
The regulation of pharmacy ownership in Australia: The potential impact of changes to the health landscape

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Australian community pharmacy ownership restrictions have been in place for many years. However, it is timely to review these structures in terms of the Commonwealth Government's proposed changes to the health care system and the need for flexibility to ensure access of vital medicines to the community. Careful consideration has to be given to the advantages and disadvantages of regulatory structures that limit ownership to pharmacists, compared to non-pharmacist ownership. Other ownership aspects that need to be evaluated include the number of pharmacies one pharmacist should be allowed to own or co-own and the extent of control required on the location of pharmacies.

INTRODUCTION

The Australian pharmacy ownership regulatory framework has been relatively static for many years despite a major revision of ownership during the term of the National Competition Policy systematic legislative review process during 1995-2000.¹ However, it is important to evaluate pharmacy ownership regulatory structures continually, as well as limitations in terms of whether it provides the best health outcomes. It is also important to consider whether the regulatory measures serve to inhibit or promote cost and competition. Recently, the Australian Government has reassured consumers that the network of community pharmacies would remain viable and at the front line of health care to deliver access to vital medicines and professional services, such as health advice.²

PHARMACY OWNERSHIP LEGISLATION

The regulation of pharmacy ownership will continue to be the responsibility of the States and Territories as the new national registration and accreditation scheme for health professionals that was introduced on 1 July 2010 does not apply to the licensing of pharmacy businesses.³ Therefore, although the Pharmacy/Pharmacist Boards in the various jurisdictions have been replaced by the Pharmacy Board of Australia pursuant to the *Health Practitioners Regulation National Law Act 2009* (Qld),⁴ the Intergovernmental Agreement between the Commonwealth, States and Territories stipulated that the licensing of pharmacy businesses and pharmacy ownership restrictions will continue to be the responsibility of the States and Territories,⁵ which enables the jurisdictions to reflect local needs and conditions.

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¹ Wilkinson WJ, *National Competition Policy Review of Pharmacy Legislation: Final Report* (8 February 2000) (the Wilkinson Review), <http://www.health.gov.au/internet/main/publishing.nsf/Content/pharmacy-ncpr-index> viewed 2 November 2010.

² Urbis, *Review of the Pharmacy Location Rules under the Fourth Community Pharmacy Agreement* (June 2010), <http://www.health.gov.au/internet/main/publishing.nsf/content/pharmacy-4cpa-reviews> viewed 2 November 2010.

³ State Government Victoria, *Victorian Pharmacy Authority – A Consultation Paper Regarding Continued Controls on Who may Own and Operate Pharmacies in Victoria* (Victorian Government, Department of Human Services, Melbourne, July 2009) Foreword.

⁴ *Health Practitioner Regulation National Law Act 2009* (Qld), s 31.

⁵ *Intergovernmental Agreement for a National Registration and Accreditation Scheme for the Health Professions* (2008) at [1.33], <http://www.ahpra.gov.au/Search.aspx?Search=intergovernmental%20agreement%20between%20the%20Commonwealth,%20states%20and%20territories> viewed 4 January 2011.

Ownership regulation will therefore remain at State and Territory level and new ownership administrative structures need to be put in place with the abolition of the State and Territory Boards. The precise arrangements are currently still being set up within the jurisdictions. For example:

- in Queensland the administration of ownership has been transferred to Queensland Health;⁶
- in Victoria this function will be managed by the Victorian Pharmacy Authority;⁷
- in Tasmania the proposal is for the Tasmanian Pharmacy Authority to perform ownership and business administration functions;⁸ and
- in South Australia function was transferred to the Pharmacy Regulation Authority South Australia.⁹

Although new administrative structures are being established, it seems that limitations similar to those previously prescribed by the States and Territories in terms of who may own pharmacies and the number of pharmacies that an individual pharmacist may own in each jurisdiction will apply. Thus, the previous ownership structures have remained mostly unchanged: except for certain jurisdictional grandfather clauses, they are restricted to pharmacists or corporate entities controlled by pharmacists. However, provisions exist in all of the jurisdictions, except the Australian Capital Territory, to enable friendly societies¹⁰ to own pharmacies.¹¹ Provisions in certain jurisdictions also provide for relatives of a pharmacist to have minority shares in a pharmacy.¹² Additionally, the Northern Territory legislation provides for Aboriginal Health Services to own pharmacies¹³ and in Queensland the Mater Misericordiae Health Services Brisbane Ltd may also own pharmacy businesses.¹⁴

The number of pharmacies a pharmacist can own or co-own varies among the jurisdictions with no restrictions in the two Territories;¹⁵ Western Australia and Tasmania allowing four;¹⁶ Queensland, New South Wales and Victoria allowing five;¹⁷ and South Australia allowing six per pharmacist.¹⁸ Under these legislative provisions, it is not clear whether the restrictions on numbers only apply to the specific jurisdiction covered under an Act or whether they extend to other jurisdictions as well. Should the various Acts only restrict ownership numbers in individual jurisdictions without cross-control, it could be possible for one pharmacist to own or co-own a large number of pharmacies, provided that the pharmacies are not all in one jurisdiction. For example, if this is the case, a pharmacist could own five pharmacies in Queensland, five in New South Wales and six in South Australia – a total of 16

⁶ *Pharmacy Business Ownership Act 2001* (Qld), s 204.

⁷ State Government Victoria, n 3, p 12.

⁸ Tasmania, Department of Health and Human Services, *Consultation Paper: Pharmacy Regulation: Ongoing Regulation of Pharmacy Ownership and Registration of Pharmacy Business Premises in Tasmania* (Tasmanian Department of Health and Human Services, Hobart, September 2009) p 9.

⁹ *Health Practitioner Regulation National Law (South Australia) Act 2010* (SA), s 26.

¹⁰ A friendly society is composed of a body of people who join together for a common purpose. Before the availability of insurances and the development of the so-called welfare state, friendly societies played an important role in people's lives providing a range of financial and social services not otherwise available to individuals. One area where traditionally friendly societies have been active is in the field of health; in Australia (and New Zealand) this translated into pharmacy ownership. Although the importance of friendly societies is somewhat diminished in contemporary Australian society, the ownership of pharmacies by friendly societies is still reflected in much of the current legislation governing pharmacy practice.

¹¹ Hattingh HL, Smith NA, Searle J, King MA and Forrester K, "Regulation of the Pharmacy Profession throughout Australia", (2007) 37(3) *JPPR* 176.

¹² *Pharmacy Business Ownership Act 2001* (Qld), ss 139B, 139C; *Pharmacy Act 2010* (WA), s 54.

¹³ *Health Practitioners Act 2004* (NT), Sch 8, subcl 2.

¹⁴ *Pharmacy Business Ownership Act 2001* (Qld), s 139B.

¹⁵ *Health Professions Act 2004* (ACT); *Health Professions Regulation 2004* (ACT); *Health Practitioners Act 2007* (NT).

¹⁶ *Pharmacy Act 2010* (WA), s 55; *Pharmacists Registration Act 2001* (Tas), s 65.

¹⁷ *Pharmacy Business Ownership Act 2001* (Qld), s 139H; *Health Practitioner Regulation National Law 2010* (NSW), Sch 5F, s 9; and *Pharmacy Regulation Act 2010* (Vic), s 5.

¹⁸ *Health Practitioner Regulation National Law (South Australia) Act 2010* (SA), s 42.

pharmacies. This number could increase up to 30 with some creative application of the ownership provisions and raises the question of exactly how many pharmacy owners there are for the just over 5,000 community pharmacies in Australia.

Regulation of pharmacy premises and practice

Apart from the differences with regard to the number of pharmacies a pharmacist can own in the various jurisdictions, other inconsistencies include premises registration and pharmacy inspection schedules.¹⁹ Although these differences have the potential to impact on the provision of services, pharmaceutical services are highly regulated. Pharmacy ownership legislation is, indeed, part of a complex regulatory system in place to control the pharmaceutical supply chain and the provision of services. The pharmacy profession is, in fact, one of the most regulated professions as medicines are not seen as an ordinary commodity and pharmacists, as the custodians of medicines, are central in the medicines supply chain.²⁰ In addition to the regulation of ownership by the various States and Territories, the precise physical location of pharmacies that supply medicines that are subsidised through the Pharmaceutical Benefits Scheme (PBS) is subject to approval by the Commonwealth, as discussed below. Furthermore, most day-to-day pharmacy activities are also regulated. These activities include dispensing fees and the pricing of medicines supplied through the PBS,²¹ medicine storage, labelling, supply and dispensing,²² the advertising of therapeutic goods,²³ specified practice processes and procedures,²⁴ and references required to be in a pharmacy.²⁵

Regulation of pharmacists

Apart from the regulation of pharmacy premises and the other practice aspects mentioned above, pharmacists, as health professionals, need to follow and comply with personal professional requirements. These requirements are specified by the Pharmacy Board of Australia whose role it is to regulate pharmacists, interns and pharmacy students.²⁶ The Board's *Continuing Professional Development Registration Standard* must be complied with for annual re-registration purposes.²⁷ The board's definition of a "practising" pharmacist includes a pharmacist who owns a pharmacy, and pharmacy owners must thus comply with continuous professional development criteria. Owners therefore have to be active members of the profession and may not be inactive, eg retirees. Although the board does not play a direct role in ownership control, it has recently released the *Guidelines on Responsibilities of Pharmacists When Practising as Proprietors*, following input from stakeholders.²⁸

¹⁹ Hattingh et al, n 11 at 174-177.

²⁰ Low J, Hattingh L and Forrester K, *Australian Pharmacy Law & Practice* (Elsevier Australia, Chatswood, 2010) Foreword.

²¹ Australian Government, Department of Health and Ageing, *Pricing PBS Prescriptions*, http://www.pbs.gov.au/info/healthpro/explanatory-notes/section1/Section_1_9_Explanatory_Notes viewed 4 January 2011.

²² Australian Government, Attorney-General's Department, *Poisons Standard* (August 2010), <http://www.comlaw.gov.au/Details/F2010L02386> viewed 4 January 2011.

²³ Therapeutic Goods Administration, *Regulation of Advertising of Therapeutic Goods in Australia* (2007), <http://www.comlaw.gov.au/Details/F2007L00576> viewed 6 January 2011.

²⁴ Pharmacy Board of Australia, *Pharmacy Guidelines for Dispensing of Medicines, Pharmacy Guidelines on Practice-specific Issues, and Pharmacy Guidelines on Specialised Supply Arrangements*, <http://www.pharmacyboard.gov.au/Codes-and-Guidelines.aspx> viewed 15 December 2010.

²⁵ Pharmacy Board of Australia, *Pharmacy Guidelines on Practice-specific Issues – Guideline 1 (List of References)*, <http://www.pharmacyboard.gov.au/Codes-and-Guidelines.aspx> viewed 15 December 2010.

²⁶ Pharmacy Board of Australia, *About the Board*, <http://www.pharmacyboard.gov.au/About-the-Board.aspx> viewed 8 December 2010.

²⁷ Pharmacy Board of Australia, *Continuing Professional Development Registration Standard* (March 2010), <http://www.pharmacyboard.gov.au/Registration-Standards.aspx> viewed 8 December 2010.

²⁸ Pharmacy Board of Australia, *Guidelines on Responsibilities of Pharmacists When Practising as Proprietors* (December 2010), <http://www.pharmacyboard.gov.au/Codes-and-Guidelines.aspx> viewed 8 December 2010.

The guidelines specify that a pharmacy owner

must maintain, and be able to demonstrate an awareness of, the manner in which that pharmacy business is being conducted and, where necessary, intervene to ensure that the practice of pharmacy is conducted in accordance with applicable laws, standards and guidelines.

The guidelines specify that the owner (proprietor) must intervene if the pharmacy business is not being conducted properly. They state that the owner must ensure that procedures and policies relevant to the conduct of the pharmacy are documented and available within the pharmacy and that pharmacy owners are responsible for the type and quality of services offered in their pharmacies.²⁹ The guidelines further stipulate:

A proprietor/owner or partner-in-ownership of a pharmacy cannot abdicate his or her professional obligations, even if that partner is silent operationally or present only infrequently. This applies to pharmacists who own a pharmacy, or pharmacies, in all forms of business structures.

Although the responsibility to comply with the applicable legislation, codes, standards and guidelines has always been on pharmacy owners through the principle of vicarious liability, this responsibility is now more clearly defined in the guidelines. However, the guidelines specifically apply to pharmacists and raise questions about the non-pharmacist owners who are allowed under the exceptions in the legislation.

The definition of pharmacy ownership

Pharmacy ownership is defined at jurisdictional level in the various State and Territory Acts. The New South Wales ownership provisions refer to the term “pecuniary interest” which is defined as:³⁰

a direct or indirect monetary or financial interest and includes

(a) a proprietary interest, including a proprietary interest as a sole proprietor, partner, director, member or shareholder, or trustee or beneficiary ...

This definition is consistent with the definition of “pecuniary interest” that was previously included in the *Pharmacy Practice Act 2006* (NSW), which was discussed in detail in the landmark case of *Attorney General (NSW) v Now.com.au Pty Ltd* [2008] NSWSC 276. This case concerned the transfer of ownership of Sydney Drug Stores Pty Ltd by a pharmacist, Mr Brown, to Coles Myer Ltd, a wholly owned subsidiary of the public company Wesfarmers Ltd, such that Coles Myer Ltd acquired all of the share capital. Although Mr Brown and other pharmacists were subsequently in charge of the administration and professional aspects of the pharmacy, Coles Myer Ltd had control over the financial management. The plaintiff, the Attorney General of New South Wales, claimed that the ownership of Sydney Drug Store by Coles Myer Ltd was in breach of the *Pharmacy Practice Act 2006* (NSW). After considering the facts and the legislation, Young CJ in Eq concluded that Coles Myer Ltd was more than a mere shareholder in the pharmacy business but was, indeed, an active controller of the business, and hence had a pecuniary interest in the pharmacy. Of specific relevance is that he further concluded that a pecuniary interest had to be more than a proprietary interest and involves a degree of active involvement and control in the “business of pharmacy” (at [49]).

In Queensland, the definition of “own”

includes having a proprietary interest in the pharmacy business, but does not include having an interest in the pharmacy business arising under a bill of sale, mortgage, or other form of security, for the pharmacy business.³¹

The Queensland legislation requires pharmacy ownership to comply with proprietary interest provisions, whereas the New South Wales legislation requires ownership to comply with pecuniary interest provisions. In terms of the comments and judgment made in *Attorney General (NSW) v*

²⁹ A recognition of this principle is acknowledged in the decision of the Supreme Court in *Loewy v Pharmacy Board (Vic)* [1991] VSC 11301. This case dealt with the supply of huge quantities of ephedrine to customers. Both Mr and Mrs Loewy were owners and although Mrs Loewy was not directly involved with the management of the pharmacy, she was reprimanded and fined; Mr Loewy’s registration was suspended.

³⁰ *Health Practitioner Regulation National Law 2010* (NSW), s 2.

³¹ *Pharmacy Business Ownership Act 2001* (Qld), s 139A.

Now.com.au Pty Ltd [2008] NSWSC 276, pecuniary interest requires a higher level of involvement and control by the owner and, on this basis, it could be argued that the ownership provisions are therefore less strict in Queensland than in New South Wales. The guidelines by the newly formed Pharmacy Board of Australia provide one definition for both proprietary and pecuniary interest:³²

Proprietary or pecuniary interest means a legal or beneficial interest and includes a proprietary interest as a sole proprietor, as a partner, as a director, member or shareholder of a company and as the trustee or beneficiary of a trust.

The board's definition is, however, not incorporated in legislation and the State and Territory definitions would hence override the board's definition. The level of control that a pharmacy owner should have therefore seems to differ in the various jurisdictions and may subsequently be applied inconsistently throughout Australia.

Challenges faced in the interpretation of the definition of ownership and the extent of control that a pharmacy owner should have are evident with the emergence of pharmacy banner groups that provide members with a range of management services that include marketing and advertising, manufacturer deals, lease negotiations, loyalty programs and also, in some cases, human resource management. Some of these banner groups have, over recent years, become more structured and professionally organised and funding models include financial assistance to new owners. It could be speculated that there are models which provide the group management executives with some degree of proprietary and/or pecuniary interest in pharmacies.

Banner group models raise a range of issues in terms of the extent of control and discretion that certain banner group pharmacist owners have compared to the management and decision-making authority that lies with the banner group executives. There are also questions as to whether the "owners" are receiving directions regarding the type and quality of services to be provided.

PHARMACY LOCATION RULES

Apart from the ownership provisions in the various State and Territory Acts, a range of location rules apply to community pharmacy, referred to as the Pharmacy Location Rules. Through these Rules the Commonwealth imposes strict controls on approving a new pharmacy and on relocating existing pharmacies for Pharmaceutical Benefits Scheme (PBS) subsidy purposes. The Rules prescribe location-based criteria that must be satisfied in order to establish a new pharmacy or relocate an existing pharmacy, with different rules applying to urban and rural/remote areas, shopping centres, medical centres and private hospitals.³³ The criteria and restrictions assist in achieving a rational distribution of PBS-funded services, and help the Commonwealth to manage the costs of the PBS as a demand-driven program.

Applications for approval are referred to the Australian Community Pharmacy Authority (ACPA), an independent statutory body³⁴ which considers applications pursuant to the *National Health Act 1953* (Cth)³⁵ before making recommendations to Medicare Australia. In making recommendations, the ACPA must comply with the requirements specified by the Minister for Health and Ageing.³⁶ These requirements are described in the *National Health (Australian Community Pharmacy Authority Rules) Determination 2006*, which has a list of 14 Rules.³⁷

³² Pharmacy Board of Australia, n 28, p 2.

³³ Australian Government, Department of Health and Ageing, *Australian Community Pharmacy Authority Applicant's Handbook, The Pharmacy Location Rules* (2007), <http://www.health.gov.au/internet/main/publishing.nsf/Content/pharmacy-acpa-handbook-contents~pharmacy-acpa-handbook-rules> viewed 10 December 2010.

³⁴ *National Health Act 1953* (Cth), s 99J.

³⁵ *National Health Act 1953* (Cth), s 90.

³⁶ *National Health Act 1953* (Cth), s 99L.

³⁷ *National Health (Australian Community Pharmacy Authority Rules) Determination 2006*, Sch 1 (March 2009), <http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrumentCompilation1.nsf/current/bytitle/0F8E578C9767EAFEC-A25757C0006EC43?OpenDocument&mostrecent=1> viewed 22 December 2010.

The Rules were originally introduced in 1990 under the First Community Pharmacy Agreement with the aim of rationalising pharmacy outlets. The Community Pharmacy Agreements are five-year agreements between the Australian Government and the Pharmacy Guild of Australia that, inter alia, determine dispensing fees and those services for which pharmacists will be paid by government.³⁸ Under the First Agreement, the national number of pharmacies was reduced from around 5,600 to around 5,000 and it has remained at the lower level since.³⁹ The Rules have been included in succeeding Community Pharmacy Agreements while being modified periodically following mutual agreement between the Pharmacy Guild of Australia and the Department of Health and Ageing. However, the National Competition Policy Review of the Rules, which took place in 2000, noted:⁴⁰

[I]n themselves, and however willingly they may be accepted by the community pharmacy industry, these location controls are an anti-competitive layer of regulation and government intrusion on the community pharmacy industry and market ... These regulations restrict free and effective competition in the community pharmacy industry.

The objectives of the Rules from the Fourth Agreement have remained unchanged in the Fifth Agreement which is currently in place, namely to ensure:⁴¹

- (a) that all Australians have access to PBS medicines;
- (b) a commercially viable and sustainable network of community pharmacies dispensing PBS medicines;
- (c) improved efficiency through increased competition between pharmacies;
- (d) improved flexibility to respond to the community need for pharmacy services;
- (e) increased local access to community pharmacies for persons in rural and remote regions of Australia; and
- (f) the continued development of an effective, efficient and well-distributed community pharmacy network in Australia.

There has been considerable criticism directed to the parties involved in the Agreements.⁴² Of specific reference to pharmacy ownership is the exclusivity of the parties involved in the negotiation of the Rules, namely the Pharmacy Guild and the Commonwealth Department of Health and Ageing.⁴³ The Commonwealth and the Pharmacy Guild determine what is incorporated in any approaching Agreement and subsequently given legislative force.⁴⁴ At the core of the criticism is the fact that the Pharmacy Guild is an employers' organisation with full membership only granted to pharmacy owners.⁴⁵ It is therefore claimed that pharmacy owners have a monopoly in terms of a range of issues, including determining the criteria of the Rules, and that they are, in the main, only concerned about their own future financial security and not that of the profession at large.⁴⁶

The retention of the Rules is, in reality, regarded as the cornerstone of all Community Pharmacy Agreements, as was demonstrated by the fact that an agreement in principle to retain the Rules was the first announcement in the Fifth Community Pharmacy Agreement negotiation process on Christmas

³⁸ Australian Government. Department of Health and Ageing. *Pharmacy and Government Arrangements – Fifth Community Pharmacy Agreement* (July 2010), <http://www.health.gov.au/internet/main/publishing.nsf/Content/fifth-community-pharmacy-agreement-copy> viewed 5 January 2011.

³⁹ Urbis, n 2, p 1.

⁴⁰ Wilkinson, n 1, p 9.

⁴¹ Australian Government, Department of Health and Ageing, n 38; Australian Government, Department of Health and Ageing, *Pharmacy and Government Arrangements – Fourth Community Pharmacy Agreement* (November 2005), <http://www.health.gov.au/internet/main/publishing.nsf/Content/pharmacy-4cpa> viewed 2 November 2010.

⁴² Plunkett W, “SCPA Disappointing for Community Pharmacy” (2010) 29 *Australian Pharmacist* 169.

⁴³ Gadiel D, *Harmacy, The Political Economy of Community Pharmacy in Australia* (Centre for Independent Studies, December 2008).

⁴⁴ Wilkinson, n 1, p 9.

⁴⁵ Pharmacy Guild of Australia, *About the Pharmacy Guild of Australia*, http://www.guild.org.au/The_Guild/tab-TheGuild/About_The_Guild/About+the+Guild.page? viewed 6 January 2011.

⁴⁶ Gadiel, n 43, pp 3, 6, 7-8.

Eve 2009, almost five months before the details of the actual Agreement were formally announced.⁴⁷ Given that PBS sales and dispensing remuneration form the most significant parts of a pharmacy's overall turnover, the Rules are indeed central to operating a financially viable pharmacy, and also provide some security to owners in assisting to shield pharmacies from new competitors in their catchment areas.

PBS prescription medicines are mainly supplied through pharmacies by "approved pharmacists"⁴⁸ who are approved to carry on business from a designated location and to supply pharmaceutical benefits only from that particular pharmacy. An approved pharmacist is entitled to be paid an amount determined by the Minister for the provision of the pharmaceutical benefit. While it is technically possible to operate a non-PBS pharmacy, almost all community pharmacies are approved to dispense PBS medicines as this is the backbone of community pharmacy business. It is crucial for a pharmacy's financial survival to be able to dispense medicines under the PBS system and the Rules therefore cause an inflation of pharmacy selling prices, making it almost impossible for young pharmacists to own their own pharmacies. The buying of a pharmacy with a PBS provider number is very costly compared to other retail businesses and this has contributed to the growth of pharmacy banner groups that provide financial assistance to pharmacists. Another growing area of concern are accusations of approved pharmacies fraudulently claiming PBS benefits on behalf of pharmacies that do not hold a PBS approval number in an attempt to circumvent the approval process.⁴⁹

A recent review of the Rules has been conducted to determine, among other things, whether changes should be made to the Rules to reflect the government's objectives in reorientating the health care system.⁵⁰ The government's proposed reform of the health care system includes the promotion of general practitioner-led medical centres, called GP Super Clinics, to function as "one-stop shops".⁵¹ One of the aims of this model is to bring services together and to improve access to primary health care providers, including access to PBS medicines. As the Rules do not currently allow for this model to be implemented, one of the recommendations made through the Review is the creation of a new Rule to enable a new approval in response to a specific need.⁵² The government and the Pharmacy Guild have yet to consider these proposals.

DISCUSSION

The regulation of pharmacy ownership has been a topic of discussion for decades, often causing tension among the various role-players as there are differing opinions as to who should be allowed to own a pharmacy, whether ownership should be opened to non-pharmacists, and the level of location control required. With a few exceptions, current State and Territory regulatory structures require ownership to be limited to pharmacists while Pharmacy Location Rules are administered by the Commonwealth Government. Ownership legislation and structures are therefore multi-tiered and require the engagement of a range of role-players that include the profession, the States and Territories and the Commonwealth Government.

Current State and Territory regulatory structures mainly restrict ownership to pharmacists or corporate entities controlled by pharmacists. Similar legislation exists in many European countries and this approach was recently supported through a ruling by the European Court of Justice, rejecting challenges to ownership legislation in Italy and Germany. Both of these countries have legislation that specifies that only pharmacists may own and operate a pharmacy. Although the court acknowledged

⁴⁷ Urbis, n 2, Executive Summary.

⁴⁸ *National Health Act 1953* (Cth), s 4, defines a pharmacist as "[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".

⁴⁹ Banks S, "Protect Your Rights: Guild Needs Your Help", *Guild Bulletin* (October 2010) p 3.

⁵⁰ Urbis, n 2, pp 1-44.

⁵¹ National Health and Hospitals Reform Commission, *A Healthier Future for All Australians* (2009), <http://www.health.gov.au/internet/nhhrc/publishing.nsf/Content/nhhrc-report> viewed 5 January 2011.

⁵² Urbis, n 2, p 44.

that pharmacist-only ownership “constitutes a restriction on the freedom of establishment and the free movement of capital”, the court stated that the restriction was justified to ensure that the provision of medicinal products to the public is reliable and of good quality.⁵³

While legislation in the States and Territories prescribe the number of pharmacies that one pharmacist can own or co-own, it could be possible for one pharmacist to own a large number of pharmacies across a number of States and Territories. The State and Territory legislation is therefore liberal compared to countries such as Austria, Finland and Spain, where a pharmacist cannot own or be responsible for more than one pharmacy.⁵⁴ The provisions in these countries have prevented the infiltration of large corporate chains such as those found in the United Kingdom and North America.⁵⁵ This is argued to be a positive outcome as it is claimed that the corporatisation of community pharmacy in the United Kingdom reduced the professional autonomy of pharmacists.⁵⁶ The deregulation of pharmacy in Iceland and Norway during 1996 and 2001 respectively resulted in horizontal integration with the creation of more powerful corporate groups, as well as vertical integration with wholesale companies purchasing community pharmacies.⁵⁷ An analysis of the situation in certain European countries, following the deregulation of ownership, found that a relaxation of location rules did cause an increase in the number of pharmacies, but that these pharmacies were clustered in metropolitan areas.⁵⁸

There have been claims that the barriers to ownership, the restrictions in place regarding the supply and dispensing of scheduled medicines, and the exclusive access to dispensing fees and other funding pursuant to the Guild – Government Agreements, not only create a highly regulated industry, but also serve to protect the retail pharmaceutical distribution chain, thereby creating a monopoly for pharmacy owners.⁵⁹ These claims do have merit as the Pharmacy Guild plays an important role in the structuring of the Location Rules, and hence in determining the location criteria.

The discussion of the regulation of pharmacy ownership should be open to dialogue in an effort to balance the need for regulatory control against changes in Australia’s health and competition policies. Pharmacy ownership regulation is indeed complicated and should involve consideration of a range of issues such as public safety and the need to have minimum standards of practice in place, timely access to medicines at affordable prices, and the financial attractiveness and viability of investing and owning a pharmacy. Policy-makers need to consider these issues with specific reference to the government’s proposed primary health care objectives.

⁵³ Curia, *Ownership and Operation of Pharmacies can be Restricted to Pharmacists Alone* (Court of Justice of the European Communities, 19 May 2009), <http://www.curia.europa.eu/jcms/upload/docs/application/pdf/2009-05/cp090044en.pdf> viewed 10 December 2010.

⁵⁴ Vogler S, Arts D and Habl C, *Community Pharmacy in Europe – Lessons from Deregulation Case Studies* (Pharmaceutical Group of the European Union, 2006), <http://www.epha.org/a/2197> viewed 27 November 2010.

⁵⁵ Kanavos P, Tater D and Taylor D, *Regulating Pharmaceutical Distribution and Retail Pharmacy in Europe* (Open University Press, Maidenhead, 2004).

⁵⁶ Bush J, Langley CA and Wilson KA, “The Corporatization of Community Pharmacy: Implications for Service Provision, the Public Health Function, and Pharmacy’s Claims to Professional Status in the United Kingdom” (2009) 5(4) *Research in Social and Administrative Pharmacy* 305; Gidman W, “Exploring the Impact of Evolving Health Policy on Independent Pharmacy Ownership in England” (2010) 32 *Pharmacy World & Science* 488.

⁵⁷ Anell A, “Deregulating the Pharmacy Market: The Case of Iceland and Norway” (2004) 75(1) *Health Policy* 9.

⁵⁸ Vogler, Arts and Habl, n 54, p v.

⁵⁹ Gadiel, n 43, pp 6, 7.