HEALTH, COMMUNITIES, DISABILITY SERVICES AND DOMESTIC AND FAMILY VIOLENCE PREVENTION COMMITTEE

Paper No. 2
56th Parliament
June, 2018

# Inquiry into the establishment of a pharmacy council and pharmacy ownership in Queensland

## This issues paper

This paper provides background information about the Health, Communities, Disability Services and Domestic and Family Violence Committee's (the committee's) inquiry into the establishment of a pharmacy council and pharmacy ownership in Queensland, the key issues the committee is interested in exploring further and how to get involved. Submissions to the inquiry close on **Friday 13 July 2018 at 5pm**.

## Inquiry terms of reference

On 3 May 2018, the Legislative Assembly referred an inquiry to the committee with the following terms of reference:

That the committee inquire into and report to the Legislative Assembly, by 30 September 2018, on:

a) the establishment of a pharmacy council, and

b) all transfers of pharmacy ownership in Queensland over the past two years to ensure compliance with existing legislation.

That, in undertaking this inquiry, the committee should consider:

a) the effectiveness of the current systems and processes in Queensland to regulate pharmacy business ownership in Queensland and protect Queensland consumers;

b) the possible role and scope of responsibility of a pharmacy council, including any powers of enforcement and/or ability to impose penalties; pharmacists' and pharmacy assistants' roles and scope of practice; and interactions with other agencies or individuals involved in regulating pharmacy businesses and practice;

c) models of regulation of pharmacy business ownership in other jurisdictions;

d) a cost-benefit analysis of establishing a pharmacy council;

e) any changes to legislation that would be required to establish a pharmacy council, including, but not limited to, changes to the *Pharmacy Business Ownership Act 2001* (Qld), the *Health Act 1937* (Qld) and subordinate legislation, namely the Health (Drugs and Poisons) Regulation 1996 (Qld) and the Health Regulation 1996 (Qld); and

f) all transfers of pharmacy ownership in Queensland over the past two years.

## The pharmacy sector

Pharmacies and pharmacists play an important role in primary health care in Queensland, most importantly through the delivery of Pharmaceutical Benefits Scheme (PBS) medicines to the community. Pharmacies also sell over-the-counter (scheduled non-prescription) medicines and complementary remedies, supply health-related products (such as personal care and grooming items), and provide hire arrangements for medical devices and equipment to the public.

The pharmacy landscape has evolved over the past 50 years. It has shifted from a focus on small independent pharmacies in the 1960s, to more sophisticated franchise and banner groups (both wholesaler-owned and independent) in the 1980s, to the arrival of big box discount pharmacies in more recent years.[1] There is now a mix of

[1] KordaMentha, *Pharmacy: A challenging and changing outlook*, Publication No 14-01, February 2014, https://www.kordamentha.com/getmedia/9ab7c48d-6d6f-448e-92b7-0ff74b19c4d1/14-01_pharmacy_1.pdf.aspx?ext=.pdf

traditional pharmacies with little or no online presence, many pharmacies that dispense through multiple channels but where a physical presence remains, and some pharmacies that are solely online.[2]

Most pharmacies derive around 70 per cent of their income from the dispensing of PBS medicines.[3] However, some pharmacies have a greater emphasis on front-of-house retail sales. In recent years many pharmacists have begun moving their focus away from medicine dispensing and front-of-house (non-medicine) sales to a more patient-centred approach providing services such as:

- wound management
- health checks
- vaccination programs
- methadone programs
- medicines review and reconciliation
- dose administration aids, and
- supply of diabetes products and advice.

This changing focus has been driven by increased competition from large, high volume, low margin pharmacies that compete on price and declining profitability brought on by the introduction, and subsequent expansion, of the Commonwealth Government's Price Disclosure Regime for PBS medicines. The Pharmacy Guild estimated that in 2014-15 the regime would reduce net profit before tax of an average pharmacy by approximately $90,000.[4]

It is estimated that on average, Australians visit a pharmacy 14 times a year.[5] As at 30 June 2015, there were around 1,100 pharmacies in Queensland that dispensed prescriptions valued at nearly $1.5 billion over 2014-15. This equated to expenditure of $309 per capita or just over $1.3 million per pharmacy on prescription medicines. As at 30 June 2015, Queensland had 20 per cent of Australia's pharmacies which is proportionate to its distribution of the nation's population.[6]

## Pharmacy legislation

The Commonwealth and state and territory governments have responsibility for different aspects of the regulation of pharmacies and pharmaceutical supply in Australia. The Commonwealth Government regulates pharmaceuticals and where pharmacies that dispense medicines subsidised under the PBS can be located (known as the 'pharmacy location rules'). State and territory governments regulate the ownership of pharmacies, as well as the licensing of pharmacists and pharmacy premises. They also restrict the sale and dispensing of prescriptions and a range of other medicines to pharmacies.[7]

### Pharmacy location rules

The location of pharmacies in Australia that are approved to supply medicines subsidised under the PBS is determined through the application of pharmacy location rules which are administered by the Commonwealth Government. These rules restrict where an approved pharmacy can either be established or re-located, and set out location-based criteria which must be met for a pharmacist to be approved to supply PBS medicines.

The pharmacy location rules comprise 11 separate rules that are applicable in certain circumstances, including restricting the relocation of an existing pharmacy within the local community (up to one kilometre) and restricting the establishment of a new pharmacy to where there is a demonstrable community need.[8] A pharmacy must also not be located within, or directly accessible from, a supermarket.

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2 Bill Kelly, 'Online pharmacies: buyer beware', *Australian Prescriber*, 1 December 2015, https://www.nps.org.au/australian-prescriber/articles/online-pharmacies-buyer-beware

3 The Pharmacy Guild of Australia, *Submission in response to the Competition Policy Review Issues Paper*, June 2014, p 30, http://competitionpolicyreview.gov.au/files/2014/07/PGA.pdf

4 As above.

5 The Pharmacy Guild of Australia', 'Vital facts on community pharmacy', May.2018, https://www.guild.org.au/__data/assets/pdf_file/0020/12908/Vital-facts-on-community-pharmacy.pdf

6 Stephen King, Bill Scott and Jo Watson, *Review of Pharmacy Remuneration and Regulation, Discussion Paper*, July 2016, http://www.health.gov.au/internet/main/publishing.nsf/content/7E5846EB2D7BA299CA257F5C007C0E21/$File/Discussion%20Paper%20-%20Review%20of%20Pharmacy%20Remuneration%20and%20Regulation.pdf

7 As above.

8 As above.

These rules aim to ensure a well distributed network of community pharmacies to provide reasonable access to PBS medicines to all Australians, regardless of where they live.

The Commonwealth's pharmacy location rules are outside the scope of this inquiry.

### Pharmacy ownership regulation in Queensland

Pharmacy ownership in Queensland is generally restricted to pharmacists. The *Pharmacy Business Ownership Act 2001* (Qld) (the Act) specifies that:

A person must not own a pharmacy business unless the person is:

a) a pharmacist; or

b) a corporation whose directors and shareholders are all pharmacists; or

c) a corporation:

   (i) whose directors and shareholders are a combination of pharmacists and relatives of the pharmacist; and

   (ii) in which the majority of shares are held by pharmacists; and

   (iii) in which only pharmacists hold voting shares; or

d) a friendly society; or

e) Mater Misericordiae Health Services Brisbane Limited.[9]

In addition, a pharmacist or eligible corporation must not have a beneficial interest in more than five pharmacy businesses at the same time. Friendly societies and Mater Misericordiae Health Services Brisbane Limited can own up to six pharmacy businesses at the same time.[10]

According to the Act these ownership restrictions are necessary 'to promote the professional, safe and competent provision of pharmacy services, and to maintain public confidence in the pharmacy profession.'[11] Other primary healthcare providers however, operate without the need for ownership (and location) restrictions. For example, ownership of medical practices is not limited to General Practitioners (GPs), nor are GP practices prevented from locating in close proximity to one another.

***Issues for consideration***

1. Are pharmacy ownership restrictions imposed by the *Pharmacy Business Ownership Act 2001* (Qld) (Act) necessary to protect consumers and deliver accessible and affordable medicines and services? Why or why not?
2. Are the ownership restrictions sufficiently clear, particularly regarding the restrictions on corporations owning pharmacies? If not, how could the restrictions be made clearer?
3. Would changing the pharmacy ownership restrictions under the Act improve community outcomes? If so, how should the restrictions be changed?
4. Should the Act be amended to allow any party to own a pharmacy, subject to requirements for dispensing only by a qualified pharmacist? Would the community be better off under such a scenario? Why or why not?
5. Is there any difference in performance of pharmacies owned by non-pharmacists in Queensland (such as those run by friendly societies or the Mater Misericordiae Health Services Brisbane Limited) in relation to protecting consumers and delivering accessible and affordable medicines and services?
6. Does the Act provide adequate protections to promote the professional, safe and competent provision of pharmacy services, and to maintain public confidence in the pharmacy profession now and in the future? If not, what additional protections should be included in the Act and why?

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9 *Pharmacy Business Ownership Act 2001,* s 139B.

10 *Pharmacy Business Ownership Act 2001*, s 139H.

11 *Pharmacy Business Ownership Act 2001*, s 8.

## Administration of pharmacy ownership regulation

The Queensland Department of Health (the department) has responsibility for administering the pharmacy ownership restrictions in the Act. A pharmacist must notify the chief executive of the department whenever there is a change of ownership of a pharmacy[12] or a change in business particulars (for example, the name or location of the business, any change in the ownership structure or the equity share of the owners).[13] On receipt of a notification from a pharmacist, the department undertakes checks to ensure that the changes do not result in a breach of the requirements of the Act and writes to the pharmacist to acknowledge their notification or request additional information.

The Act provides a range of offences and penalties related to pharmacy ownership restrictions, notification requirements for changes to pharmacy ownership, operating a pharmacy without supervision by a pharmacist, and impeding the work of inspectors who are inspecting apparent breaches of the legislation. These provisions and the maximum penalties that apply are set out in the table below. The maximum penalties prescribed in the Act are the same for individuals and corporations.

The ownership regulations were previously administered by the Pharmacists Board of Queensland under the *Pharmacists Registration Act 2001* (Qld). However, following the establishment of the National Registration and Accreditation Scheme (NRAS) in July 2010, the Pharmacists Board of Queensland was abolished and its regulatory functions for pharmacy ownership were taken over by the department.

| ***Pharmacy Business Ownership Act 2001*–offence provisions** | **Maximum penalty[14]** |
|---|---|
| Section 139B Restriction on who may own a pharmacy business | 200 penalty units ($26,110) |
| Section 139C Pharmacist whose registration is suspended or cancelled may own pharmacy business for limited period | 200 penalty units ($26,110) |
| Section 139H Restriction on number of pharmacy businesses in which a person may have a beneficial interest | 200 penalty units ($26,110) |
| Section 141 Pharmacy business to be carried on under supervision of pharmacist | 50 penalty units ($6,527.50) |
| Section 141A Notification of change of ownership of a pharmacy business | 50 penalty units ($6,527.50) |
| Section 141B Notification of change of ownership particulars of a pharmacy business | 50 penalty units ($6,527.50) |
| Section 157 Failure to help inspector | 50 penalty units ($6,527.50) |
| Section 158 Failure to give information | 50 penalty units ($6,527.50) |
| Section 171 Failure to give name or address | 50 penalty units ($6,527.50) |
| Section 173 Failure to produce document | 50 penalty units ($6,527.50) |
| Section 177 False or misleading information | 50 penalty units ($6,527.50) |
| Section 178 False or misleading documents | 50 penalty units ($6,527.50) |
| Section 179 Obstructing an inspector | 100 penalty units ($13,055) |
| Section 180 Impersonating an inspector | 50 penalty units ($6,527.50) |

The committee will consider the extent to which the Act is being complied with and whether changes are needed to achieve better community outcomes.

***Issues for consideration***

7. Are you aware of any transfers of pharmacy ownership which have not conformed to the requirements under the *Pharmacy Business Ownership Act 2001* (Qld) (Act)?
8. Are the offences prescribed in the Act necessary and sufficient to ensure the objectives and intent of the legislation are being met, and are the maximum offences that apply appropriate?

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12 *Pharmacy Business Ownership Act 2001*, s 141A.

13 *Pharmacy Business Ownership Act 2001*, s 141B.

14 The Penalties and Sentences (Penalty Unit Value) Amendment Regulation 2018 states that the value of a penalty unit is $130.55 from 1 July 2018.

## Pharmacy ownership regulation in other Australian jurisdictions

As in Queensland, pharmacy ownership in other Australian states and territories is restricted to pharmacists. Other Australian states also have restrictions on the number of pharmacies a pharmacist may own, while the territories have no such restrictions. The maximum allowable number of pharmacies per pharmacist in each state is:

- Western Australia and Tasmania: four
- Queensland, New South Wales and Victoria: five, and
- South Australia: six.[15]

***Issues for consideration***

9. Do you think there should be restrictions on the number of pharmacies a pharmacist may own in Queensland? Are the current restrictions under the *Pharmacy Business Ownership Act 2001* (Qld) appropriate?
10. Given there are no restrictions in the Australian Capital Territory and the Northern Territory, are community outcomes in the Australian territories different from the Australian states? If so, how are they different?

## Administration of pharmacy ownership regulation in other jurisdictions

In all other Australian jurisdictions except the ACT and the NT, ownership regulation is administered by governing bodies that sit outside the relevant departments of health:

- in New South Wales, the Pharmacy Council of New South Wales
- in the Australian Capital Territory, ACT Health
- in Victoria, the Victorian Pharmacy Authority
- in Tasmania, the Tasmanian Pharmacy Authority
- in South Australia, the Pharmacy Regulation Authority SA
- in Western Australia, the Pharmacy Registration Board of Western Australia, and
- in the Northern Territory, the Pharmacy Premises Committee, Department of Health.

In other jurisdictions, such as New South Wales, pharmacy businesses must submit an annual renewal of pharmacy registration and an annual declaration of financial interest to the administering authority (Pharmacy Council of New South Wales). Registration of pharmacy premises does not occur in Queensland. Pharmacy authorities/councils in other jurisdictions are funded by fees from annual pharmacy ownership and premises registration.[16]

***Issues for consideration***

11. Has pharmacy ownership regulation in other Australian jurisdictions improved community outcomes (relative to Queensland)? If so, how?
12. What functions might a pharmacy council perform in Queensland? How would these functions differ from the current functions performed by Queensland Health?
13. How would the establishment of a pharmacy council in Queensland improve community outcomes?
14. What would be the costs and benefits to the community of establishing a pharmacy council in Queensland?
15. What other viable alternatives should be considered to deliver superior community outcomes?
16. If a pharmacy council was established in Queensland, what issues would need to be considered in its interactions with other agencies or individuals involved in regulating pharmacy businesses and practice? What legislation would need to be changed?

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[15] Laetitia Hattingh, 'The regulation of pharmacy ownership in Australia: The potential impact of changes to the health landscape. *Journal of Law and Medicine*, 2011, vol 19, p 148, https://research-repository.griffith.edu.au/bitstream/handle/10072/41413/73312_1.pdf.

[16] Pharmacy Guild of Australia, correspondence dated 30 May 2018.

## Competition issues with pharmacy ownership regulation

Pharmacy regulation has been the subject of numerous reviews over the past 20 years. Most notably, in 2000 the National Competition Policy (NCP) Review of Pharmacy ('Wilkinson Review') was undertaken as part of the NCP legislation review process. It investigated state and territory licensing and ownership regulations and the pharmacy location rules embodied in the Australian Community Pharmacy Agreement (ACPA). The Wilkinson Review recommended removing the restrictions on how many pharmacies a pharmacist can own, but supported the retention of the prohibition on non-pharmacist ownership or control. In addition, the Wilkinson Review recommended that the location rules be overhauled to encourage rationalisation in the pharmacy sector.[17]

In response, in 2002 a Council Of Australian Governments (COAG) Working Group criticised the Wilkinson Review for ignoring evidence from other health sectors and overseas, which suggested that ownership restrictions were unnecessary. Despite this, the COAG Working Group backed the limited recommendations of the Wilkinson Review, arguing that more radical reform would create excessive adjustment pressures. However, few of the recommendations for change were implemented. For example, the proposed lifting of the restrictions on the number of pharmacies a pharmacist may own were withdrawn after intervention by the then Prime Minister.[18]

More recently, in 2015 the independent Panel of the Australian Government's Competition Policy Review ('Harper Review') recommended that state and territory pharmacy ownership regulations (and the pharmacy location rules) should be removed in the long term interests of consumers:

> *The Panel considers that current restrictions on ownership and location of pharmacies are not needed to ensure the quality of advice and care provided to patients. Such restrictions limit the ability of consumers to choose where to obtain pharmacy products and services, and the ability of providers to meet consumers' preferences.*
>
> *The Panel considers that the pharmacy ownership and location rules should be removed in the long-term interests of consumers. They should be replaced with regulations to ensure access to medicines and quality of advice regarding their use that do not unduly restrict competition.*[19]

The Australian Government's response to the Harper Review noted this recommendation and encouraged the 'states and territories to consider the appropriateness of existing restrictions on pharmacy ownership in pursuing public policy objectives' stating that it was 'willing to consider payments to states and territories for reforms that improve productivity and lead to economic growth'.[20]

In many developed countries including, Canada, Ireland, Japan, the Netherlands, the United Kingdom and the United States, there are no restrictions on pharmacy ownership. In Norway and Sweden, only doctors and the pharmaceutical industry are excluded from ownership. While in New Zealand and Denmark, non-pharmacists can have part ownership in a pharmacy if a pharmacist is the majority owner. Consistent with the ownership restrictions in Australia, in Spain and France ownership of pharmacies is limited to pharmacists.[21]

***Issues for consideration***

17. What effect would relaxing pharmacy ownership restrictions have on community outcomes (such as protecting consumers and delivering accessible and affordable medicines and services) in Queensland? What are the potential risks to consumers?

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[17] Productivity Commission, *Review of National Competition Policy Reforms*, Report no. 33, Canberra, 28 February 2005, http://www.pc.gov.au/inquiries/completed/national-competition-policy/report/ncp.pdf.

[18] As above.

[19] Ian Harper et al, *Competition Policy Review, Final Report*, March 2015, p 190, http://competitionpolicyreview.gov.au/final-report/.

[20] Australian Government, *Australian Government Response to the Competition Policy Review*, 24 November 2015, p 14, https://static.treasury.gov.au/uploads/sites/1/2017/06/Govt_response_CPR.pdf.

[21] Deloitte Access Economics, *Remuneration and regulation of community pharmacy, Literature review*, November 2016, http://www.health.gov.au/internet/main/publishing.nsf/Content/4E0B6EEE19F56A40CA2581470016D688/$File/deloitte-community-pharmacy-literature-review-2016.pdf.

## Pharmacists' and pharmacy assistants' roles and scopes of practice

There are approximately 4,500 pharmacists and over 10,000 pharmacy assistants working in Queensland pharmacies.[22] The pharmacy profession is regulated by the Pharmacy Board of Australia (supported by the Australian Health Practitioner Regulation Agency). The board registers pharmacists, deals with matters concerning professional practice, develops standards, codes and guidelines and handles complaints, investigations and disciplinary hearings. The board also approves training of ancillary staff.

Some sectors of the pharmacy industry have proposed an extension of the scope of practice for pharmacists and pharmacy assistants in Queensland:

> *Key areas where an enhanced role could occur are in medicine adherence and management (including in the post-acute setting and aged care), vaccination and immunisation services, a wider role to fill health gaps in rural and remote areas, preventative health intervention reducing avoidable hospitalisations and reducing pressure on hospital emergency departments, treatment of minor ailments and better management of long-term conditions and prescription renewals, underpinned by appropriate data collection and use of e-health technologies.*[23]

For example, opportunities to enhance pharmacy care include:

- allowing pharmacists to provide certain medicines to treat cardiovascular disease, respiratory illnesses and dermatitis without long-term patients needing to obtain a repeat prescription from a GP
- vaccinating against a wider range of illnesses and a broader range of people than currently allowed, and
- supplying pharmaceuticals such as contraceptive pills and erectile dysfunction pills[24] over the counter without the need for a repeat prescription.[25]

There are also proposals by the pharmacy industry to enable pharmacy assistants to undertake activities beyond their current scope of practice. Changes to the roles and scopes of practice of pharmacists and pharmacy assistants could extend the services offered by pharmacies to services already being undertaken by general practitioners.

The ordinary duties of pharmacy assistants require them to order, handle and supply therapeutic goods (under pharmacist supervision) and respond to/ask questions when clients request pharmacy medicines and pharmacist only medicines, and refer to a pharmacist, as required. There is no minimum mandatory training for pharmacy assistants in Queensland.[26]

In 2014 the Victorian Legislative Council's Legal and Social Issues Legislation Committee conducted an inquiry into community pharmacy in Victoria and made a number of recommendations to expand the role of community pharmacy. In particular the committee found 'A proportion of general practitioner visits are for 'less complex' conditions, some of which could potentially be treated within a community pharmacy'.[27]

In evidence provided to the Victorian committee, the Grattan Institute identified that:

> *… of more than 122 million GP visits in Australia annually, around 19 per cent (23 million visits) can be categorised as 'less complex' – that is, they involve management of only one problem, with only one or two medications prescribed, and do not involve referrals, tests or other treatment (apart from advice and explanation).*[28]

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22 Pharmacy Guild of Australia, correspondence dated 30 May 2018.

23 As above, attachment, p 5.

24 Viagra is available in pharmacies without a prescription in the United Kingdom, https://www.independent.co.uk/life-style/health-and-families/viagra-buy-without-prescription-over-counter-uk-pharmacies-male-impotence-erectile-dysfunction-a8275461.html.

25 Steven Scott, 'Chemists bid to fill drug role', *Courier Mail*, 22 May 2018, p 3. Lucy Stone, 'Doctors concerned over 'low-risk' medication prescription proposal, *Brisbane Times*, 23 May 2018. Heather Saxena,'Inquiry set up to probe ownership breaches', *Pharmacy News*, 22 May 2018.

26 Pharmacy Guild of Australia, correspondence dated 30 May 2018.

27 Victorian Legislative Council Legal and Social Issues Legislation Committee, *Inquiry into Community Pharmacy in Victoria*, October 2014, p 39, https://www.parliament.vic.gov.au/lsic/inquiries/article/2372.

28 As above, p 38.

Within the 'less complex' category of GP visits, the Grattan Institute calculated that:

> *… at least four million involve a GP issuing a repeat for a prescription the patient is already taking. Nearly 1.3 million visits involve a vaccination to prevent a disease with no 'diagnosis' or other treatment. Around 2.7 million visits are for colds, 220,000 for hay fever and 53,000 are for excess ear wax.*[29]

Due to the short amount of time between the Victorian committee's report being tabled (October 2014) and the Victorian parliament dissolution (November 2014) there was no formal government response to the inquiry report.

***Issues for consideration***

18. Should the scope of practice of pharmacists and pharmacy assistants in Queensland be extended? If so, in what areas of practice?
19. What additional training for pharmacists/pharmacy assistants, or other risk reduction measures, should be implemented to ensure patient safety?

**How to get involved**

The committee welcomes public participation in its work.

**Register your interest**

You can subscribe to receive regular email updates about the work of the committee for this inquiry, here. We will notify you of dates and venues for the committee's public meetings and hearings as well as briefs and other documents the committee publishes for the inquiry.

**Make a written submission**

The committee invites written submissions on the issues identified for comment in this issues paper, and any other issues relevant to the terms of reference. Guidelines on making submissions are available from the committee's webpage here.

Written submissions should be posted to:

Committee Secretary
HCDSDFVPC
PARLIAMENT HOUSE QLD 4000

or faxed to: 07 3553 6699

or emailed to: pharmacy@parliament.qld.gov.au

Submissions close on **Friday 13 July 2018 at 5pm**.

## Committee Members

**Aaron Harper MP (Chair)**

Member for Thuringowa (ALP)

**Mark McArdle MP (Deputy Chair)**

Member for Caloundra (LNP)

**Michael Berkman MP**

Member for Maiwar (GRN)

**Marty Hunt MP**

Member for Nicklin (LNP)

**Barry O'Rourke MP**

Member for Rockhampton (ALP)

**Joan Pease MP**

Member for Lytton (ALP)

## Contacting the committee

Questions about the inquiry should be directed to the Committee Secretary:
Phone: 07 3553 6632 or Freecall: 1800 504 022 Email: pharmacy@parliament.qld.gov.au

29 As above, p 39.