COAG agreed to: “a national competition policy legislative package providing for uniform protection of consumer and business rights and increased competition in all jurisdictions”.⁸ Various intergovernmental agreements supported, and resulted from, the 19 August 1994 agreement, including the NCP Implementation IGA and CPA.⁹ These are generally referred to collectively as the National Competition Policy. In summary, the National Competition Policy required States to:

[assess] all restrictions on competition contained in the Act and Regulations and removing those that could not be shown to provide a net public benefit.¹⁰

4.8 The National Competition Council (NCC) was established by COAG in 1995 to, amongst other things, assess the various jurisdictions’ progress in implementing the findings of their competition policy legislative reviews. Failure to implement review findings generally resulted in the NCC recommending a reduction in the financial grant otherwise available under the NCP Implementation IGA.¹¹

4.9 Under the National Competition Policy, each jurisdiction was free to determine its own agenda for reform of legislation restricting competition, subject to the proviso that the jurisdictions develop a timetable by June 1996 for the review and reform all existing legislation restricting competition by 2000.¹² Clause 5(7) of the CPA provides:

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. ...

⁸ Council of Australian Governments, *Meeting Outcomes, Meeting 11 April 1995*. (Available World Wide Web URL http://www.coag.gov.au/coag_meeting_outcomes/1995-04-11/index.cfm, viewed 20 June 2010).

⁹ The Competition Principles Agreement 1995 sets out the competition policy principles and requires legislative review in accordance with those principles; the National Competition Policy and Related Reforms Intergovernmental Agreement 1995 specified a program of financial grants contingent on implementation of national competition policy reforms.

¹⁰ Government of Victoria, Department of Health, webpage: *Pharmacists Act Review 2004* (<http://www.vic.gov.au/pracreg/hp-review/pharmacact>, viewed on 8 June 2010).

¹¹ For example: “the NCC recommended that the New South Wales Government should have \$10 million deducted from its competition payments for failing to justify its initial decision not to implement some recommendations of its review of rice regulation. It has also recommended a suspension of 25 per cent of Queensland’s 1999-2000 competition payments due to concerns about progress with water reform.” Productivity Commission of Australia, Report No 8, *Impact of Competition Policy Reforms on Rural and Regional Australia*, 8 September 1999, p84.

¹² Clauses 5(3) and (4) of the Competition Principles Agreement 1995.

National review of pharmacy legislation

4.10 On 13 May 1997, COAG proposed a joint, national competition policy review of pharmacy regulation. The national review was agreed to by all jurisdictions.¹³ The Victorian Department of Health describes the purpose of the national review as follows:

*all Australian jurisdictions agreed to a National Review as a means of promoting a consistent approach to regulation of the profession of pharmacy and dealing with the complex issues of regulation of ownership.*¹⁴

4.11 COAG tasked the review, known as the Wilkinson Review, with reviewing a number of specified pieces of Commonwealth, State and Territory legislation, including the *Pharmacy Act 1964*, and:

*to assess the effects on competition of referred legislation on the ownership of pharmacies, the location of pharmacies for the purposes of the Commonwealth Pharmaceutical Benefits Scheme, and the registration of pharmacists.*¹⁵

4.12 The Wilkinson Review presented its final report on 8 February 2000, making a number of recommendations as to the provisions that should form part of the legislation of all jurisdictions, as well as particular comment on Commonwealth legislation. Most relevant to the *Pharmacy Bill 2010*, the Wilkinson Review recommended:

- retention of restrictions on ownership of pharmacies;
- recognition of different corporate structures of ownership;
- clarification of what constitutes an “*interest*” in a pharmacy;
- removal of restrictions on number of pharmacies that might be owned;
- removal of requirement to register pharmacy businesses and premises; and

¹³ National Competition Policy Review of Pharmacy, *Final Report*, 2000, ‘Transmittal letter’ dated 8 February 2000, Appendix 1, p1.

¹⁴ Government of Victoria, Department of Health, webpage: *Pharmacists Act Review 2004*, (<http://www.vic.gov.au/pracreg/hp-review/pharmact>, viewed on 8 June 2010).

¹⁵ National Competition Policy Review of Pharmacy, *Final Report*, 2000, Transmittal letter dated 8 February 2000, p1.

- regulation of commercial activities be wound back and replaced with a regulatory focus on the safe and competent practice of pharmacy without undue influence or unethical interference.
- 4.13 The relevant Wilkinson Review findings are set out in Appendix 2. (See paragraph 4.16 below.) Recommendation 20 of the Wilkinson Review was that:

*in the interests of promoting occupational and commercial mobility, the Commonwealth, State and territories explore and consider adopting nationally consistent or uniform legislation, or specific legislative provisions, on pharmacy ownership, pharmacist registration and the regulation of pharmacy professional practice.*¹⁶

COAG Agreement on co-ordinated regulation of pharmacy

- 4.14 COAG referred the Wilkinson Review to the working group (comprising senior Commonwealth, state and territory government officers) which had been tasked with overseeing implementation of the National Competition Policy (**COAG Senior Officials Working Group**), to advise whether a co-ordinated response could be made by all jurisdictions to each of the Wilkinson Review recommendations and, if not, advise on a response by COAG or individual jurisdictions.¹⁷
- 4.15 The COAG Senior Officials Working Group released the COAG Working Group Commentary, recommending a COAG co-ordinated response to the Wilkinson Review's recommendations on ownership and registration of pharmacies.¹⁸ The COAG Working Group Commentary states:

*These suggestions have been arrived at consensually on the basis of agreeing the principle and allowing jurisdictions to manage the implementation.*¹⁹

- 4.16 **Appendix 2** is an extract from the table found in the COAG Working Group Commentary, which sets out the recommendations of the Wilkinson Review and response of the COAG Senior Officials Working Group to each recommendation. (The recommendations of the COAG Working Group Commentary in respect of the regulation of pharmacists have been omitted - see paragraph 4.29 below).
- 4.17 The agreement in principle only is explained as arising from the need to consider harmonisation of the regulation of all health professionals within a jurisdiction in

¹⁶ National Competition Policy Review of Pharmacy, *Final Report*, 2000, p13.

¹⁷ Council of Australian Governments Senior Officials Working Group *Commentary on the National Competition Policy Review of Pharmacy*, August 2002, Executive Summary, p1.

¹⁸ Ibid.

¹⁹ Ibid.

addition to: “*gaining consistency in regulatory approaches to pharmacy across jurisdictions*”.²⁰ The various COAG Working Group Commentary recommendations are noted to be in accord with the agreed principles.²¹ Where a State has not endorsed a recommendation, or where there is to be further consideration of a recommendation, that circumstance is reported in the COAG Working Group Commentary. The COAG Working Group Commentary, therefore, comprises a list of provisions identifying where the provision: is agreed by all jurisdictions; is subject to agreement as to principle but with potential for particular jurisdictions to further assess impact during implementation; and should not form part of the co-ordinated regulatory response;

- 4.18 COAG subsequently endorsed the recommendations of the COAG Working Group Commentary.²²

Subsequent intergovernmental agreement as to the number of pharmacies that may be owned

- 4.19 The *Pharmacy Act 1964* restricts the number of pharmacies that may be owned by a person to two. The Wilkinson Review recommended that the States and Territories lift the restrictions on the number of pharmacies that a person might own or have an interest in. (See Recommendation 4(a) in Appendix 2.) The COAG Working Group Commentary recommended that Recommendation 4(a) of the Wilkinson Review be accepted (subject to New South Wales’ implementation process involving a further impact assessment process).

- 4.20 Notwithstanding COAG’s endorsement of this recommendation, removing restrictions on the number of pharmacies that a person might own or have an interest in remained problematic.²³ The Productivity Commission of Australia’s *Review of the National Competition Policy*, 2005, states:

*The proposed changes to ownership restrictions were withdrawn after intervention by the Prime Minister.*²⁴

- 4.21 The 2005 NCC Assessment reports:

In September 2004, the government endorsed the majority of recommendations of the NCP review of pharmacy and approved the drafting of new legislation to replace the Pharmacy Act. ... Rather

²⁰ Ibid.

²¹ Ibid, p2.

²² National Competition Council, *Assessment of Governments’ progress in implementing the national competition policy and related reforms: 2004*, p19.9.

²³ Failure to implement the findings of the National Competition Policy Review of Pharmacy on pharmacy ownership was identified as problematic in the Productivity Commission of Australia’s *Review of the National Competition Policy*, 28 February 2005, pxxii.

²⁴ Productivity Commission of Australia, *Review of the National Competition Policy*, 28 February 2005, p262.

than remove the cap on the number of pharmacies that an individual pharmacist (or friendly society) may own or have an interest in, Western Australia intends to relax the restriction in line with the Prime Minister's advice of November 2004 that:

Provided Western Australia, as a minimum, relaxes ownership restrictions to allow pharmacists to own up to four pharmacies each and permits ... friendly societies to own up to four pharmacies each, Western Australia will not attract competition payments deductions.²⁵

4.22 Accordingly, in 2004 Western Australia agreed with (at least) the Commonwealth that it would implement through legislation “*the majority*” of the Wilkinson Review reforms, and reached a compromise agreement in respect of the number of pharmacies that might be owned by a person or entity.

4.23 The 2005 NCC Assessment stated in respect of Western Australia's response to the Wilkinson Review:

Given that Western Australia has not implemented reforms consistent with COAG requirements, the state has failed to meet its CPA obligations in relation to this profession.²⁶

Continuation of NCP legislative reform under National Reform Agenda

4.24 On 3 June 2005, COAG agreed to a review of the National Competition Policy. The COAG NCP Background Paper recommended a new national competition policy reform agenda but also noted that:

there are some areas of unfinished business, most of which involve the legislative review program.²⁷

4.25 While it is sometimes stated that the National Competition Policy concluded in 2006, being replaced by the National Reform Agenda, it was agreed by COAG on February 2006 that, as part of the National Reform Agenda, each jurisdiction would:

complete outstanding priority legislation reviews from the current NCP Legislation Review Program in accordance with the NCP public benefit test;²⁸

²⁵ National Competition Council, *Assessment of Governments' progress in implementing the national competition policy and related reforms: 2005*, p14.21.

²⁶ Ibid.

²⁷ Council of Australian Governments, *Background Paper: COAG National Competition Policy Review*, February 2006, p8.

²⁸ Council of Australian Governments, *Communiqué 10 February 2006, Attachment B*, p1.

and the COAG Regulatory Reform Plan, agreed 13 April 2007, states:

*COAG agreed that each jurisdiction will complete outstanding priority legislation reviews from the current National Competition Policy (NCP) Legislation Review Program in accordance with the NCP public benefit test. Governments will report annually to COAG on their progress in meeting this commitment.*²⁹

- 4.26 The CPA was re-endorsed by COAG at its meeting on 13 April 2007 and remains extant.³⁰

Relationship to Health Practitioner Regulation National Law

- 4.27 As seen above, historically the States and Territories have regulated the profession of pharmacist under the same legislation as that regulating ownership of a pharmacy business and pharmacy premises and regulation of the profession of pharmacist was considered in both the Wilkinson Review and COAG Working Group Commentary.
- 4.28 However, in 2005 the Commonwealth asked the Productivity Commission to undertake a research study to examine issues impacting on the health workforce including the supply of, and demand for, health workforce professionals and propose a solution to ensure the continued quality of healthcare over the next ten years. The Productivity Commission's report, *Australia's Health Workforce*, recommended that the Australian Health Ministers' Conference establish a single national registration board for health professionals and a single national accreditation board for health professional education and training.³¹ In July 2006, COAG agreed to establish a single national registration scheme.
- 4.29 On 26 March 2008, Western Australia signed the Intergovernmental Agreement for a National Registration and Accreditation Scheme for the Health Professions, thereby agreeing to participate in the National Scheme. The regulation of pharmacists is discussed in the Committee's Report 52. The National Scheme in respect of regulation of health professionals does not deal with regulation of pharmacy businesses or premises.
- 4.30 The Bill is consequent on the proposed repeal of the *Pharmacy Act 1964* by clause 14(j) of the Health Practitioner Regulation National Law (WA) Bill 2010, but represents a separation of regulation of pharmacists as a profession from regulation of the ownership and location of pharmacy business and premises.

²⁹ Council of Australian Governments, National Reform Agenda, *COAG Regulatory Reform Plan*, p10.

³⁰ The Competition Principles Agreement 1995 is noted to be as amended at April 2007.

³¹ Australian Government, Productivity Commission, Research Report, *Australia's Health Workforce*, 22 December 2005, Recommendation 7.2, pxi and Recommendation 6.1, pxxxix respectively.

5 OVERVIEW OF THE BILL

Purpose

5.1 The Second Reading speech to the Bill states that:

*The key objective of this bill is to protect the public from harm by ensuring that pharmacy premises meet appropriate standards.*³²

Provisions

Registration of pharmacy premises

5.2 Clause 53 of the Bill provides that a person must not own, or hold a “*proprietary interest*” in, a “*pharmacy business*” unless the business is carried on at premises registered as a pharmacy. “*Pharmacy business*” is defined in clause 3 of the Bill to mean:

a business -

- (a) *consisting of the provision of pharmaceutical services; and*
- (b) *from which goods and services relating to the provisions of pharmaceutical services may be available,*

other than a business carried on at premises operated by -

- (c) *a public hospital, as defined in the Hospitals and Health Services Act 1927 section 2(1) or*
- (d) *the holder of a permit or licence under the Poisons Act 1964 of a type prescribed by the regulations.*

5.3 Clause 42 of the Bill provides that an application for registration of premises is to be: “*accompanied by such information as is required by the regulations*”. The application is considered by the Pharmacy Registration Board of Western Australia (**Pharmacy Board**), established by clause 4 of the Bill (or a delegee of the Pharmacy Board - see clause 10 of the Bill). The Pharmacy Board may request (in writing) an applicant to provide such further information as it reasonably requires to decide an application for registration (clauses 42(2) and (4)).

5.4 Clause 39 of the Bill provides that unless clause 43 applies, an application for registration must be granted. Clause 43 sets out the following grounds for refusal:

³² Hon Simon O’Brien MLC, Minister for Transport, Western Australia, Legislative Council, *Parliamentary Debates (Hansard)*, 25 May 2010, p3201.

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- the Board is not satisfied that the premises meet the requirements prescribed in regulations for the: “*minimum standards of fitness for the competent and safe practice of pharmacy*”. (However, see clause 48, discussed in paragraphs 8.8 to 8.11 below);
 - information provided is false or misleading in a material particular;
 - the applicant has not complied with a request to provide further information;
 - registration would breach the limitations proposed by clause 55 on the number of pharmacy businesses that a person might own or hold a proprietary interest in or by clause 44 on St John of God Health Care Incorporated only carrying on a pharmacy business at current premises; and
 - the premises are:
 - located wholly or partly within a supermarket;
 - capable of being entered through a supermarket; or
 - capable of being used to enter a supermarket.
- 5.5 Clause 43(e) of the Bill, imposing restrictions on registration of premises by reason of proximity to a supermarket, is discussed in paragraphs 6.3 to 6.6 below.
- 5.6 The Board may impose conditions on registration for the purpose of ensuring that the premises are of a minimum standard for the competent and safe practice of pharmacy (clause 47). In this respect, it appears that the Board is not bound by the minimum standards prescribed in regulations, as clause 48 provides that the Board may grant (or renew) registration of premises even though the premises do not meet the requirements of the regulations if conditions have been imposed under section 47. Clause 48 of the Bill also enables the Board to register premises that do not meet the minimum standard requirements of the regulations in the event it is satisfied that it is in the “*public interest*” for the premises to be registered. Clause 48 is discussed further below.
- 5.7 Clause 44 empowers the Board to enter any registered pharmacy during business hours to inspect the pharmacy to ensure that the pharmacy meets the requirements prescribed by the regulations for the minimum standards of fitness.
- 5.8 Registration of premises has effect for the time prescribed in regulations but may be cancelled, or not renewed, in the event of the person owning the business ceasing to be a person entitled to own (or have a proprietary interest in) a pharmacy business or any breach of a matter set out in clause 43.
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Ownership of pharmacy limited

5.9 Clause 54 of the Bill provides that a person must not own, or hold a proprietary interest in, a pharmacy unless the person is:

- a pharmacist (defined in clause 3 to be a person registered under the *Health Practitioner Regulation National Law (Western Australia)* in the pharmacy profession);
- a partner in a partnership that carries on the business and in which every partner is either a pharmacist or a “*close family member*” of a partner who is pharmacist (“*close family member*” is defined in clause 3 to be: a spouse, a de facto partner; child or parent or other family member prescribed by regulations);
- a “*pharmacist controlled company*”;
- a friendly society; or
- the “*preserved company*” (defined in clause 3 of the Bill to be St John of God Health Care Incorporated).

5.10 Clause 55 provides that a pharmacist, friendly society or close family member of a pharmacist, must not own, or hold a “*proprietary interest*”, in more than four pharmacy businesses at any one time. St John of God Health Care Incorporated may only own one pharmacy business and:

(5) *A new friendly society must not acquire, or acquire a proprietary interest in, a pharmacy business, if the total number of pharmacy businesses which are owned by a new friendly society, or in which a new friendly society holds a proprietary interest, is 9 or more than 9.*

5.11 As reported in Part 4 above, while COAG initially endorsed the view that there should be no restriction on the number of pharmacies that a pharmacist might own or have an interest in, that position was later resiled. Clause 55 of the Bill reflects the agreement reached with the Commonwealth that Western Australia would increase the cap to four pharmacies. The Second Reading Speech states that it is: “*consistent with jurisdictions elsewhere in Australia*”.³³

5.12 The Bill introduces the concepts of partnerships limited to other pharmacists or “*close family members*” of the pharmacists and “*pharmacist controlled company*”.

³³ Hon Simon O’Brien MLC, Minister for Transport, Western Australia, Legislative Council, *Parliamentary Debates (Hansard)*, 25 May 2010, p3201.

5.13 “*Pharmacist controlled company*” is defined in clause 3 of the Bill to be a company in which at least one director is a pharmacist and every director is either a pharmacist or a close family member of a pharmacist who is a director and where each holder of shares (or of a beneficial or legal interest in shares) is a pharmacist or close family member of such a pharmacist and in which the pharmacist (or pharmacists) are entitled to control the exercise of more than 50% of the voting power.

5.14 The Second Reading Speech states:

*The Bill expands ownership structures to include that a pharmacist may own a pharmacy business through a company or partnership where the pharmacist has the controlling interest in the company or partnership; and that new friendly societies may own a pharmacy business.*³⁴

5.15 However, it appears to the Committee that under the *Pharmacy Act 1964* a wider range of companies may be permitted to carry on a pharmacy business than those provided for in clause 54 of the Bill.

5.16 The *Pharmacy Act 1964* permits a company that carries on the practice of pharmacy “by and under the supervision” of a pharmacist to apply for registration of a pharmacy, which application the regulator is to grant if satisfied that the company intends to carry on the business of a chemist and druggist or pharmaceutical chemist (sections 23 and 36). Section 28 of the *Pharmacy Act 1964* provides that a pharmacist who (on his own behalf, as agent, employee, partner or other associate of another person or body) concurrently carries on the practice of pharmacy in relation to more than two pharmacies, or has a “pecuniary interest” in more than two pharmacies, commits an offence. The *Pharmacy Act 1964* does not appear to require the pharmacist to be an owner of the pharmacy business.

Recommendation 1: The Committee recommends that the responsible Minister explain to the Legislative Council how the Bill expands “ownership structures” in respect of pharmacies in the context of sections 28 and 36 of the *Pharmacy Act 1964*.

5.17 The new provisions are consistent with the COAG requirements that, in the short term, legislative restriction on ownership of pharmacies be retained and confined to registered pharmacists (see Appendix 2, Recommendation 1) but that ownership structures recognise corporations with shareholders who are all registered pharmacists or prescribed relatives of those pharmacists (see Appendix 2, Recommendation 3).

³⁴

Ibid.

The COAG requirement, however, was that any current restrictions may be retained, not that restrictions be introduced.

Limitation on commercial interest in pharmacy business

5.18 The *Pharmacy Act 1964* uses the undefined term “*pecuniary interest*” to limit the number of pharmacies in which a persons may have an interest (section 28) and tying ability to derive income from the business of a pharmacy to registration of the pharmacy (section 36).

5.19 In clauses 54 and 55, the Bill uses the term “*proprietary interest*” to limit who may have an interest in a pharmacy business. Only the persons identified in clause 54 may hold such an interest. “*Proprietary interest*” is defined in clause 3(1) of the Bill and further explained in clause 3(2) to include both a legal and beneficial interest as:

- sole proprietor;
- partner;
- director, member or shareholder of a company;
- trustee or beneficiary of a trust;
- a party to an arrangement of a kind prescribed in regulations;
- a person who provides a benefit to another for which the person is entitled to receive the profits or income (or a share thereof) of a pharmacy business; or
- a franchisee (or other commercial arrangement) giving a right to consideration that varies in accord with the profits or income of a pharmacy business.

5.20 On proprietary interest, the Wilkinson Review recommendations were that:

(a) Any statutory prohibition on natural persons or bodies corporate, not being a registered pharmacist, or other permitted entity, having a direct proprietary interest in community pharmacies are retained;

(b) “Proprietary interest” be defined clearly in Pharmacy Acts as relating to the direct ownership of, or a partnership, shareholding or directorship in a pharmacy operating entity;

(c) Subject to the proprietor of a pharmacy remaining responsible and accountable for the safe and competent practice of professional services in that pharmacy, provisions in Pharmacy Acts relating to:

(1) Preventing parties other than a registered pharmacist to have a lawfully permitted association with a pharmacy business, but not including a proprietary interest as defined in Recommendation 6(b);

(2) Inserting specific terms in commercial documents relating to those businesses;

(3) Preventing considerations for third parties based on of a pharmacy's turnover or profit;

(4) Preventing pharmacies having preferred wholesale suppliers of medicines;

(5) Otherwise preventing pharmacy proprietors from developing lawful business associations with other parties; and

(6) Allowing regulatory authorities to intervene inappropriately in matters of this nature;

are removed; and

(d) Removed provisions of the types described in Recommendation 6(c) are replaced in each Pharmacy Act with a statutory offence, with appropriate and substantial penalties for individuals and corporations, of improper and inappropriate interference with the professional conduct of a pharmacist in the course of his or her practice.³⁵

5.21 In respect of these recommendations, the COAG Working Group Commentary stated:

Recommendations 6(a) and (b) narrow the definition of pecuniary interests to proprietary interests only in a pharmacy business. The effect of this is to continue to exclude non-pharmacists from pharmacy ownership but permit a normal range of commercial transactions between pharmacists and non-pharmacists that have been excluded by the current broad-brush legislative provisions. This approach would remove some of the uncertainty inherent in the existing pecuniary interest provisions.

Recommendation 6(c) lists a series of commercial activities currently prohibited by State Pharmacy Acts with, what the Review believes are, little or no justification in terms of safeguarding the public

³⁵

National Competition Policy Review of Pharmacy, *Final Report*, 2000, pp7-8.

interest. The Working Group supports this proposal to repeal and replace the existing patchwork of attempts to circumscribe commercial arrangements. However, the Recommendation should more clearly draw on the distinction made in the Report between the aspects of a pharmacy business that make up pharmacy services (working definition on page 21) and the non-pharmacy aspects (eg banking, general goods retail, cosmetics and lotteries). Regulation should only be concerned with the former aspects.

The present pecuniary interest provisions are not effective in ensuring that the practice of pharmacy can occur without undue or improper interference from third parties. Recommendation 6(d) attempts to provide pharmacists with some support in their dealings with commercially strong enterprises by introducing a statutory offence to deter third parties exerting improper influence over the conduct of a pharmacy. This could also include inappropriate direction of an employed pharmacist by a proprietor, whether or not the proprietor is a registered pharmacist.³⁶

- 5.22 The COAG Working Group Commentary recommended acceptance of the Wilkinson Review's recommendation. Clause 55 of the Pharmacy Bill 2010 is not, therefore, consistent with COAG's requirements in this respect.
- 5.23 The expanded definition of "proprietary interest" is not explained in the explanatory materials related to the Bill. In this respect, it is noted that clause 3(2) empowers regulations to further expand on the types of arrangements that may be taken to constitute a "proprietary interest". The Committee draws the apparent inconsistency with COAG requirements to the attention of the House.

³⁶ Council of Australian Governments Senior Officials Working Group *Commentary on the National Competition Policy Review of Pharmacy*, August 2002, pp19-20.

Recommendation 2: The Committee recommends that the responsible Minister:

- explain to the Legislative Council the rationale for the definition of “*proprietary interest*” proposed by clause 3 of the Bill in light of the recommendations of the COAG Senior Officials Working Group Commentary;
- advise the Legislative Council whether the definition of “*proprietary interest*” proposed by clause 3 of the Bill is consistent with equivalent definitions in other jurisdictions; and
- if not, advise the Legislative Council whether the definition of “*proprietary interest*” proposed by clause 3 of the Bill results in a greater limitation of ownership of pharmacies in Western Australia than in other jurisdictions.

Recommendation 3: The Committee recommends that the responsible Minister advise the Legislative Council of the type of “*arrangements*” that it is contemplated will be prescribed under clause 3(2)(a) of the Bill.

The Board

5.24 Clause 4 of the Bill establishes the Board as a body corporate. Clause 79 provides that the Board is a continuation of, and the same legal entity as, the Pharmaceutical Council of Western Australia (**Council**) in relation to:

functions, powers, rights, assets or liabilities that immediately before the commencement day related to the regulation by that council of a pharmacy business, pharmacy premises, a pharmacy department or any other pharmacy related entity that is not an individual.

5.25 The Council is established by sections 7(1) and 8 of the *Pharmacy Act 1964* as a body corporate, responsible for the management of the Pharmaceutical Society of Western Australia.

5.26 The Pharmaceutical Society of Western Australia is an unincorporated association under the *Pharmacy Act 1964*. Clause 88(1) of the Bill, deems the Pharmaceutical Society of Western Australia to be incorporated on the commencement day, which is defined in clause 77 to be the day of operation of clause “15(j) of the *Health Practitioner Regulation National Law (WA) Act 2010*”.

- 5.27 The Committee notes that there has been a renumbering of the clauses of the Health Practitioner Regulation National Law (WA) Bill 2010, and that it is now proposed to repeal the *Pharmacy Act 1964* by clause 14(j) of that bill.

Recommendation 4: The Committee recommends that the definition of “commencement day” proposed by clause 77 of the Bill be amended to reflect the renumbering of the clauses of the Health Practitioner Regulation National Law (WA) Bill 2010. This can be effected in the following manner:

Page 44, line 17 - To delete “15(j)” and insert -

14(j)

- 5.28 By clause 89 of the Bill, the assets, rights and liabilities of the Council that relate to the management of the unincorporated Pharmaceutical Society of Western Australia are transferred to the incorporated Pharmaceutical Society of Western Australia. By clause 88 of the Bill, members of the Council are taken to be members of the committee or other body having management of the unincorporated Pharmaceutical Society of Western Australia.
- 5.29 Members of the Board, of which there are to be four, are appointed by the Minister. Three members are to be pharmacists and one is to have experience in representing the interests of consumers. (See clause 5 of the Bill.) The Boards functions are set out in clause 8.
- 5.30 Clause 11 of the Bill provides that the Minister may direct the Board in writing with respect to the performance of its functions, either generally or in relation to a particular matter, and that the Board is to give effect to any such direction. The Minister must not issue such a direction in respect of a particular person or application or proceeding. The text of any direction is to be laid before Parliament, and noted in the annual report, but the directions are not disallowable.
- 5.31 The Committee observes that the power conferred by clause 11 has potential to allow the Minister of the day to significantly undermine the independence of the Board which, by clause 4(3) of the Bill, is not an agent of the Crown.
- 5.32 Clause 11 of the Bill is not explained in the explanatory materials related to the Bill.
- 5.33 Clause 28(2) of the Bill provides that in the event the Board cannot deal with a matter under clause 28(1) (allowing two members to constitute a quorum) due to clause 26 (a

member is disqualified from participating or voting in respect of matters that involve a “*material personal interest*”), the Minister is to deal with the matter.

5.34 While the Committee might speculate that clause 28(2) arises from three of the four Board members being pharmacists, clause 28(2) is not explained in the explanatory materials relating to the Bill and appears to confer power on the Minister to, in particular, determine a matter in respect of a particular person or application or proceeding.

5.35 Clause 18(3)(d) of the Bill also confers power on the Minister to intervene with the Board. It provides that a member of the Board may be removed for a number of specified reasons or:

any other act or omission that in the opinion of the Minister may cause injury or prejudice to the Board.

5.36 By clause 29 of the Bill the Minister may declare that clause 26 (a member is disqualified from participating or voting in respect of matters that involve a “*material personal interest*”) or clause 28 ((1) two members may constitute a quorum in the event clause 26 applies and (2) that the Minister may deal with a matter in the event the Board cannot deal with it under (1)), do not apply. Such declarations must be laid before the Parliament.

5.37 Each of clauses 11, 28 and 29 confer unusual powers on the Minister to intervene in matters relating to the function of the apparently independent Board. While the requirement for tabling in the Parliament of directions made under clause 11 and declarations made under clause 29 address concerns as to transparency, the reasons the Executive considers these Ministerial powers necessary have not been explained to the Parliament, which is simply asked to pass the Bill.

Recommendation 5: The Committee recommends that the responsible Minister explain to the Legislative Council:

- **the purpose of, and necessity for, clause 11 of the Bill;**
- **the purpose of, and necessity for, clause 28(2) of the Bill;**
- **the purpose of, and necessity for, clause 29 of the Bill; and**
- **whether or not it is intended that the Board be independent of the Minister and, if so, the role of clauses 11, 28(2) and 29 in maintaining that independence.**

6 CONSISTENCY WITH SUPPORTING DOCUMENTS

6.1 The Pharmacy Bill 2010 is largely consistent with the supporting documents.

6.2 The main deviations are:

- clause 3(2) expanding the meaning of “*proprietary interest*”; and
- clauses 39 to 48 requiring registration of pharmacy premises, whereas the COAG Senior Officials Working Group Commentary accepted the Wilkinson Review Recommendation 7(a) that registration of pharmacy premises be removed (See Appendix 2, Recommendation 7(a)).

Clause 43(e) - supermarkets

6.3 Clause 43(e) of the Bill proposes that an application for registration of a pharmacy be refused in the event the pharmacy premises are:

- located wholly or partly within a supermarket;
- capable of being entered through a supermarket; or
- capable of being used to enter a supermarket.

6.4 As noted above, the Wilkinson Review, and COAG Senior Officials Working Group Commentary, recommended removal of provisions in State Acts requiring registration of pharmacy premises. The COAG requirements do not, therefore, specifically address provisions in legislation stipulating where pharmacies may be located.

6.5 However, the Commonwealth PBS imposes, through the Pharmacy Location Rules, rules on where pharmacies may be located for the purposes of approval under that scheme. A general requirement under the Pharmacy Location Rules for approval of premises of the purposes of the PBS is:

(d) the proposed premises are not directly accessible by the public from within a supermarket.³⁷

6.6 Although inconsistent with the supporting documents, and worded differently from the terms of the Pharmacy Location Rules, clause 43(e) of the Bill is consistent with the Commonwealth legislation with which it interlocks.

³⁷ Section 9 and item 201 of Schedule 2 of the *National Health (Australian Community Pharmacy Authority Rules) Determination 2006* (Cwlth).

7 SOVEREIGNTY

- 7.1 The Committee has previously reported that in some respects, all legislation to which Standing Order 230A applies derogates from the sovereignty of the Parliament.
- 7.2 However, the Committee is of the view that the Bill raises no particular sovereignty issues for the Parliament or the State.

8 PARTICULAR PROVISIONS OF THE BILL

Henry VIII clauses - where administrative decisions may override legislative provision

Pharmacy businesses may be exempted from premises registration requirement by Executive

- 8.1 As noted above, by clause 3 of the Bill, clause 53 of the Bill requiring pharmacy businesses to be carried on at registered premises does not apply to public hospitals: “as defined in the *Hospitals and Health Services Act 1927* section 2(1)” or to holders of permits or licences under the *Poisons Act 1964* “of a type prescribed by the regulations”.
- 8.2 Section 2(1) of the *Hospitals and Health Services Act 1927* provides:

public hospital means any hospital that is —

(a) conducted or managed by —

(i) a board constituted under this Act; or

(ii) the Minister under this Act; or

(b) declared to be a public hospital under section 3.

(Original emphasis)

- 8.3 Section 3 of the *Hospitals and Health Services Act 1927* provides:

The Minister, acting on the written recommendation of the Executive Director and with the consent of the governing body of the institution, may by notice published in the Gazette declare any institution to be a public hospital subject to and for the purposes of this Act.

- 8.4 The definition of “*pharmacy business*” in clause 3 of the Bill, therefore, proposes extending the operation of Section 3 of the *Hospitals and Health Services Act 1927* to the purposes of the Bill. This definition is not explained in the explanatory materials relating to the Bill.

- 8.5 However, the Committee notes that section 23(6) of the *Pharmacy Act 1964* currently exempts any pharmacy “attached to or operated by” a hospital to which the *Hospitals and Health Services Act 1927* applies from the requirement for registration of pharmacy premises (see section 23).

Clauses 47 and 48

- 8.6 Clause 47 of the Bill empowers the Board to impose “such conditions ... as the Board reasonably requires” on registration of pharmacy premises. Section 23(2) of the *Pharmacy Act 1964* empowered that Act’s equivalent of the Board to withhold registration of a pharmacy:

until the applicant complies with such conditions as may be prescribed.

- 8.7 No explanation is provided for the shift from prescription of conditions in subsidiary legislation to conditions imposed at the discretion of the regulator.

Recommendation 6: The Committee recommends that the responsible Minister explain to the Legislative Council the shift from prescription of conditions on registration of pharmacy premises in subsidiary legislation to conditions determined by the regulator.

- 8.8 As reported above, clause 48 of the Bill provides that despite clause 43(a), the Board may grant (or renew) registration of premises even though the premises do not meet the requirements of the regulations as to minimum standards if conditions have been imposed under section 47. Clause 48 of the Bill also enables the Board to register premises that do not meet the requirements of the regulations in the event it is satisfied that it is in the “public interest” for the premises to be registered.
- 8.9 The “*Explanatory Memorandum*” merely paraphrases the relevant provisions: it does not explain them.
- 8.10 While the Committee can speculate that the “public interest” exception may be related to the need to provide access to pharmaceutical services in rural areas, there is nothing in the Bill linking the exception to that purpose. The discretion is, therefore, very wide for the Board to determine the policy imperatives that justify an exception.
- 8.11 Where a “key objective” of the Bill is said to be:

to protect the public from harm by ensuring that pharmacy premises meet appropriate standards,³⁸

the Committee considers that the Legislative Council is entitled to an explanation of clause 48 and the lack of guidance in the Bill as to what will constitute the public interest.

Recommendation 7: The Committee recommends that the responsible Minister explain to the Legislative Council the purpose of clause 48 of the Bill and what it is intended will constitute “public interest” for the purposes of that clause.

Other issues

- 8.12 There does not appear to be in the Bill any power for the Board to inspect a pharmacy for the purpose of ensuring that conditions imposed under clause 47 are met or to cancel registration for failure to meet conditions of registration. (Clauses 44 and 46 of the Bill respectively confer power to inspect to ensure the pharmacy meets the minimum standards prescribed by the regulations and cancel registration in the event the Board is not satisfied that the minimum standards prescribed by the regulations have been met, but confer no powers in respect of conditions imposed under clause 47.) This may particularly be an issue where premises have been registered under clause 48, despite not meeting the minimum standards prescribed in the regulations.
- 8.13 In this respect it is noted that clause 47 removes the prohibition on registration until a pharmacy meets prescribed conditions imposed by the regulator (section 23(2) of the *Pharmacy Act 1964*) to allowing registration on imposition of conditions.

Recommendation 8: The Committee recommends that the responsible Minister identify for the Legislative Council the provision/s of the Bill empowering the Board to:

- **inspect a pharmacy for the purpose of ensuring that conditions imposed under clause 47 of the Bill are met; and**
- **cancel registration of a pharmacy for failure to meet conditions imposed under clause 47 of the Bill;**

or, in the event there are no such provisions, explain to the Legislative Council why such provisions are not required.

³⁸ Hon Simon O’Brien MLC, Minister for Transport, Western Australia, Legislative Council, *Parliamentary Debates (Hansard)*, 25 May 2010, p3201.

Right of inspection and powers on inspection

- 8.14 Clause 44 of the Bill empowers the Board to enter any registered pharmacy during business hours to inspect the pharmacy to ensure that the pharmacy meets the requirements prescribed by the regulations for the minimum standards of fitness. (Fundamental Legislative Scrutiny Principle 5 - *Does the Bill confer power to enter premises, and search for or seize documents or other property, only with a warrant issued by a judge or other judicial officer?*)
- 8.15 By way of contrast, sections 31A to 31I of the *Pharmacy Act 1964*, which are set out in **Appendix 3**, provide a detailed regime of issuing warrants prior to inspection, notice to produce information etcetera. These sections of the *Pharmacy Act 1964* are primarily directed at investigation of disciplinary matters in respect of pharmacists, which will not occur under the Pharmacy Bill 2010. However, the sections also apply in respect of the regulator's other functions, such as registration of pharmacies.

Recommendation 9: The Committee recommends that the responsible Minister explain to the Legislative Council:

- **the reasons for the different inspection regime proposed by the Bill from the regime existing under the *Pharmacy Act 1964*;**
- **whether the regulations will prescribe any of the matters prescribed in section 31A to 31I of the *Pharmacy Act 1964* and; if so, which matters; and**
- **how the inspection regime proposed by the Bill will work in the absence of prescription of any matters prescribed by sections 31A to 31I of the *Pharmacy Act 1964*.**

Regulations may prohibit sale of prescribed goods

- 8.16 Clause 62(2)(b) of the Bill proposes that regulations may be made:

prohibiting or regulating the sale or supply of goods and services of a prescribed type at a registered pharmacy in association with the practice of pharmacy.

- 8.17 The Committee was not, however, able to identify any provision of the Bill that provided guidance as to the factors that were to be taken into consideration in determining what goods and services should be prohibited or regulated. (Fundamental

Legislative Scrutiny Principle 1 - *Are rights, freedoms or obligations dependent on administrative power only if sufficiently defined and subject to appropriate review?*)

8.18 In this respect, the Committee notes the COAG Working Group Commentary recommendation, endorsed by COAG, that pharmacy regulation should only be concerned with

the aspects of a pharmacy business that make up pharmacy services (working definition on page 21),

not:

the non-pharmacy aspects (eg banking, general goods retail, cosmetics and lotteries).

Recommendation 10: The Committee recommends that the responsible Minister provide the House with advice as to whether clause 63(2)(b) of the Bill is restricted in its operation to prescription of pharmacy goods and services and:

- **if so, identify the relevant clause/s imposing that restriction;**
- **if not, provide the House with the rationale for the need to regulate the sale or supply of non-pharmaceutical goods and services at a registered pharmacy in association with the practice of pharmacy; and**
- **if not, explain to the House the wide ambit of the delegated legislation-making power.**

Removal of presumption of innocence

8.19 Clause 71(2) of the Bill is a deeming provision. It provides that in the event a corporation is convicted of an offence under the Bill, any officer who is also charged with that offence is taken to have been convicted of the offence. Therefore, in the circumstance of conviction of a body corporate, an officer who is also charged with the offence is deprived of the presumption of innocence.

8.20 Clauses 71(3) and (4) of the Bill take the removal of the presumption of innocence even further.

8.21 Clauses 71(3) and (4) of the Bill provide:

- clause 71(3):

*If a body corporate **commits an offence** under this Act, then, **although the body corporate is not charged** with the offence, every person who was an officer of the body corporate at the time the offence was committed may be charged with the offence;*

(Committee's emphasis)

and

- clause 71(4):

If an officer is charged as permitted by subsection (3) and it is proved that the body corporate committed the offence, the officer is taken to have also committed the offence, subject to subsection (5).

- 8.22 Clause 71(3) clearly contemplates that a body corporate may be viewed as having “commit[ed] an offence” when there has been no charge and, therefore, no conviction. Clause 71(4) relies on establishing during the criminal prosecution of an officer of a corporation the ‘guilt’ of a corporation in respect of an offence with which the corporation has not been charged (that is, that the offence is “proved”).
- 8.23 The words “committed the offence” and “proved” assume a process which is not set out in the Bill. Who, for example, decides that a corporation has “committed” the offence for the purposes of clause 73(3)? What is the standard of proof required for a court to determine that an offence has been “proved” against a corporation, without conviction, in the course of a prosecution of an officer of the corporation? Due to the time constraints imposed by Standing Order 230A, the Committee has not had the opportunity to examine these matters.
- 8.24 The Committee does, however, draw attention to the most concerning issue arising from clauses 71(3) and (4) of the Bill. Regardless of the answers to the questions posed in paragraph 8.23, clauses 71(3) and (4) have the effect that a corporation can be found to have committed an offence in the course of a criminal proceeding to which it is not a party. An officer may then be deemed to be guilty of an offence which has not been subject to examination through a recognised trial process.
- 8.25 Clause 71(5) of the Bill provides what it terms a “defence” to prosecutions under clause 71. That subclause provides that it is a “defence” for an officer of a corporation to prove:
- that the offence was committed without the officer’s consent or contrivance; and
 - that the officer took all reasonable steps to prevent the commission of the offence.

- 8.26 Generally, when presenting such clauses to the Legislative Council, the Executive argues that the clause does not constitute a reversal of the onus of proof but provides a defence.
- 8.27 However, the need for an officer to prove the alleged “defences” only arises because of the deeming of guilt in clauses 71(2) and (4) without the prosecution having to establish the offence committed by the officer, or in the case of clause 71(4), the offence committed by the corporation through a proper trial process to which the corporation is a party.
- 8.28 The Committee notes that while provisions such as clauses 71(2) and (5) of the Bill are becoming increasingly part of proposed legislation, clauses 71(3) and (4) go a step further in eroding the presumption of innocence.
- 8.29 The Committee is of the view that provisions such as those proposed by clause 71(2), 71(3) and (4), removing the rights that a person would otherwise have to be presumed innocent (a fundamental precept of criminal law in the State), require cogent explanation.

Recommendation 11: The Committee recommends that the responsible Minister advise the Legislative Council of:

- the response of the courts and legal professional bodies to the removal of the presumption of innocence inherent in clauses 71(2) and 71(4) of the Bill;
- the process by which, and by whom, it will be determined that a corporation “*commit[t]ed the offence*” for the purposes of clause 71(3); and
- the basis on which a court will determine that an offence is “*proved*” against a corporation for the purposes of clause 71(4).

Recommendation 12: The Committee recommends that the responsible Minister provide the Legislative Council with the reasons for the removal of the presumption of innocence inherent in clauses 71(2), (3) and (4) of the Bill.

Recommendation 13: The Committee recommends that, subject to a cogent explanation being provided by the responsible Minister in respect of recommendation 12, the Legislative Council amend clause 71(3) of the Bill, to remove the assumption of committal of an offence by the corporation, and not enact clause 71(4) of the Bill. This can be effected in the following manner:

Page 41, line 5 - To delete “body corporate commits an offence” and insert -

body corporate is suspected, on reasonable grounds, to have committed an offence

Page 41, line 8 - To delete “the offence was committed” and insert -

the suspected offence is believed, on reasonable grounds, to have been committed

Page 41, lines 10 to 13 - To delete the lines

Page 41, line 14 - To delete “(5)” and insert -

(4)



Hon Adele Farina MLC

Chairman

Date: 24 June 2010

APPENDIX 1
IDENTIFIED STRUCTURES FOR UNIFORM LEGISLATION

APPENDIX 1

IDENTIFIED STRUCTURES FOR UNIFORM LEGISLATION

The former Legislative Assembly Standing Committee on Uniform Legislation and Intergovernmental Agreements identified and classified nine legislative structures relevant to the issue of uniformity in legislation which were endorsed by the 1996 Position Paper. A brief description of each is provided below.

Structure 1: *Complementary Commonwealth-State or Co-operative Legislation.* The Commonwealth passes legislation, and each State or Territory passes legislation which interlocks with it and which is restricted in its operation to matters not falling within the Commonwealth's constitutional powers.

Structure 2: *Complementary or Mirror Legislation.* For matters which involve dual, overlapping, or uncertain division of constitutional powers, essentially identical legislation is passed in each jurisdiction.

Structure 3: *Template, Co-operative, Applied or Adopted Complementary Legislation.* Here a jurisdiction enacts the main piece of legislation, with the other jurisdictions passing Acts which do not replicate, but merely adopt that Act and subsequent amendments as their own.

Structure 4: *Referral of Power.* The Commonwealth enacts national legislation following a referral of relevant State power to it under section 51 (xxxvii) of the Australian Constitution.

Structure 5: *Alternative Consistent Legislation.* Host legislation in one jurisdiction is utilised by other jurisdictions which pass legislation stating that certain matters will be lawful in their own jurisdictions if they would be lawful in the host jurisdiction. The non-host jurisdictions cleanse their own statute books of provisions inconsistent with the pertinent host legislation.

Structure 6: *Mutual Recognition.* Recognises the rules and regulation of other jurisdictions. Mutual recognition of regulations enables goods or services to be traded across jurisdictions. For example, if goods or services to be traded comply with the legislation in their jurisdiction of origin they need not comply with inconsistent requirements otherwise operable in a second jurisdiction, into which they are imported or sold.

Structure 7: *Unilateralism.* Each jurisdiction goes its own way. In effect, this is the antithesis of uniformity.

Structure 8: *Non-Binding National Standards Model.* Each jurisdiction passes its own legislation but a national authority is appointed to make decisions under that legislation. Such decisions are, however, variable by the respective State or Territory Ministers.

Structure 9: *Adoptive Recognition.* A jurisdiction may choose to recognise the decision making process of another jurisdiction as meeting the requirements of its own legislation regardless of whether this recognition is mutual.

APPENDIX 2
EXTRACT FROM THE COAG WORKING GROUP
COMMENTARY

**COAG RESPONSES TO THE RECOMMENDATIONS OF THE NATIONAL COMPETITION POLICY
 REVIEW OF PHARMACY**

RECOMMENDATION	<u>RESPONSE</u>
<p>Recommendation 1: Pharmacist-Only Ownership of Pharmacies</p> <p>The Review recommended that:</p> <p>(a) Legislative restrictions on who may own and operate community pharmacies are retained; and</p> <p>(b) With existing exceptions, the ownership and control of community pharmacies continues to be confined to registered pharmacists.</p>	<ul style="list-style-type: none"> • Accept Recommendations 1(a) and (b) noting that the impact of opening up the ownership of pharmacies could be too disruptive for the industry in the short term. Accepting this recommendation does not imply an obligation on the Australian Capital Territory and Northern Territory to amend their legislation as the Territories' legislation falls within the boundary of acceptable regulation as set out in Recommendation 1.
<p>Recommendation 2: Residential And Local Registration Requirements</p> <p>The Review recommended that:</p> <p>(a) Any State or Territory's residential requirements for pharmacy ownership are removed; and</p> <p>(b) Any State or Territory's requirements that a pharmacist be registered in that jurisdiction to own a pharmacy are retained, pending any consistent national arrangements that may be adopted.</p>	<ul style="list-style-type: none"> • Accept Recommendations 2(a) and (b).

RECOMMENDATION	RESPONSE
<p>Recommendation 3: Ownership Structures</p> <p>The Review recommended that:</p> <p>(a) Pharmacy ownership structures permitted by various State and Territory <i>Pharmacy Acts</i> be retained as being consistent with the defined principle of pharmacist ownership and effective control of pharmacy businesses;</p> <p>(b) <i>Pharmacy Acts</i> recognise, in addition to sole trading pharmacists and pharmacist partnerships, corporations with shareholders who are:</p> <ol style="list-style-type: none"> (1) All registered pharmacists; and (2) Registered pharmacists and prescribed relatives of those pharmacists; and <p>(c) Due to the risk of conflicts of interest of shareholders, and the difficulties in determining the extent to which minority shareholdings of non-pharmacists may compromise pharmacist control of a pharmacy, operating companies with minority shareholdings held by non-pharmacists are not considered to be appropriate ownership structures for pharmacy businesses.</p>	<ul style="list-style-type: none"> • Accept Recommendation 3(a) • Accept Recommendation 3(b) where jurisdictions' legislation requires pharmacist-only pharmacy ownership. • Accept Recommendation 3(c) where jurisdictions' legislation requires pharmacist-only pharmacy ownership.

RECOMMENDATION	RESPONSE
<p>Recommendation 4: Number of Pharmacies Owned by Proprietors and Pharmacist Supervision of Pharmacies</p> <p>The Review recommended that:</p> <p>(a) State and Territory restrictions on the number of pharmacies that a person may own, or in which they may have an interest, are lifted;</p> <p>(b) The effects of lifting such restrictions be monitored to ensure that they do not lead to undue market dominance or other inappropriate market behaviour; and</p> <p>(c) Legislative requirements that the operations of any pharmacy must be in the charge, or under the direct personal supervision, of a registered pharmacist are retained.</p>	<ul style="list-style-type: none"> • Accept Recommendation 4(a), noting that NSW remains concerned as to the potential for the development of monopolies in regional areas, and as such, as part of the implementation process for this recommendation, the State will further assess the impact of the proposal on competition within New South Wales. • Accept Recommendation 4(b) noting that the effects of lifting the restrictions on the number of pharmacies that a person can own will be assessed in discussions on the Australian Community Pharmacy Agreement in 2004; and that some jurisdictions, concerned about the impact of this proposal on regional areas, will further assess its impact during implementation. • Accept Recommendation 4(c)

RECOMMENDATION	RESPONSE
<p>Recommendation 5: Permitted Exceptions to Pharmacist Ownership</p> <p>The Review recommended that:</p> <p>(a) Friendly societies may continue to operate pharmacies, but that:</p> <ol style="list-style-type: none"> (1) Regulations specific to the establishment and operation of pharmacies by friendly societies, that do not also apply to other pharmacies and classes of proprietors, should be removed; and (2) Any friendly society that did not operate pharmacies in a jurisdiction on 1 July 1999 or any other prescribed date should not own, establish, or operate a pharmacy in that jurisdiction in the future, unless it is an entity resulting from an amalgamation of two or more friendly societies operating a pharmacy at that date; <p>(b) Permitted corporately-owned pharmacies continue to be restricted under grand-parenting arrangements where these apply;</p>	<ul style="list-style-type: none"> • Accept Recommendation 5(a)(1) noting that jurisdictions will ensure that the same benefits, standards and constraints will apply to friendly society pharmacies as apply to pharmacist-owned pharmacies. • Reject Recommendation 5(a)(2) as to accept this would severely limit the scope of Recommendation 5(a)(1). Friendly society pharmacies are a permitted exception to the pharmacist-owned pharmacy rule and therefore should be able to operate accordingly. • Accept Recommendation 5(b).

RECOMMENDATION	RESPONSE
<p>Recommendation 5: Permitted Exceptions to Pharmacist Ownership (Cont'd)</p> <p>(c) The relative financial and corporate arrangements of pharmacist-owned pharmacies and friendly society pharmacies, as these may affect the competitiveness of such pharmacies with each other, could be referred for definitive advice to the Australian Competition and Consumer Commission (ACCC), or another agency or authority of comparable and appropriate standing; and</p> <p>(d) The findings of any such inquiry may be taken into account as part of legislative reform processes in this regard.</p>	<ul style="list-style-type: none"> • Accept Recommendations 5(c) and (d). While advice from consultants given a brief to report on this matter was that there did not appear to be an unfair tax advantage to friendly societies, they also made clear their advice was subjective due to it being based on information from a limited sample of pharmacist owned pharmacies. • Note that there is no change proposed to the current provisions for deceased estates and bankrupt individuals and businesses.

<p>Recommendation 9: New Pharmacy Approvals</p> <p>The Review recommended that:</p> <p>(a) Some form of restriction on the number of pharmacies as outlets for the Pharmaceutical Benefits Scheme (PBS) is retained;</p> <p>(b) The parties to the Australian Community Pharmacy Agreement consider, in the interests of greater competition in community pharmacy, a remuneration system for PBS services that restricts the overall number of pharmacies by rewarding more efficient pharmacy businesses and practices, and providing incentives for less efficient pharmacy businesses to merge or close; but</p> <p>(c) If remuneration arrangements consistent with Recommendation 9(b) are not practical, controls on the number of pharmacies through restricting new pharmacies' eligibility for approvals to supply pharmaceutical benefits could be retained but if so, any "definite community need" criteria for those approvals should be made more relevant to the needs of underserved communities, particularly in rural and remote areas.</p> <p>Recommendation 10: Relocation of Existing Pharmacies</p> <p>The Review recommended that Pharmaceutical Benefits Scheme (PBS) related restrictions on the relocation of pharmacies from one site to another are phased out.</p> <p>Recommendation 11: Timing of Proposed Changes</p> <p>The Review recommended that, consistent with recommendations 9 and 10, the current Pharmaceutical Benefits Scheme (PBS) new pharmacy and relocated pharmacy approval restrictions be reformed and/or phased out from 1 July 2001.</p>	<ul style="list-style-type: none"> • The Working Group notes that the Commonwealth's rules on locating new and existing pharmacies have the most impact of all the restrictions on pharmacy businesses. The rules are inherently anti-competitive in their operation and effects. Since the Review reported in February 2000, the Commonwealth has entered into the third Australian Community Pharmacy Agreement (ACPA) with the Pharmacy Guild of Australia for the period 1 July 2000 to 30 June 2005. The Commonwealth, while accepting that the Review's recommendations on location rules may well offer real alternatives to the existing approach, has opted for an incremental and targeted easing of existing regulations in the third ACPA.
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RECOMMENDATION	RESPONSE
<p>Recommendation 12: Rural and Remote Pharmacies</p> <p>The Review recommended that:</p> <p>(a) Legislation to support specific programs and initiatives to assist the retaining and enhancing of pharmacy services in rural and remote areas is considered to be of a net public benefit; and</p> <p>(b) Non-transferable approvals to supply pharmaceutical benefits conferred, in limited circumstances, on a specific rural or remote locality are considered to be a justifiable restriction on competition in the public interest.</p> <p>Recommendation 13: Medical Centres and Aged Care Facilities</p> <p>The Review recommended that, should new pharmacy and relocated pharmacy approval restrictions continue after 1 July 2001, that:</p> <p>(a) Approvals, for Pharmaceutical Benefits Scheme (PBS) purposes, of pharmacies located in eligible medical centres, private hospitals and aged care facilities, and intended to serve those facilities, are considered without reference to the distance of a given facility's site from the nearest existing pharmacy; and</p> <p>(b) Measures as proposed in Recommendation 13(a) are incorporated in any transitional or ongoing regulatory measures concerning the approval of new and relocated pharmacies to supply PBS benefits.</p>	<ul style="list-style-type: none"> ● The Working Group notes that the third ACPA contains a set of initiatives, costing \$76m over five years, to improve access to pharmacy services in rural and remote areas, and to encourage pharmacists to work in these areas. ● The Working Group notes that the third ACPA provides for pharmacy to relocate, without reference to distance criteria, to a private hospital with more than 150 beds (about 10% of all private hospitals).

RECOMMENDATION	RESPONSE
<p>Recommendation 14: General Regulatory Principles</p> <p>The Review recommended that:</p> <p>(a) <i>Pharmacy Acts</i>, delegated legislation and statutory instruments concentrate on setting out the minimum regulatory requirements for the safe and competent delivery of pharmacy services by, or under the supervision of, pharmacists;</p> <p>(b) Legislation sets out clearly the roles, responsibilities and powers of decision-making, regulatory and reviewing authorities in administering that legislation; and</p> <p>(c) <i>Pharmacy Acts</i> distinguish between the responsibilities of governments to approve and formally set professional practice standards, professional instructions and procedural guidelines, and those of regulatory authorities to implement and enforce those standards, instructions and guidelines.</p>	<ul style="list-style-type: none"> • Accept Recommendation 14(a) • Accept Recommendation 14(b) • Accept Recommendation 14(c)
<p>Recommendation 15: Regulatory Authorities</p> <p>The Review recommended that:</p> <p>(a) The appointment, composition, functions and charter of regulatory authorities should be set out clearly in legislation and should not unduly restrict or hamper competitive and commercial activity in the pharmacy industry by the way they operate; and</p> <p>(b) Regulatory authorities are appointed, composed and structured so that they are accountable to the community through government, and focus at all times on promoting and safeguarding the interests of the public.</p>	<ul style="list-style-type: none"> • Accept Recommendation 15(a) <p>Accept Recommendation 15(b) noting that the means of achieving this, whether by establishing a system for direct appointment of all board members or relying on a mix of appointed or elected members, are matters for the States to consider in implementation.</p>
RECOMMENDATION	RESPONSE

APPENDIX 3

INVESTIGATION PROVISIONS OF THE *PHARMACY ACT 1964*

APPENDIX 3

INVESTIGATION PROVISIONS OF THE *PHARMACY ACT 1964*

31A. Investigator

- (1) The Council may appoint a person to investigate a matter relevant to the performance of the Council's functions under this Act and report to the Council.
- (2) The Council is to issue to each investigator it appoints a certificate of appointment in an approved form.

Pharmacy Act 1964

Part IV Provisions relating to the practice of pharmacy

s. 31B

- (3) A certificate purporting to have been issued under this section is evidence in any court of the appointment to which the certificate purports to relate.

[Section 31A inserted by No. 55 of 2004 s. 931.]

31B. Report of investigator

- (1) An investigator must —
- (a) within such period as the Council requires prepare a report on the investigation, and make recommendations as to the manner in which the matter should be dealt with; and
 - (b) immediately after preparing the report, provide the Council with a copy of the report.
- (2) The investigator must return his certificate of appointment at the time the Council is provided with a copy of the report.

[Section 31B inserted by No. 55 of 2004 s. 931.]

31C. Powers of investigator

- (1) An investigator may for the purposes of an investigation —
- (a) enter and inspect the premises of a person named in a warrant issued under section 31E(1), and exercise the powers referred to in section 31E(2)(b) and (c);
 - (b) require a person to produce to the investigator any document or other thing concerning the investigation that is in the possession or under the control of the person;
 - (c) inspect any document or other thing produced to the investigator and retain it for such reasonable period as the investigator thinks fit, and make copies of a document or any of its contents;
 - (d) require a person —
 - (i) to give the investigator such information as the investigator requires; and

Pharmacy Act 1964
Provisions relating to the practice of pharmacy **Part IV**

s. 31C

- (ii) to answer any question put to that person, in relation to the matter the subject of the investigation; and
 - (e) exercise other powers conferred on an investigator by the regulations.
- (2) A requirement made under subsection (1)(b) —
 - (a) must be made by notice in writing given to the person required to produce the document or other thing;
 - (b) must specify the time at or within which the document or other thing is to be produced;
 - (c) may, by its terms, require that the document or other thing required be produced at a place and by means specified in the requirement; and
 - (d) where the document required is not in a readable format, must be treated as a requirement to produce —
 - (i) the document itself; and
 - (ii) the contents of the document in a readable format.
- (3) A requirement made under subsection (1)(d) —
 - (a) may be made orally or by notice in writing served on the person required to give information or answer a question, as the case may be;
 - (b) must specify the time at or within which the information is to be given or the question is to be answered, as the case may be; and
 - (c) may, by its terms, require that the information or answer required —
 - (i) be given orally or in writing;
 - (ii) be given at or sent or delivered to a place specified in the requirement;

Pharmacy Act 1964

Part IV Provisions relating to the practice of pharmacy

s. 31D

- (iii) in the case of written information or answers be sent or delivered by means specified in the requirement; and
 - (iv) be verified by statutory declaration.
- (4) If under subsection (1)(d) an investigator requires a person to give information or answer a question, the investigator must inform that person that the person is required under this Act to give the information or answer the question.
- (5) An investigator must produce his certificate of appointment if requested to do so by a person in respect of whom the investigator has exercised, or is about to exercise, a power under this section.

[Section 31C inserted by No. 55 of 2004 s. 931.]

31D. Warrant to enter premises

- (1) If the Council has determined in a particular case that an investigator has reasonable grounds for believing that entry to premises is necessary for the purpose of an investigation, the investigator may apply to a magistrate for a warrant to be issued in respect of those premises.
- (2) An application for a warrant must —
 - (a) be in writing;
 - (b) be accompanied by a notice in writing from the Council stating that it has determined in the particular case that the investigator has reasonable grounds for believing that entry to premises is necessary for the purpose of the investigation;
 - (c) set out the grounds for seeking the warrant; and
 - (d) describe the premises that are to be entered.

Pharmacy Act 1964
Provisions relating to the practice of pharmacy **Part IV**

s. 31E

- (3) A magistrate to whom an application is made under this section must refuse it if —
- (a) the application does not comply with the requirements of this Act; or
 - (b) when required to do so by the magistrate, the investigator does not give to the magistrate more information about the application.
- (4) The information in an application or given to a magistrate under this section must be verified before the magistrate on oath or affirmation or by affidavit, and the magistrate may for that purpose administer an oath or affirmation or take an affidavit.

[Section 31D inserted by No. 55 of 2004 s. 931.]

31E. Issue of warrant

- (1) A magistrate to whom an application is made under section 31D may issue a warrant, if satisfied that there are reasonable grounds for believing that entry and inspection of the premises are necessary for the purpose referred to in that section.
- (2) A warrant under subsection (1) authorises the investigator —
- (a) to enter and inspect the premises named in the warrant;
 - (b) to require a person on the premises to answer questions or produce documents or other things in the person's possession concerning the investigation; and
 - (c) to inspect documents and other things, and take copies of or extracts from documents, produced in compliance with a requirement made under paragraph (b).
- (3) There must be stated in a warrant —
- (a) the purpose for which the warrant is issued;
 - (b) the name of the person to whom the warrant is issued; and
 - (c) a description of the premises that may be entered.

Pharmacy Act 1964

Part IV Provisions relating to the practice of pharmacy

s. 31F

- (4) A magistrate who issues a warrant must cause a record to be made of particulars of the grounds that the magistrate has relied on to justify the issue of the warrant.

[Section 31E inserted by No. 55 of 2004 s. 931.]

31F. Execution of warrant

- (1) If asked by the occupier or a person in charge of the premises, the person executing a warrant must produce it for inspection.
- (2) A warrant ceases to have effect —
- (a) at the end of the period of one month after its issue;
 - (b) if it is withdrawn by the magistrate who issued it; or
 - (c) when it is executed,

whichever occurs first.

[Section 31F inserted by No. 55 of 2004 s. 931.]

31G. Incriminating information, questions, or documents

Without prejudice to the provisions of section 11 of the *Evidence Act 1906*, where under section 31C a person is required to —

- (a) give any information;
- (b) answer any question; or
- (c) produce any document,

he shall not refuse to comply with that requirement on the ground that the information, answer, or document may tend to incriminate the person or render the person liable to any penalty, but the information or answer given, or document produced, by the person shall not be admissible in evidence in any proceedings against the person other than proceedings in respect of an offence against section 31H(1)(b).

[Section 31G inserted by No. 55 of 2004 s. 931.]

Pharmacy Act 1964
Provisions relating to the practice of pharmacy **Part IV**

s. 31H

31H. Failure to comply with investigation

- (1) Where under section 31C a person is required to give any information, answer any question, or produce any document and that person, without reasonable excuse (proof of which shall lie on him) —
- (a) fails to give that information or answer that question at or within the time specified in the requirement;
 - (b) gives any information or answer that is false in any particular; or
 - (c) fails to produce that document at or within the time specified in the requirement,
- the person commits an offence.
Penalty: \$2 000.
- (2) It is a defence in any proceeding for an offence under subsection (1)(a) or (c) for the defendant to show —
- (a) that, in the case of an alleged offence arising out of a requirement made orally under section 31C, the investigator did not, when making the requirement, inform the defendant that he was required under this Act to give the information or answer the question, as the case may be;
 - (b) that, in the case of an alleged offence arising out of a requirement made by notice in writing under section 31C, the notice did not state that he was required under this Act to give the information, answer the question, or produce the document or thing, as the case may be;
 - (c) that the time specified in the requirement did not afford the defendant sufficient notice to enable him to comply with the requirement; or

Pharmacy Act 1964

Part IV Provisions relating to the practice of pharmacy

s. 31I

- (d) that, in any case, the investigator did not, before making the requirement, have reasonable grounds to believe that compliance with the requirement would materially assist in the investigation being carried out.

[Section 31H inserted by No. 55 of 2004 s. 931.]

31I. Obstruction of investigator

A person shall not prevent or attempt to prevent an investigator from entering premises or otherwise obstruct or impede an investigator in the exercise of his powers under section 31C.

Penalty: \$2 000.

[Section 31I inserted by No. 55 of 2004 s. 931.]