Review of the *Pharmacists Act 1974*

Discussion Paper

August 2002

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Foreword

Pharmacists play a unique role in the Victorian health care system. Working in both community and hospital settings across the State, they help ensure the safe and effective use of medicines and also maintain responsibility for the custody of large quantities of drugs, poisons and controlled substances.

The Act of Parliament which requires pharmacists to be registered and regulates the practice of pharmacy in Victoria is the *Pharmacists Act 1974* ('the Act'). The Act protects the public by establishing the Pharmacy Board of Victoria ('the Board') and providing statutory powers for the Board to regulate the profession. Only registered persons can practise pharmacy, and pharmacies cannot open without the approval of the Board. The Board is responsible for maintaining high standards of education and practice, ensuring premises where pharmacy is practised meet certain standards, as well as investigating complaints regarding the professional conduct of pharmacists.

As part of its commitment to competition policy, Victoria undertook to review all existing health practitioner registration Acts to identify and examine regulatory measures that restrict competition. Under National Competition Policy, such measures are justifiable only if it can be demonstrated that:

- the benefits of the restriction to the community as a whole outweigh the costs, and
- the objectives of the legislation can only be achieved by restricting competition.

Unlike other Victorian health practitioner registration Acts, restrictions on competition in pharmacy legislation were subject to a national review process, commissioned by the Council of Australian Governments (COAG). The National Review was completed in 1999 and its final report tabled in February 2000. The Victorian Review of the *Pharmacists Act 1974* will involve both implementation of the relevant national recommendations and examination of outstanding restrictions on competition within the legislation to ensure the State's obligations under National Competition Policy are satisfied.

At the same time, the Victorian Government is keen to ensure that a common set of standards apply to those common core activities of all health practitioner groups that serve the Victorian community. Common standards should apply in areas such as processes for registration of practitioners, regulation of advertising, investigation of complaints, conduct of inquiries and investigations, application of penalties where necessary, and appeal processes. Other aspects of pharmacy practice may be unique and may require unique regulatory solutions. This paper highlights a broad range of issues on which the input of interested parties is sought.

This discussion paper is an opportunity for pharmacists and other interested persons and organisations to comment on the way in which standards of pharmacy practice are protected, as well as provide input into emerging issues that impact pharmacy. I commend this paper to you and encourage you to use this opportunity to contribute to the review process, for the benefit of all Victorians.

Hon John Thwaites MP
Minister for Health

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PART A - BACKGROUND

1 Introduction

An independent review of the *Pharmacists Act 1974* and associated Regulations is being conducted as part of an extensive program of legislative review undertaken by the Victorian Government.

The *Pharmacists Act 1974* provides for the registration of pharmacists, establishing the Pharmacy Board of Victoria ('the Board') as the body responsible for regulation of pharmacy practice in Victoria. Pharmacists cannot practise unless registered, and pharmacies cannot open without the approval of the Board. The Board is also responsible for taking disciplinary action against pharmacists, where necessary.

1.1 Purpose of the Paper

This discussion paper has been released to provide interested parties with the opportunity to comment on how the practice of pharmacy might be regulated in the State of Victoria. The paper has several key purposes:

- To seek input on options for implementing those recommendations arising from the National Competition Policy Review of Pharmacy Legislation ('the National Review') that relate to the Victorian Act.
- To examine any restrictions on competition within the current Act not considered in the National Review and assess whether they meet the public interest test.
- To examine how the *Pharmacists Act* might be updated to include provisions common to other Victorian health practitioner acts.
- To canvas stakeholder views on other evolving issues relevant to Victorian pharmacy, such as potential strategies for improving access to pharmacy services in rural and regional Victoria.

1.2 Structure of the Paper

The paper is divided into three main parts. Part A provides an overview of the pharmacy profession and the legislative and policy context in which pharmacy is practised. Part B addresses implementation issues for Victoria arising from the recommendations of the National Competition Policy Review of Pharmacy Legislation. Part C addresses additional proposals for reform that arise from the need to generally update the Victorian pharmacy legislation to be consistent with other Victorian health practitioner registration Acts, including an examination of those NCP issues not addressed by the National Review. Specifically:

- Section 2 sets out the policy context in which the review is being conducted.
- Section 3 provides an overview of the pharmacy profession in Victoria and the legislative framework that governs pharmacy practice.
- Section 4 highlights current restrictions on the practice of pharmacy in Victorian legislation and options for reform.
- Section 5 summarises current restrictions on the ownership and operation of pharmacy in Victorian legislation and options for reform.
- Section 6 highlights other current restrictions on competition in Victorian pharmacy legislation not examined by the National Review and highlights options for reform.
- Section 7 provides an overview of the proposed model to update Victorian pharmacy legislation.

- Section 8 raises other emerging issues relating to the regulation and practice of pharmacy in Victoria.

1.3 Background Information

Those interested in commenting in detail on the legislative regulation of pharmacy are encouraged to obtain copies of the *Pharmacists Act 1974* and associated Regulations, as well as the *Medical Practice Act 1994*, the *Health Practitioner Acts (Further Amendments) Act 2002* and the *Drugs, Poisons and Controlled Substances Act 1981*.

These documents are available from:

Information Victoria
356 Collins Street
Melbourne 3000
Tel: 1300 366 356
http://www.bookshop.vic.gov.au/infovic

Electronic versions of this legislation may be accessed via the Victorian Legislative and Parliamentary Documents home page: http://www.dms.dpc.vic.gov.au/

Various other documents are also useful references. These include:

- The Pharmacy Board of Victoria's *Guidelines for Good Pharmaceutical Practice 2002*, available from the Pharmacy Board of Victoria, 381 Royal Parade, Parkville 3052. Tel 03 9903 9588. Email admin@pbvic.com.au
- The *National Competition Policy Review of Pharmacy–Final Report February 2000*, which can be downloaded from the Commonwealth Department of Health and Aged Care's website at www.health.gov.au/haf/pharmrev/index.htm
- The *COAG Senior Officials Working Group Commentary on the National Competition Policy Review of Pharmacy*, which can be downloaded from the Commonwealth Department of Health and Aged Care's website at http://www.health.gov.au/coag_sowg.pdf
- *Regulation of Medical Practitioners and Nurses in Victoria – A Discussion Paper*, released by the Department of Human Services in August 2001. This can be downloaded from the Department's website at www.dhs.vic.gov.au/pdpd/. Hard copies can also be obtained by phoning the Workforce Policy Section of Service and Workforce Planning Branch on 03 9616 6944.

1.4 Process and Timetable

It is anticipated that the review process will result in the preparation of a new Bill governing the registration of pharmacists for consideration by the Parliament of Victoria. The legislative program is determined by Cabinet in the light of many competing priorities. At this stage it is planned, subject to Cabinet endorsement, that the new Bill be put to Parliament in its Autumn 2003 sittings. The tentative timetable for the review is as follows:

- Discussion paper released **August 2002**.
- Responses to discussion paper received by **Monday 11 November 2002**.
- Ongoing consultation and negotiations with stakeholders, other government departments and bodies affected by the proposed legislation, **October–December 2002.**
- Bill to Parliament **March–June 2003.**

1.5 Consultation Arrangements

Further information on this review is available from:

Ms Anne-Louise Carlton	Tel: (03) 9616 6137
Workforce Policy	Fax: (03) 9616 7767
Policy and Strategic Projects Division	E-mail:Anne-Louise.Carlton@dhs.vic.gov.au
or:	
Ms Bernadette Fallon	Tel: (03) 9616 6944
Workforce Policy	Fax: (03) 9616 7767
Policy and Strategic Projects Division	E-mail: Bernadette.Fallon@dhs.vic.gov.au

Members of the Workforce Policy section are available to meet with groups to discuss issues pertaining to the review. Please contact Ms Carlton or Ms Fallon if you would like to arrange a meeting.

1.6 Copies of Discussion Paper

Further copies of this discussion paper can be obtained by contacting:

Ms Kerryn Bradley
Tel: (03) 9616 7523
Fax: (03) 9616 7767
Email: Kerryn.Bradley@dhs.vic.gov.au

The discussion paper is also located on the Internet at http://www.health.vic.gov.au/pracreg

1.7 Submissions

Those interested in commenting on the above proposals may make a written or taped submission. Submissions should be forwarded to:

Bernadette Fallon
Workforce Policy
Policy and Strategic Projects Division
Department of Human Services
GPO Box 1670N
MELBOURNE 3001

Email submissions should be sent to: Bernadette.Fallon@dhs.vic.gov.au

Submissions should be received by Monday 11 November 2002.

2 Context of the Review

Various State and Commonwealth initiatives impact upon the current review of the *Pharmacists Act 1974*, including National Competition Policy (NCP) and the Victorian model of health practitioner registration. Victoria's obligations under Mutual Recognition legislation must also be considered.

This section provides an overview of these, as well the National Competition Policy Review of Pharmacy Legislation and how its recommendations will be incorporated into the Victorian review of the *Pharmacists Act 1974.*

2.1 National Competition Policy

2.1.1 Overview

The review is being conducted within the context of National Competition Policy (NCP). Under the Competition Policy Agreement, all jurisdictions must review existing health practitioner registration Acts to give effect to NCP. The *Competition Policy Reform (Victoria) Act 1995* came into effect on 21 July 1996, accompanied by complementary *Guidelines for the Review of Existing Legislation* and *Guidelines for the Application of Competition Test to New Legislative Proposals*.

Occupational registration creates barriers to entering a profession, which effectively limit the number of persons engaged in an occupation and prevent other parties from engaging in certain activities of that occupation. Such restrictions are considered to reduce competition and promote unwarranted rigidities in the workplace, as well as segmentation in the labour market. Clause 5 of the Competition Principles Agreement requires State Governments to review any legislation that restricts competition and remove restrictions where a net public benefit to the community cannot be demonstrated.

As a result, the 'competition test' must be applied to all existing and new regulatory measures, including Acts of Parliament, ordinances and regulations. This requires the relevant jurisdiction to justify the retention of any regulatory measure which might restrict competition by demonstrating that:

- the benefits of the restriction to the community as a whole outweigh the costs; and
- the objectives of the legislation can only be achieved by restricting competition.

2.1.2 Restrictions on Competition in Pharmacy Legislation

Four main types of regulatory control on the activities of pharmacists can be identified:

- Control of practitioners via occupational registration.
- Licensing of premises where pharmacy is practised.
- Licensing of proprietors of pharmacy businesses.
- Controls on storage, sale and supply of medicinal poisons.

A number of competition restrictions exist within Victorian pharmacy legislation. The ***Pharmacists Act 1974*** contains restrictions that relate to:

- Standards required for registration (s12).
- Educational and assessment requirements for registration (s13–14).
- Restrictions on who may own/hold interests in pharmacies (s21, 22).

- Board approval of premises (s23, 24).
- Where pharmacy may be practised (s27).
- Requirements for a pharmacist to be in attendance at all times (s28).
- Who may practise pharmacy (s33).

Within the ***Pharmacists Regulations 1992***, there are restrictions that relate to:

- The course of practical training required for registration (r301–304).
- Subjects to be included in the final examination (r305).
- Retraining programs required after an absence from clinical practice (r306).
- Requirements that trainees enter into articles of traineeship (r307).
- Advertising by pharmacists (r404).
- Board approval of pharmacy depots (r503).

2.1.3 National Review of Pharmacy Legislation

A Victorian NCP review of the *Pharmacists Act 1974* was commenced in 1997, then postponed after all jurisdictions agreed to a national review, commissioned by the Council of Australian Governments (COAG). The National Competition Policy Review of Pharmacy Legislation ('the National Review') was asked to examine competition restrictions contained in:

- State and Territory legislation relating to the registration of pharmacists, including provisions relating to pharmacy ownership (except in Queensland and Tasmania, which had already been reviewed).; and
- Commonwealth legislation relating to the location of pharmacies under the Pharmaceutical Benefits Scheme (PBS).

In particular, the National Review was asked to determine whether such restrictions provided a net public benefit and, if not, whether they should be removed. This was the first single national review of a profession commissioned under the NCP systematic legislative review process.

The National Review received over 100 submissions from government, industry and stakeholder groups, practising pharmacists, allied health practitioners and members of the general public. A Preliminary Report was submitted to COAG in November 1999, with additional feedback on this received from pharmacy and industry bodies.

The Final Report of the National Review was tabled in February 2000. The National Review recommended retaining:

- Statutory registration of pharmacists.
- Restrictions on who may practice pharmacy and use protected titles such as 'pharmacist'.
- Systems for the investigation of complaints against registered pharmacists.
- Restrictions on who may own a pharmacy.

In addition, the Review recommended removal of business licensing restrictions and made recommendations regarding Commonwealth controls on the location of pharmacies. The latter are beyond the scope of the current Victorian review.

The Prime Minister subsequently wrote to Premiers and Chief Ministers in each jurisdiction, proposing that COAG provide a coordinated response to the recommendations of the National Review to promote a nationally consistent approach to pharmacy regulation. COAG referred it

to a Senior Officials Working Group comprising Commonwealth, State and Territory Officers, asking the Group to advise whether 'a co-ordinated response could be made by COAG on behalf of all jurisdictions to each recommendation, and if not, advise on an appropriate response by either COAG or individual jurisdictions' (Commonwealth of Australia 2002, p 3).

The COAG Senior Officials Working Group Report was publicly released on 2 August 2002. It recommended that COAG accept most of the National Review's recommendations, highlighting various issues that may require further consideration as part of the implementation process. Appendix 1 contains a summary of the National Review's recommendations, and the Working Group's response to each of these.

It is anticipated that the Victorian Review process will focus upon implementation of recommendations arising from the National Review process, rather than re-examination of those issues considered at a national level. This review will also examine any restrictions on competition within the Victorian Act that were not considered by the National Review, along with any new proposals for regulation that would restrict competition if implemented.

In making its recommendations, the COAG Senior Officials Working Group noted that the while jurisdictions may agree in principle on proposed NCP reforms to pharmacy legislation arising from the National Review, a State's desire to have a consistent approach to the regulation of all registered health professions may influence how such reforms are implemented (Commonwealth of Australia 2002A, pp 24-25). This is particularly relevant in Victoria, where implementation of the National Review recommendations is part of a review process that will also update pharmacy legislation to achieve consistency with other Victorian health practitioner Acts.

2.2 Victorian Model of Health Practitioner Legislation

In Victoria, model provisions for health practitioner registration have been developed and applied to registration Acts governing 10 Victorian health professions, with the aim of achieving consistency in the regulation of health practitioners in this State. Appendix 2 contains a summary of the key features of the Victorian model.

The first registration Acts to be reviewed under the Victorian model were those regulating medical practitioners and nurses. These reviews resulted in the passage of two new Victorian Acts: the *Nurses Act 1993* and the *Medical Practice Act 1994*. These have since been subject to further review and NCP assessment, with the most recent amendments made to the *Medical Practice Act* via the *Health Practitioner Acts (Further Amendments) Act 2002*.

As it is the most recently updated registration Act, the *Medical Practice Act* will serve as a model for the current review. While many of the amendments made via the *Health Practitioner Acts (Further Amendments) Act 2002* have yet to be proclaimed, these should also be considered part of the model.

While Section 7 of this paper examines the model in detail and how it might be applied to the statutory registration of pharmacists, some aspects of the proposed model (such as requirements for registration and legislative restrictions on title) were examined by the National Review and are thus considered in earlier sections of this paper[1].

2.3 Mutual Recognition Legislation for Registration of Health Professionals

The registration of health professionals, like other professional groups, is subject to the principles embodied in mutual recognition legislation[2].

[1] For example, requirements for registration and legislative restrictions on the use of certain professional titles are examined in Section 4.
[2] The *Commonwealth Mutual Recognition Act 1992* and the *Mutual Recognition (Victoria) Act 1998.*

These principles provide a person who has met the registration requirements in one State or Territory of Australia a legal as-of-right to practice his or her profession and to gain registration in another State or Territory, without the need to meet any further requirements that may be peculiar to that other State or Territory. It should therefore be kept in mind that any new legislative proposal must not inhibit the right of professionals to practice across jurisdictions within Australia.

The National Review (2000, pp 116–117) recommended that options for achieving a nationally consistent approach to pharmacy regulation be explored, to promote occupational and commercial mobility. This is examined in further detail in Section 8.2 of this paper.

3 The Pharmacy Profession in Victoria

The National Review (pp 13–18) examined the profession of pharmacy in considerable detail, including the nature of pharmacy practice, the functions of contemporary pharmacy and the various factors that influence the practice of pharmacy in Australia.

This Section provides an overview of the Victorian pharmacy profession, highlighting aspects of the regulatory framework that directly impact the provision of pharmacy services in this State.

3.1 The Pharmacy Workforce

3.1.1 How Many Pharmacists Are Registered in Victoria?

At 30 June 2002, there were 4768 pharmacists registered in Victoria, an increase of 158 from the same time in 2001. According to Pharmacy Board records, 48 per cent of registrants are female.

3.1.2 Education and Training

Pharmacy education typically involves a four year undergraduate degree, with an additional period of practical training[3].

In Victoria, two universities offer four year, undergraduate pharmacy courses: Monash University, Parkville (via the Victorian College of Pharmacy campus) and Latrobe University, Bendigo[4]. These courses include study in areas such as physiology, biochemistry, pharmacology, microbiology, pharmaceutical chemistry, pharmacy practice, clinical pharmacy and drug development.

In addition to successful completion of an approved undergraduate course in pharmacy, to be eligible for registration in Victoria, applicants must complete a prescribed course of practice training on premises approved by the Board (r302)[5] and pass a competency-based examination set by the Board. Section 4 of this paper examines educational requirements for registration in further detail.

3.1.3 Where Do Pharmacists Work?

In Victoria, pharmacists practise in a range of metropolitan and rural settings:

- Almost 80 per cent[6] of Victorian pharmacists work in **community pharmacies** located throughout the State, either as employees or owners. Community pharmacies form a retail network through which prescription medicines and scheduled over-the-counter medicines are delivered to the Victorian public. They also employ pharmacy assistants and sales staff.
- Around 17 per cent of registered pharmacists work in **clinical pharmacy**, which includes the provision of pharmacy services in public hospitals, private hospitals, laboratories and various other clinical and research settings. Clinical pharmacy typically includes the preparation of compounds and solutions, as well as the dispensing of pre-prepared medicines. Pharmacy departments only service patients of the hospital in which they are situated–unlike community pharmacies, they do not provide pharmacy or retail services

[3] Over the past 5 years, pharmacy undergraduate courses in most jurisdictions (including Victoria) have increased from 3 to 4 years duration.
[4] This course commenced in 2000.
[5] Regulation 302 states that this must be a minimum of 2280 hours, of which at least 912 hours must be in community pharmacies or hospital pharmacy departments. It is understood that these requirements were set prior to the introduction of the 4 year course, and the Pharmacy Board has indicated its intention to monitor whether the same level of practice and training requirements are required in view of the additional university training.
[6] 76.8 per cent according to 1996 data published in 1998 by the Australian Institute of Health and Welfare (AIHW).

to the general public at large. While hospital pharmacists are often employed within a pharmacy department[7], some are contracted as external providers.

The remainder work in a range of administrative, education and industrial roles (AIHW 1998).

According to the most recent data published by the Australian Institute of Health and Welfare (1998), approximately 77 per cent of pharmacists practise in metropolitan Melbourne. This gives a pharmacist to population ratio of approximately 1:1400 in metropolitan Melbourne and 1:1800 in rural and regional Victoria.

Various studies (DEWRSB 2002, Health Care Intelligence P/L 1999, AIHW 1998) have found that there are shortages of community and hospital pharmacists in most States, including Victoria. Like many health professions, workforce shortages are more pronounced in rural and regional Victoria, where it has proven more difficult to recruit and retain trained pharmacists.

For example, recent data compiled by the Society of Hospital Pharmacists of Australia (SHPA 2002) indicates that:

- Twelve rural hospitals have less than 80 per cent of their required pharmacy staff.
- On average, vacant positions took 13 months to fill in rural areas, compared to 6 months in metropolitan areas.
- Rural hospitals had an overall pharmacy staff vacancy rate of 19 per cent, compared to a vacancy rate of 9 per cent in metropolitan areas[8].

In considering reforms to pharmacy legislation, it will be important to ensure that any restrictions retained do not unreasonably hinder the development of innovative and responsive service models to enhance the delivery of pharmacy services, particularly to rural and remote Victoria.

3.1.4 Pharmacy Ownership

At 30 June 2002, there were a total of 1160 community pharmacies in Victoria, of which 1106 were owned by pharmacists and 54 were owned by Friendly Societies. In addition, there were 63 pharmacy departments and 35 pharmacy depots[9] (Pharmacy Board 2002).

Current provisions within the *Pharmacists Act 1974* restrict ownership of community pharmacies to registered pharmacists, with a few permitted exceptions:

- friendly societies;
- non-registered individuals and companies who were permitted to own pharmacies prior to the commencement of the current Act[10]; and
- administrators of deceased estates and bankrupt or insolvent pharmacy businesses.

Pharmacy departments (established within hospitals and certain other registered funded agencies for the purpose of compounding and dispensing pharmaceuticals) are also exempt from the requirement to be owned by a pharmacist.

The Act not only prevents non-pharmacist owners (other than permitted exceptions) from owning pharmacies, it also voids any provisions in a bill of sale, mortgage, lease or other commercial arrangement which would provide a non-pharmacist with the right to control or share in the profits of a pharmacy practice.

[7] The *Pharmacists Act 1974* defines a hospital pharmacy department as 'the portion of the premises of the (hospital)…set aside for compounding or dispensing drugs and medicines'.

[8] Issues regarding rural and remote pharmacy are discussed in section 8.3 of this paper.

[9] A pharmacy depot is a secure drop-off point to which a pharmacist can send prescription medicines for collection by patients. Issues pertaining to pharmacy depots are discussed in sections 6.2 and 8.3 of this paper.

[10] In Victoria, one non-pharmacist currently owns 4 pharmacies under this provision.

Pharmacists must be registered in Victoria if they wish to own pharmacies in this State, and the Act prevents an individual pharmacist owning (or holding an interest in) more than three pharmacies. There are no such limitations on the number of pharmacies that may be owned by friendly societies or other non-pharmacist owners, and Victoria has more friendly society pharmacies than any other Australian jurisdiction.

According to data supplied by the Australian Friendly Society Pharmacies Association ('AFSPA'), 13 friendly societies own pharmacies in Victoria, which are located in both metropolitan and rural areas. Table One provides a summary of the data provided by AFSPA, which indicates the number and location of friendly society pharmacies in Victoria.

Table One: Friendly Society Pharmacies in Victoria (Source: AFSPA data, July 2002)

Friendly Society	Number of pharmacies owned in Victoria
Australian Unity Dispensaries Friendly Society Limited (Melbourne)	14
Friendly Society Medical Association Limited (National Pharmacies)	9
UFS Dispensaries Ltd (Ballarat)	7
Community Pharmacy Friendly Society Ltd (Elsternwick)	5
Friendly Pharmacy (Vic) Ltd (Coburg/Brunswick)	4
Yallourn Friendly Society Limited	4
Community Care Chemist Friendly Society Ltd (Geelong)	3
North West Dispensaries Friendly Society Ltd (Fairfield/Sunshine)	3
Bendigo United Friendly Societies Dispensaries Limited	2
Cheltenham Friendly Society Dispensary Ltd	2
Box Hill Pharmacist Advice Friendly Society Ltd	1
Eaglehawk United Friendly Socialities Dispensary Ltd	1
Wonthaggi Miners Friendly Societies Dispensary Ltd	1

Legislative restrictions on the ownership of pharmacies are examined in detail in Section 5 of this paper.

3.1.5 Scope and Nature of Pharmacy Practice

The *Pharmacists Act 1974* defines 'practice as a pharmacist' as including 'the supplying compounding or dispensing of drugs and medicines on an order or prescription', however various pharmacy stakeholders have emphasised that pharmacists also provide cognitive services such as counselling regarding the safe use of medicines[11].

Within Victoria, contemporary pharmacy practice may incorporate:

- Appropriate dispensing of prescriptions written by authorised persons.
- Rational supply of a range of over-the-counter medications[12], therapeutic devices and aids to compliance.

[11] This role has been formalised through pharmacy's participation in government initiatives such as the Commonwealth's Quality Use of Medicines program.
[12] Including "pharmacy only" (Schedule 2) and "pharmacist only" (Schedule 3) medicines.

- Provision of advice on the safe use of medications and in some instances, medication reviews.
- Supply of pharmacy services to residential care facilities.
- Distribution of public health education and information material.
- Provision of drug advice and information to community support groups, other health practitioners and the public.
- Provision of facilities for the safe storage of large quantities of drugs, poisons and controlled substances.
- Provision of facilities for the safe disposal of unwanted medicines.

Community pharmacies often combine the provision of pharmacy services with a range of retail services unrelated to professional pharmacy practice, such as photo processing and cosmetic sales[13]. As the National Review (2000, p 14) noted, this makes them 'somewhat unique' and also 'complicates any evaluation of the professional regulation of the professional services offered by pharmacies'. Pharmacy also differs from most Victorian health professions in other key areas:

- As the National Review (2000, p 14) noted, **community pharmacy does not have the professional–client relationship based upon a fee for service** that is common to most professions. Instead, a pharmacist's income is generated from medicines dispensed and other products sold.
- Pharmacists hold a unique role in the health system as **custodians of large quantities of controlled substances**, with responsibility for their safe storage, handling and dispensing. While medical practitioners and other authorised persons may store and on occasions dispense small quantities of certain controlled substances, pharmacists retain control of large quantities and play a key role in ensuring the safe use of medications (Pharmacy Board 1998, pp 13-15).
- **The risks associated with misuse of medicinal poisons** are significant and pharmacy plays a unique role in ensuring such risks are minimised through patient counselling, participation in medication management programs and other services.

3.1.6 Risks Associated with Practice of Pharmacy

Medicinal poisons are a special class of goods, which, because of the potential to cause harm, require secure custody, carefully regulated supply, and the provision of competent advice and judgement about their use. These substances can directly affect the health, safety or wellbeing of consumers, in that:

- While they may have beneficial effects, most drugs also have the potential to do harm[14].
- The use of many drugs must be regulated, for sound public health reasons.
- Many drugs in common legitimate use are also valuable on the illicit market and are much sought after for that purpose (Pharmacy Board of Victoria 1998, p 16).

There are a number of risks associated with unregulated access to medicinal poisons. These include:

- Excessive or overuse with potential for reduced effectiveness, drug dependence and/or serious side-effects.
- Use without attention to dosage schedules.
- Inappropriate use (for example when contraindicated or when there are interactions with another medicine).

[13] According to data compiled by the COAG Senior Officials Working Group (2002, p 31), around 37 per cent of community pharmacy income is derived from these retail activities.

[14] For example, medication errors are recognised as a leading cause of adverse events in the Australian health system (Wilson *et al*, 1995), with an assessment of the Australian Incident Monitoring System indicating that 11.6 per cent of incidents were due to medication errors. The most serious of these occur at the ordering and dispensing stages (ACQSHC 2001A, pp 10- 11).

- Illicit use.

The above can result in pain and suffering, unnecessary medical and hospital treatment, and a reduction in productivity.

In Australia, as in most countries, members of the public are restricted in their access to and use of toxic medicinal substances, with medications placed in restricted schedules according to their potential for harm and restrictions placed on who can prescribe and dispense certain medicines. Governments require by law that the judgement, direction and supervision of prescribers and pharmacists be exercised in allowing individual access to these substances. Australia is also a signatory to two United Nations conventions designed to ensure the public is protected from uncontrolled access to potentially dangerous drugs, poisons and controlled substances[15] (Pharmacy Board of Victoria 1998, p 16).

Given these risks and the potential for harm, it is accepted that it is in the public interest for the market in medicinal poisons to be limited and controlled, along with access to these substances. The challenge in examining the legislation governing Victorian pharmacists is to establish what level of regulation is necessary to provide adequate protection of the public, without overly restricting the public's access to pharmacy services.

3.2 Current Legislation Governing Pharmacy Practice

Pharmacists operate within a highly regulated environment. In addition to professional regulation under the *Pharmacists Act 1974*, their activities are also subject to significant regulatory constraints via a range of legislation including the Victorian *Drugs, Poisons and Controlled Substances Act 1981,* and the *National Health Act 1958*. As the National Review (2000, p 15) noted, this combination of State and Commonwealth legislation

> *controls or influences virtually every aspect of pharmacy, including who is able to provide pharmacy services, who can profit from them, where they can be provided and, for the vast majority of prescription of medicines, the cost at which they can be sold to consumers.*

While this discussion paper focuses upon review of the *Pharmacists Act 1974*, it is important to have an appreciation of other legislation impacting pharmacy practice. Each of the key legislative influences is discussed below, with Figure One on page 22 providing a summary of how these impact on pharmacy.

3.2.1 Pharmacists Act 1974

Pharmacists have been subject to statutory registration in Victoria since 1876. Currently, registration of pharmacists is via the *Pharmacists Act 1974* and its associated Regulations, the *Pharmacists Regulations 1992*.

The *Pharmacists Act 1974* establishes the Pharmacy Board of Victoria as the body responsible for ensuring standards of education and training necessary to register pharmacists, their registration, the circumstances under which they may practise and processes for receiving and investigating complaints regarding the professional conduct of registered pharmacists.

The *Pharmacists Regulations 1992* support the operation of the Act, providing for the form of the register, the process for seeking registration, requirements for approval of pharmacy depots, fees payable under the Act and procedures regarding appointments to the Pharmacists Board. These Regulations were due to sunset in August 2002, but have been extended for 12 months pending completion of this review.

In addition to this legislation, the Pharmacy Board of Victoria produces its *Guidelines for Good Pharmaceutical Practice* on an annual basis, to advise pharmacists of:

- The Board's interpretation of certain parts of the Act and Regulations.

[15] The *United Nations Single Convention on Narcotics 1961* (as amended by the 1972 protocol) and the *United Nations Convention on Psychotropic Substances 1971.*

- How the Board exercises its discretion in regard to certain parts of the Act and Regulations.
- What the Board has determined to be minimum standards of good practice.
- How the Board expects the duties and responsibilities may best be observed.

(Pharmacy Board of Victoria 2002A, p 1)

The Guidelines cover many subjects including registration, pharmaceutical education and training, practise as a pharmacist, advertising and requirement for the approval of pharmacy premises, pharmacy depots and pharmacy departments.

The provisions of the Act and Regulations (as well as Guidelines, where relevant) are examined in detail throughout the body of this discussion paper.

3.2.2 Drugs, Poisons and Controlled Substances Act 1981

In addition to the *Pharmacists Act 1974*, services provided by Victorian pharmacists are regulated by the *Drugs, Poisons and Controlled Substances Act 1981* (*'DPCS Act'*). The *DPCS Act* and its associated regulations restrict certain medicines to schedules (according to their potential for harm) and also limit who can possess, sell and supply certain scheduled medicines[16]. Under the current legislation:

- only persons authorised under s13 of the DPCS Act[17] can prescribe certain medications; and
- other persons (or organisations) wishing to sell scheduled medicines in a retail setting must obtain a permit or license to do so[18].

In addition, DPCS legislation provides minimum standards for:

- The storage of substances in Schedules 3, 4, and 8.
- The role of the pharmacist in the supply of the above substances.
- Record-keeping in relation to Schedules 3, 4 and 8 substances.
- The sale of Schedule 2 ('pharmacy only') and Schedule 3 ('pharmacist only') substances.

While the *Pharmacists Act 1974* regulates practitioners and ownership of premises, DPCS legislation regulates the substances that pharmacists use in their practice. As such, many aspects of a pharmacist's practice—for example, how s/he stores drugs, and under what circumstances these can be dispensed—are regulated by controls within this legislation.

Given this interrelationship between pharmacy practice and legislative controls on the possession, sale and supply of medicines, it is not surprising that in the past, pharmacist registration acts have empowered pharmacy boards to ensure the premises of a pharmacy business are suitable for the secure storage and supply of medicinal poisons[19]. Where relevant, provisions of the *DPCS Act* will be taken into consideration as part of the review of the *Pharmacists Act*.

[16] Appendix 3 provides an overview of the process of how medicines are scheduled and also provides a summary of each of the 9 schedules into which drugs, poisons and controlled substances may be placed , based upon an assessment of their potential to cause harm.
[17] This includes registered medical practitioners, vets and dentists; endorsed optometrists and nurse practitioners may also prescribe certain drugs.
[18] Appendix 4 provides more detail on such permits and licences.
[19] One of the key issues for consideration in this review is what powers the Pharmacy Board should retain to approve and/or inspect premises for such purposes, given the controls and powers contained in DPCS legislation. These issues are examined in sections 5.4 and 7.6 of this paper.

3.2.3 Commonwealth Therapeutic Goods Act 1989

The (Commonwealth) ***Therapeutic Goods Act 1989***, establishes a national system of controls and standards relating to the quality, safety and efficacy, advertising, labelling and product appearance of therapeutic goods (including medicines) that are used in Australia. Various restrictions within this legislation (such as the controls on advertising of scheduled medicines) directly affect how a pharmacist conducts his or her business.

3.2.4 National Health Act 1953

The Commonwealth Government has a major influence upon the operation and viability of community pharmacies in Victoria, via the **Pharmaceutical Benefits Scheme** (PBS), which provides a government subsidy for the full cost of medicines above a patient co-payment. Established under the Commonwealth *National Health Act 1953*, the PBS exists to provide 'timely, reliable and affordable access for the Australian community to necessary and cost effective medicines' (Industry Commission, 1996).

Since 1990, the Federal Minister responsible for the Pharmaceutical Benefits Scheme and the Pharmacy Guild of Australia have negotiated formal agreements that set controls on the number and location of PBS-approved pharmacies. This agreement, the **Australian Community Pharmacy Agreement**, also sets the terms for remuneration of pharmacists dispensing PBS medications. The current agreement came into effect on 1 July 2000 and will remain in force until 30 June 2005.

Pharmacists are heavily reliant upon income generated via the PBS. Most medicines purchased by the Australian public attract the PBS subsidy: data collected by the Senior Officials Working Group indicates that around 80 per cent of income from prescription medicines is derived from the PBS[20] (Commonwealth of Australia 2002, p 34).

Under current legislation, a pharmacy or pharmacy department that wishes to dispense PBS-subsidised medications must be approved under the *National Health Act 1953* to do so, and the approval number issued for this purpose is specific to a pharmacy premises[21]. Via the exercise of these powers, the Commonwealth effectively controls where a pharmacist can establish a pharmacy.

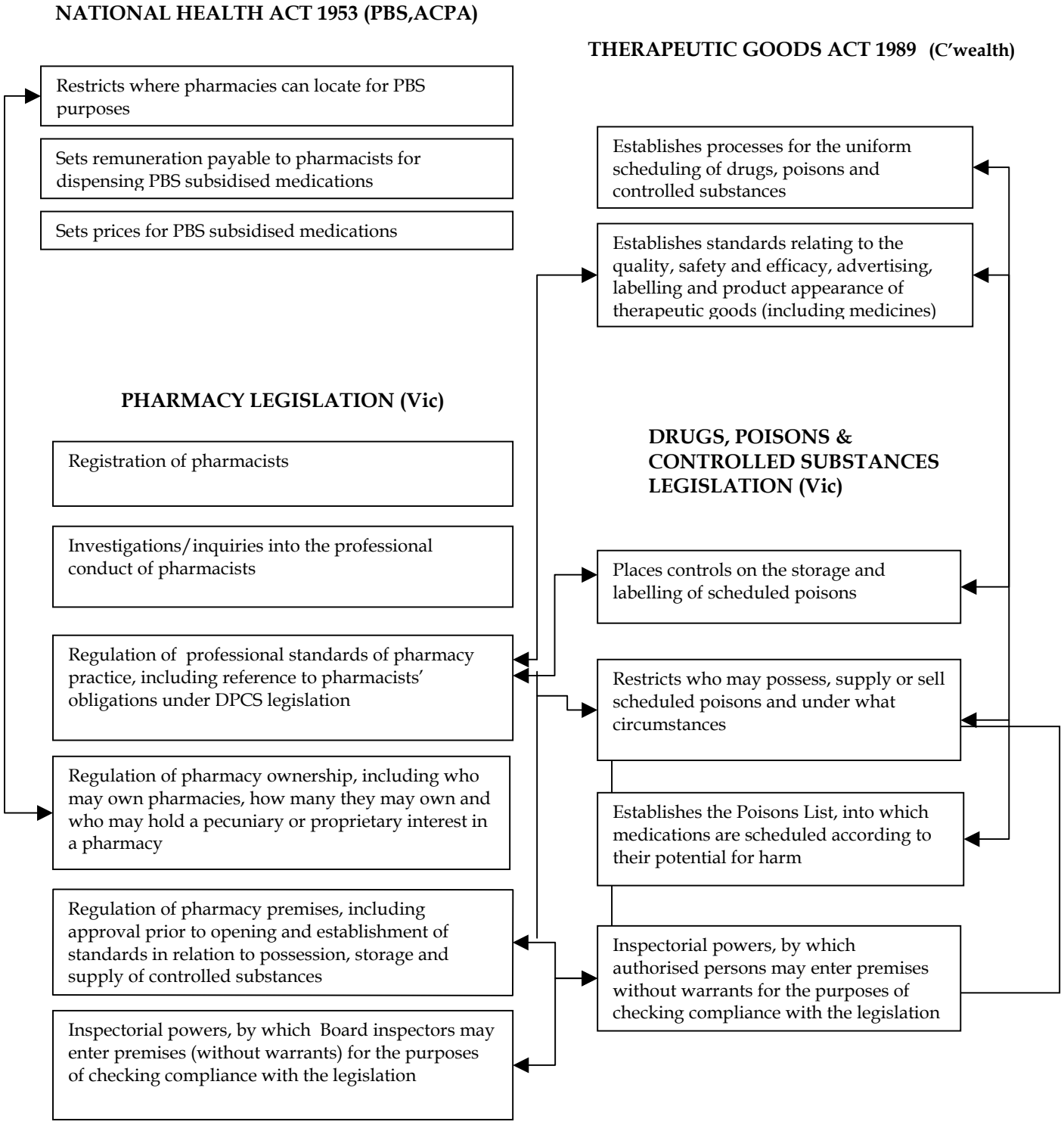
The National Review (2000, p 17) noted that the agreement significantly discourages price competition between community pharmacies on PBS-related dispensing and also constricts the market's power to distribute pharmacies according to consumer demand. It concluded that the PBS location rules 'represent heavy government intervention in the market for pharmacy services, while generally protecting pharmacy's established catchment areas from new competition' (2000, p 87).

The Senior Officials Working Group agreed, noting that these restrictions on where a pharmacy can locate if it wishes to participate in the PBS 'have the most impact of all the restrictions on pharmacy businesses…(and) are inherently anti-competitive in their operation and effects' (2002A, p 24). **While the PBS and the Australian Community Pharmacy Agreement are Commonwealth responsibilities and thus beyond the scope of this current review, they significantly limit the capacity for reforms of Victorian pharmacy legislation to increase competition in the market for pharmacy services.**

[20] This data, extrapolated from information in the 1999 *Pharmacy Trade Report* and data from the Commonwealth Department of Health and Aged Care, indicated that around 43 per cent of total community pharmacy income was from medicines dispensed under the PBS and around 10 per cent from the PBS co-payment and private (non-PBS) medicines. An additional 10 per cent of income was derived from Schedule 2 medicines, with the remaining 37 per cent of community pharmacy income derived from retail activities.

[21] This differs from the Medicare Benefits Scheme, where provider numbers are issued to individual practitioners.

Figure One: Legislative Impacts on Victorian Pharmacy



PART B – NATIONAL COMPETITION POLICY ISSUES

4 Restrictions on the Practice of Pharmacy

This section examines restrictions on competition contained within the current Act and regulations on the practice of pharmacy and seeks views on potential options for reform. Where these restrictions have been examined in the National Review, relevant recommendations are summarised and input sought on options for their implementation.

4.1 Statutory Registration of Pharmacists

The provisions within the Act which require registration of pharmacists restrict competition by limiting who can enter the profession and who can practise. These restrictions generate both costs and benefits to the community at large.

The National Review (2000, pp 100–107) examined the costs and benefits of statutory registration of pharmacists as well as alternatives to statutory registration. From this detailed analysis, the National Review concluded that continued compulsory registration of pharmacists satisfied the competition test, noting:

> *Regulating whom may practise pharmacy, and how it is practised, helps to assure the Australian public that pharmacists are competent and the professional services that they provide are safe…On balance, and taking into account that there is an information asymmetry between pharmacists and consumers, the Review believes that it is reasonable to regulate aspects of the practice of pharmacy and its practitioners.* (2000, p 8)

The National Review (2000, p 9) did, however, recommend that 'legislation governing registration…be the minimum necessary to protect the public interest by promoting the safe and competent practice of pharmacy'. It is in this context that reforms to Victorian legislation governing the registration of pharmacists will be considered.

4.2 Reserved Titles—'Protection of Title' Restrictions

Current Restrictions

Section 33(1)(a) of the Act makes it an offence for a person who is not a registered pharmacist to practise as, or hold themselves out to be, a registered pharmacist.

Section 33(1)(b) of the Act restricts use of the titles 'pharmacist', 'pharmaceutical chemist', 'chemist', 'druggist', 'chemist and druggist', 'homeopathic chemist' and various other synonyms to registered pharmacists. It also restricts use of 'any title or sign or symbol' that might suggest a person is 'qualified to perform the duties of a pharmacist' to registered pharmacists. Section 33(1)(c) also prohibits a person who is not a registered pharmacist from designating premises as a pharmacy, by restricting use of the words 'pharmacy', 'apothecary's hall', 'medical drug hall', 'pharmaceutical institution' and 'drug store' [22].

Contravention of these provisions is an offence under the Act.

Recommendations arising from the National Review

The National Review (2000, pp 110-111) recommended that restrictions on the use of professional titles such as 'pharmacist' and 'chemist' be retained in legislation as they help 'protect the public from incompetent, fraudulent and charlatan practice by non-registered persons'. This recommendation was supported by the COAG Senior Officials Working Group (2002, p 30).

[22] Friendly societies, registered funded agencies, private hospitals and privately operated hospitals are exempted from this provision under s21(4) and 21(5).

Discussion

Although these are clearly restrictions on competition, similar restrictions on the use of professional titles have been judged to be in the public interest and have been retained within all other Victorian health practitioner registration acts[23].

If the Victorian model for health practitioner regulation is applied to pharmacy, provisions similar to section 62 of the *Medical Practice Act 1994* would:

- Restrict the use of specific titles such as 'pharmacist'[24] to persons who are registered pharmacists.
- Establish offences for use of such titles by non-registered persons or bodies corporate.
- Establish offences for non-registered persons or bodies corporate who hold themselves out to be registered pharmacists.

Given that other professions such as industrial chemists and Chinese herbal pharmacists use these (or similar) titles, it may be necessary to exempt such groups from certain offence provisions.

The current *Pharmacists Act* also prevents unregistered persons (except permitted exceptions) from using words such as 'pharmacy' to describe premises. Under the Victorian model, only professional titles are restricted although an unregistered person who designated his/her premises as a pharmacy might be considered to be holding him/herself out as a pharmacist.

What Are Your Views?

- Which professional titles should be protected to ensure adequate protection of the public? Would it be adequate to establish a provision that restricted use of the title 'pharmacist' and any other titles calculated to induce a belief that a person is registered?
- Are there other professional groups (not registered under pharmacy legislation) that legitimately use titles such as 'pharmacist' or 'chemist'? If these are protected titles, should those professional groups be exempted from the relevant offence(s)?
- What are the risks associated with removing protection of the word 'pharmacy' and other synonyms used to designate premises? Would the inclusion of the standard Victorian 'holding out' provisions offer sufficient protection against these risks?

4.3 Restrictions on Who May Practice Pharmacy

4.3.1 Personal Characteristics

Current Restrictions

Currently, personal characteristics that are preconditions for registration as a pharmacist under section 12 of the *Pharmacists Act 1974* are:

- good character; and
- an adequate understanding of the English language.

The National Review noted that 'considerable parts of laid down requirements for a pharmacist to be registered are not contained in either the Act or Regulations, but in the Board's Guidelines'

[23] In addition, the *Drugs, Poisons and Controlled Substances Act 1981* authorises pharmacists (along with various other registered health practitioners) to possess, use, sell or supply poisons and controlled substances. While this Act defines a pharmacist as 'a person for the time being registered as a pharmacist under the *Pharmacists Act 1974'*, retaining restrictions on who may use the title pharmacist may assist in the enforcement of relevant sections of the *DPCS Act.*

[24] Or any other title calculated to induce a belief that a person is registered under that Act.

(2000, p140). For example, Guidelines 201, 204, and 205 provide additional details regarding the Board's expectations and requirements for registration, while Guideline 202 also requires applicants to provide

- a level 2 Basic First Aid Certificate, 'or other such evidence of being proficient in administering first aid as may be acceptable to the Board'; and
- evidence of successful completion of 'an approved management course'.

Guideline 320 requires demonstration of fluency of both written and spoken English during the Board's final examination for trainee pharmacists.

Recommendations arising from the National Review

The National Review (2000, p 110) concluded that 'good character' and 'proficiency in spoken and written English' should be the only personal characteristics required as preconditions for registration, a recommendation supported by the COAG Senior Officials Working Group (2002A, p 31). In considering restrictions within the Victorian Act, the National Review recommended that the Guidelines' requirement for certain pharmacists to have first aid qualifications be removed (2000, p 140).

Discussion

To implement this recommendation and achieve consistency with other Victorian health practitioner Acts, the Board would be empowered to refuse a grant of registration if:

- the character of the applicant was such that it would not be in the public interest to allow the applicant to practise as a registered pharmacist; or
- the applicant's competency in speaking or communicating in English is not sufficient for that person to practise as a registered pharmacist[25].

The requirement for an applicant to have first aid training as a precondition for registration would be removed.

What Are Your Views?

- Are there any other factors that should be taken into consideration in implementing this recommendation of the National Review?

4.3.2 Educational Requirements for Registration

Current Restrictions

Under Section 12 of the Act, the Board can register a person as a pharmacist if he or she has:

- completed study at a prescribed institution; and
- completed a prescribed course of practical training for a minimum number of hours; and
- passed entrance examinations, including a final examination under the auspices of the Board.

Course of Study Required for Registration

Section 13 of the Act empowers the Board to determine educational requirements for persons seeking entrance to the study of pharmacy and the course of study leading to annual and final examinations. Section 13 also enables the Board to consult with the Dean of the Pharmacy College or the equivalent on course content. Part 3 of the Regulations sets out subjects for study

[25] Proposed grounds for refusal of registration are discussed in further detail in section 7.4.1 of this paper.

towards a pharmacy degree, while Part 3 of the Guidelines provides further detail regarding requirements for overseas-trained pharmacists and pharmacists seeking restoration to the register[26].

Course of Practical Training

Regulation 307 requires a pharmacy trainee to enter into an agreement for articles of traineeship with a pharmacy practical tutor. A pharmacy practical tutor is defined in the Regulations as a pharmacist who conducts his or her pharmacy practice on premises that have been approved by the Board for the purpose of tutoring trainees.

Part 3 of the Regulations sets out topics to be included in practical training courses (r301) and the prescribed period for practical training (r302) for the purposes of section 12(1)(a)(i) of the Act. Topics involved in the practical training and instruction include dispensing procedures and practice, treatment of commonly occurring minor ailments, communication to patients, health professionals and the community, law applying to pharmacy practice and drug information procedures.

Final Board Examination

Section 14 sets out a final examination for all candidates to be completed under the auspices of the Board, with subjects for the Board's final examination set out in Part 3 of the Regulations (r304).

Recommendations arising from the National Review

The National Review (2000, p 111) recommended that 'legislative requirements specifying qualifications, training and professional experience needed for initial registration as a pharmacist (be) retained', a recommendation supported by the COAG Senior Officials Working Group (2002, p 31).

In examining current Victorian pharmacy legislation, the National Review noted that

> *the Act and Regulations, coupled with the Board's qualifications, give the Board great authority over the setting of professional education and training standards and curricula in Victoria. It is a matter for the jurisdiction to consider whether the extent of this statutory mandated involvement of the Board is justified* (2000, p 140)

In a separate recommendation, the National Review (2000, p 111) recommended that

> *State and Territories move towards replacing qualification-based criteria with solely competency-based registration requirements if and as appropriate workable assessment mechanisms can be adopted and applied.*

Discussion

The current provisions of the *Pharmacists Act* and *Regulations* are prescriptive and provide little flexibility for the Board. To implement the National Review's recommendations in a manner consistent with the model applied to other Victorian health practitioner registration Acts, these provisions would be replaced with more generally worded provisions regarding qualifications for general registration. These might include:

- successful completion of a course of study accredited by the Board or a recognised accrediting body[27]; or
- a qualification that, in the opinion of the Board, is substantially equivalent or is based on similar competencies to an accredited course; or
- passing an examination set by or on behalf of the Board; or

[26] Requirements around re-entering the profession after a period of absence are examined in section 7.7 of this paper.

[27] This might be worded to make reference to both formal and practical training. Alternatively, additional powers for the Board to approve courses of practical training which provide qualifications for registration as a pharmacist could be established, similar to those contained in s 68(1) of the *Psychologists Registration Act 2000*.

- a qualification that is recognised in another State or Territory of the Commonwealth for the purposes of undertaking work of a similar nature to that which a person, holding a qualification to which any of the 3 apply, is qualified to undertake.

Such an approach does not rule out the use of competency-based assessment mechanisms, instead providing the Board with the discretion to adopt whatever assessment mechanisms it considers appropriate.

Some Victorian health practitioner Acts (such as the *Nurses Act 1993* and the *Psychologists Registration Act 2000*) also empower their respective Boards to recognise qualifications in addition to those required for general registration. This enables those Boards to enter additional qualifications (such as postgraduate training in specific fields of nursing or psychological practice) on the register. Similar powers could be established for the Pharmacy Board, if appropriate.

What Are Your Views?

- Are the powers outlined above suitable for the purposes of determining which persons are appropriately qualified for registration as pharmacists?
- In addition to these general powers, does the Board require specific statutory powers to:
    - Direct which subjects should be included in pharmacy training?
    - Require successful completion of a pre-registration examination administered by the Board?
    - Approve courses of practical training required for registration, and if so, what level of control over placements would be appropriate?
- Does the Board need statutory powers to recognise and enter on the register pharmacy qualifications in addition to those required for registration?

4.3.3 Reserved Practice—'Protection of Practice' Restrictions

Current Restrictions

Section 3 of the Act defines practice as a pharmacist as including 'the supplying compounding or dispensing of drugs and medicines on an order or prescription'.

Section 33(1)(a) of the Act makes it an offence for a person who is not a registered pharmacist to practise as or hold themselves out to be a registered pharmacist.

Recommendations arising from the National Review

The National Review (2000, p 110) found that 'restricting the lawful practice of pharmacy to registered persons is also justifiable in the public interest' but stated that

> *limited exceptions to this general rule…are also justifiable. There is a public interest in allowing at least limited pharmacy services to be provided by experienced allied health professionals to people in rural and remote areas, and in medical emergencies, who otherwise may not have ready access to a dispensing pharmacist* (2000, p 110).

The COAG Senior Officials Working Group (2002, p 28) expressed reservations about the National Review's recommendation to restrict the practice of pharmacy in legislation, noting that the National Review '(did) not define the practice of pharmacy nor make it clear why it should be restricted'. The Working Group noted that without a workable definition, protecting the practice of pharmacy appeared 'so open-ended as to defeat the purpose of offering certainty to the general public and could also lead to unnecessary restriction of related practices such as homeopathy and Eastern medicine' (2002, p 28).

The Working Group also expressed the view that legislation governing the registration of pharmacists should focus on registration matters rather than establishing safety standards, and that the latter already existed in drugs and poisons legislation, which established controls over the possession, sale and supply of drugs by qualified pharmacists (2002, p 28). In this context, the Working Group suggested that the only practices that should be considered for protection are those that cannot be controlled by other legislation, and pose a substantially higher risk of significant harm to the public if they are carried out by persons other than qualified pharmacists.

Furthermore, the Working Group recommended that 'if no acceptable set of protected practices can be agreed upon according to these criteria, general practice protection for pharmacists should be removed' (2002A, p 28).

Discussion

Statutory restrictions on who can practise pharmacy limit competition by preventing other potential competitors from providing services. In addition to the adverse effects of reduced competition, such restrictions may also have the effect of reducing access to medicines in certain areas (such as parts of rural and remote Victoria), by preventing other practitioners from providing medication services in areas where pharmacists are not available.

The nature of pharmacy practice has evolved over time to include various cognitive services, which are both difficult to define and have significant capacity for overlap with the legitimate activities of many other health professions. As the COAG Senior Officials Group noted, such factors limit the effectiveness of legislative definitions of scope of practice and restrictions on practice, and may result in unnecessary restrictions on other professions who utilise similar techniques or practices.

In addition to these limitations, it is unclear whether restrictions on the practice of pharmacy are appropriate or necessary in pharmacy legislation, given that other mechanisms exist to protect the public from the potential harm that could occur from the abuse or misuse of certain drugs, poisons and controlled substances. For example, the *Drugs, Poisons and Controlled Substances Act 1981* ('DPCS Act') and its associated regulations restrict certain substances to schedules (according to their potential for harm) and regulate which poisons and controlled substances a registered pharmacist may possess, obtain and sell.

Adopting the Victorian model of health practitioner regulation, in which professional titles and not practices are protected, would appear to provide adequate protection of the public while avoiding the problems identified above[28]. Under this approach, a non-registered person who holds him/herself out to be a pharmacist would be guilty of an offence under the Act.

What Are Your Views?

- Are there aspects of pharmacy practice that cannot be adequately regulated by other legislation (such as DPCS legislation) and pose a substantially higher risk of significant harm to the public if they are carried out by a person other than a qualified pharmacist?

[28] Assuming the National Review's recommendations on pharmacy ownership are implemented, definitions of 'pharmacy business' and possibly 'pharmacy department' might be included in legislation if necessary. This is examined in Section 5 of this paper.

5 Restrictions on the Ownership and Operation of Pharmacies

The National Review examined the nature, costs and benefits of restrictions on ownership of pharmacies in detail as well as alternative approaches to the current restrictions (2000, pp 25–69).

This section provides an overview of restrictions relating to pharmacy ownership contained in the Victorian Act and potential options for implementing recommendations of the National Review. These restrictions are in four main areas:

- Controls on who may own pharmacies.
- Restrictions on ownership structures.
- Limitations on how many pharmacies an individual may own.
- Requirements for approval and oversight of pharmacy premises.

5.1 Restrictions on Who May Own Pharmacies

Current Restrictions

Section 3 of the current Act defines a pharmacy as 'any premises in or upon which a pharmacist practises as a pharmacist, and includes the portion of the premises where he compounds or dispenses drugs or medicines and the portion of the premises where he sells or offers to sell goods of any kind, but does not include a pharmacy department'.

Under section 3, a pharmacy department includes:

- the portion of the premises of a (registered funded) agency[29] set aside for compounding or dispensing drugs and medicines; and
- the premises or portion of any premises established for a dispensary for the purposes of the Friendly Societies (Victoria) Code[30]

Section 21 of the *Pharmacists Act 1974* prevents bodies corporate and natural persons who are not pharmacists from owning or holding a pecuniary interest in a pharmacy practice. The exceptions are:

- recognised friendly societies[31]
- administrators of deceased estates and bankrupt or insolvent pharmacy businesses, who may continue the business 'for a period of 6 months or for such further term as may be permitted by the Board is and so long as the business is bona fide conducted by a registered pharmacist' (s32 & 32A)
- non-registered individuals and companies who were permitted to own pharmacies prior to the commencement of the current Act (s21(6); and
- pharmacy departments operated by a registered funded agencies (these include hospital pharmacy departments).

There are no residential requirements for ownership of pharmacies, however a person must be registered in Victoria to own a pharmacy.

[29] Defined in the *Health Services Act 1988* as including public hospitals, denominational hospitals, community health centres, State funded residential care services and other agencies registered under Division 2 of Part 3 of that Act.
[30] Or its successor.
[31] While the society is acting in accordance with the Act.

Section 33 provides penalties for a person who is not a registered pharmacist, but who holds him/herself out to be a pharmacist or carries on the business of a pharmacist.

Hospitals and a range of other health services contain pharmacy departments providing pharmacy services to inpatients and outpatients. Unlike community pharmacies, pharmacy departments do not provide pharmacy or retail services to the general public. Section 21(5) of the current Act exempts these pharmacy departments from the requirement to be owned by a registered pharmacist. This allows public hospitals and other registered funded agencies (within the meaning of the *Health Services Act 1988*) to own and operate pharmacy departments.

Recommendations arising from the National Review

Pharmacist Ownership

The National Review (2000, pp 46-49) concluded that 'there is a net public benefit from the value-added dimension of pharmacist ownership of pharmacies[32]' and recommended that

> *Legislative restrictions on who may own and operate community pharmacies are retained; and with existing exceptions, the ownership and control of community pharmacies continues to be confined to registered pharmacists...*

The COAG Senior Officials Working Group (2002, p 8) concluded that 'the impact of opening up the ownership of pharmacies could be too disruptive for the industry in the short term' and thus recommended that the National Review's recommendation be accepted.

Residential Requirements for Pharmacist Ownership

The National Review (2000, p 49) recommended that

> *the requirement for a pharmacist be registered in that jurisdiction to own a pharmacy be retained, pending any consistent national arrangements that may be adopted.*

This was seen as a means of promoting the accountability of the owner by ensuring s/he is 'conversant with the laws and professional requirements of the local jurisdiction' (2000, p 49). The COAG Senior Officials Working Group endorsed this recommendation, noting that 'it is appropriate that as the ownership regulatory framework is managed at the State or Territory level pharmacy owners register with local authorities' (2002, p9).

The Working Group also observed that the reference to national arrangements reflected ' the (National) Review's desire that jurisdictions move to recognise each other's registration for pharmacy ownership purposes' (2002, p 9). The Working Group noted that under Mutual Recognition legislation, a pharmacist who is registered in one jurisdiction may register in others, concluding that 'although these provisions do not apply to ownership registration, they go some way towards satisfying the Review's concerns' (2002, p 9). The issue of a national scheme for registration of pharmacists is discussed in section 8.2 of this paper.

Deceased Estates and Bankrupt Individuals and Businesses

While none of the National Review's recommendations specifically refer to arrangements for deceased estates and bankrupt individuals and business, the National Review (200, p56) highlighted that these are temporary arrangements and saw such provisions 'with a reasonable transition time allowing the winding up and disposal of the decease proprietor's business, as being justifiable regulation'. The COAG Senior Officials Working Group (2002, p14) supported this view.

Grand-Parented Corporately Owned Pharmacies

[32] These benefits were seen to include ensuring professional accountability and also 'accessibility to (professional pharmacy services) for people in all parts of Australia (2000, P 47).

The National Review (2000, pp 56-57) noted that relatively few of these exist and their numbers were likely to decrease further with industry attrition over time. It did not propose any changes to current legislation with respect to these.

The COAG Senior Officials Working Group (2002, p 14) supported this view, noting that any change of treatment would be inconsistent with the principle of pharmacist-owned pharmacies.

Friendly Societies

The National Review examined whether friendly societies should be able to own pharmacies (and if so, under what circumstances) in considerable detail (2000, pp 57–60). It recommended that those friendly societies that currently operate pharmacies be permitted to continue doing so, but that:

- *regulations specific to the establishment and operation of pharmacies by friendly societies, that do not also apply to other pharmacies and classes of proprietors, be removed; and*
- *friendly societies that did not operate pharmacies at a prescribed date should not own, establish, or operate a pharmacy in that jurisdiction in the future*[33].

In examining models for regulation of friendly societies, the National Review suggested the provisions in the Victorian *Pharmacists Act 1974* be used as a model for the regulation of friendly societies in all jurisdictions (2000, p 60). In addition, the National Review (2000, p 60) recommended that 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… and the findings of such inquiry may be taken into account*[34].

The recommendations regarding friendly society ownership were amongst the most contentious of those made by the National Review, and the COAG Senior Officials Working Group appears to have undertaken a detailed assessment of these recommendations, both from a public benefit perspective and also in relation to other recommendations of the National Review.

The Working Group (2002, p 16) noted that there had been strong responses to these recommendations of the National Review, with some employee pharmacists arguing that friendly society pharmacies should be able to operate without restriction as:

- they stimulate competition in the community pharmacy market, with beneficial outcomes for consumers; and
- proposals to restrict friendly society pharmacies are anti-competitive and have the potential to benefits non-friendly society pharmacies rather than consumers.

By contrast, pharmacist proprietors advised the Working Group that friendly societies should not be permitted to continue owning pharmacies, as:

- this recommendation is at odds with other recommendations of the National Review, which adopt the principle of pharmacist-only ownership of pharmacies;
- friendly societies have an unfair tax advantage over pharmacist-owned pharmacies; and
- friendly societies have an unfair competitive advantage because their corporate structure that allows for economies of scale.

While the Working Group took the concerns of pharmacy proprietors into consideration, it concluded that 'friendly society pharmacies provide a safe and competent pharmacy service' and saw 'no reason to restrict their operations'. In light of this, the Senior Officials Working

[33] Unless it is an entity resulting from an amalgamation of two or more friendly societies operating a pharmacy at that date.
[34] The National Review (2000, p 59) did however note that such an analysis should not hold up the States' 'timely consideration of any amendments to their legislation arising from the Review's recommendations.

Group accepted the view that friendly societies should continue to be permitted exceptions and noted that this would ensure 'that friendly society pharmacies are subject to the same standards and constraints of pharmacist-owned pharmacies' (2002, p 18).

The Senior Officials Working Group recommended against introducing restrictions that would prevent the entry of new friendly societies into the pharmacy industry, noting that the National Review did not demonstrate a net public benefit for the introduction (or retention) of such restrictions. (2002, p 15). In examining this issue, the Working Group sought independent advice from chartered accountants as to whether friendly societies could use this opening as an opportunity to dominate community pharmacy, or new ones would enter the industry, establish themselves, demutualise and operate as 'for-profit' corporate bodies. This advice suggested that

> *friendly societies do not have a significant comparative competitive advantage over pharmacists owned pharmacies and therefore in a post Wilkinson environment are no more likely to dominate community pharmacy than are pharmacists* (2002, p 16).

The Working Group also examined the issue of whether friendly societies that demutualise and become 'for-profit' corporate bodies should be permitted to own pharmacies. It concluded that the feature that distinguishes friendly society pharmacies from 'for-profit' corporate bodies is that they are organisations that are primarily concerned with providing a benefit to their members.

In light of this, the Working Group (2002, p 18) concluded that should a friendly society

> *demutualise and lose that characteristic of primarily providing benefits to its members then it should no longer be a permitted exception to pharmacist ownership as there is little to distinguish it from a for-profit corporate body.*

Other Permitted Exceptions

The National Review did not examine legislative restrictions on clinical (hospital) pharmacy. As the COAG Senior Officials Working Group noted (2002, p 2),

> *the arguments for restricting ownership of community pharmacies (such as protecting independent pharmacy businesses from perceived "unfair competition" and market dominance from large pharmacy-owning corporations) are not relevant for hospital pharmacies…For these reasons, legislative restrictions on ownership for hospital pharmacies are not necessary'.*

Discussion

To implement these recommendations in Victoria, restrictions on who may own pharmacies would be retained, limiting ownership to:

- pharmacists registered to practice in Victoria;
- non-registered persons or corporations who owned pharmacies at the time the *Pharmacists Act 1974* was established; and
- administrators of deceased estates and bankrupt or insolvent pharmacy businesses, who would be permitted to continue running the businesses for certain timeframes approved by the Board.

Pharmacy departments (such as those located in hospitals and other registered funded agencies) would be exempt from this ownership requirement.

If the Senior Officials' Working Group recommendations were implemented, additional restrictions on new friendly societies entering the market would not be introduced although there would be some restrictions on the circumstances under which friendly societies may own pharmacies if they demutualise. Further examination of how the recommendations regarding demutualised friendly societies might be implemented will be undertaken as part of the current

review. In addition, it is recognised that various definitions and powers will be required in legislation to support effective administration of these ownership provisions. Particularly if new legislation does not define the practice of pharmacy, it might be necessary to define what a pharmacy business is to allow the Board to administer the ownership provisions effectively[35].

What Are Your Views?

- How should 'friendly society' be defined for purposes of a new Act?
- If a friendly society should go through a process of demutualisation, at what point should it be prohibited from owning pharmacies?
- For the Board to effectively administer restrictions on ownership of pharmacies, an appropriate definition of 'pharmacy business' may be required in legislation. What should this definition include?
- What powers would the Board require to administer these provisions effectively?

5.2 Restrictions on Ownership Structures and Pecuniary Interests

Current Restrictions

Section 21 of the current Act prevents a body corporate or a natural person who is not a pharmacist from owning or holding a proprietary or pecuniary interest in a pharmacy practice. Under s21(7) of the Act, a pharmacist must provide the Board with information regarding proprietary or pecuniary interests in any pharmacies on request. Refusal or failure to do so is an offence under s21(8).

Section 22 of the Act complements these provisions, providing that:

- A copy of every partnership agreement must be lodged with the Board registrar within two months of its execution; and
- No bill of sale, mortgage, lease or in any other commercial arrangement in respect of the practice of a pharmacist can require:
    - the provision of goods or services for the pharmacy business by a specific supplier;
    - the right of a third party to control the manner in which a pharmacy practice is carried on;
    - right of access to a pharmacy business's books except for the purpose of the bill of sale or other specified document; and/or
    - the right to receive any consideration from the pharmacy business that varies according to the profits or takings by a pharmacist.

Recommendations arising from the National Review

Permitted Ownership Structures

The National Review (2000, p 53) recommended that 'ownership structures permitted by various Sate and Territory Pharmacy acts be retained as being consistent with the defined principle of pharmacist ownership and effective control of pharmacy businesses', a recommendation supported by the COAG Senior Officials Working Group (2002, p 10).

[35] Currently "pharmacy" is defined in terms of the premises in which a pharmacist operates, but pharmacy is also commonly used to describe the practice of pharmacy. Replacing this with a definition of "pharmacy business" may improve clarity.

The National Review did however recommend that ownership structures available to pharmacists be expanded to include corporations with shareholders who are all registered pharmacists; or registered pharmacists and prescribed relatives of those pharmacists, along the lines of the family company model permitted in South Australia. Table 2 provides a summary of the key features of the South Australian model.

Table 2: Features of the South Australian Model for Family Company Ownership of Pharmacies

A company registered as a pharmacist must satisfy the Board that its memorandum and articles of association provide that:
The sole object of a company must be to practise as a pharmacist;
The directors must be persons who are registered pharmacists or, if there are only two directors, one may be a prescribed relative (parent, spouse, de facto partner, child or grandchild);
Shares are owned by a registered pharmacist director or a prescribed relative of that pharmacist;
Total voting rights in the company are held by registered pharmacists who are directors or employees of the company;
The directors are not directors of any other company registered as a pharmacist without the Board's approval;
Shares in the company cannot be transferred beyond the company and members of the company; and
Shares held by a spouse or de facto partner must redeemed by the company on the dissolution of the marriage or the ending of cohabitation.

(Source: s18(2) of the South Australian *Pharmacy Act 1991)*

The National Review (2000, pp 52-53) considered that expanding available structures for pharmacist owners might:

- enable younger pharmacists to more readily to become proprietors and develop a greater sense of professional responsibility;
- promote greater competition between proprietor entities in the community pharmacy industry;
- enable pharmacist businesspeople to realise economies of scale;
- assist in the growth and development of rural pharmacy services; and
- provide greater professional and commercial competition.

The National Review (2002, p 53) also recommended that

> *due to the risks of conflicts of interest of shareholders, and the difficulties in determining the extent to which the 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.*

The COAG Senior Officials Working Group (2002, pp 10–11) recommended that the National Review's recommendations regarding permitted structures for pharmacy ownership be accepted, noting that the proposal to expand structures available to pharmacist owners 'introduces a limited form of incorporation that allows pharmacists to take advantage of corporate structures and the tax and other benefits that these bring'.

Pecuniary Interests in Pharmacy Businesses

The National Review (2000, p 66) recommended that the

> *current prohibitions on natural persons or bodies corporate, not being a registered pharmacist or other permitted entity, having a direct proprietary interest in community pharmacies be retained*

and supported inclusion of a clear definition of 'proprietary interest' in legislation.

In examining whether current restrictions on business associations with non-pharmacists could be justified in the public interest, the National Review (2000, p 61) concluded that

> *so long as the proprietor or director of a pharmacy business is a pharmacist or a permitted non-pharmacist and remains responsible and accountable for the professional services delivered under their responsibility, regulatory authority scrutiny generally should not apply to the commercial relations and transactions of their business. The only qualification should be that authorities are able to act on matters where safe and competent pharmacy practice has, or appears to have been compromised*

In light of this, the National Review (2000, p 4) recommended that 'regulation of the commercial aspects of pharmacy practice …be wound back, or removed'. In relation to the Victorian Act, the National Review (2000, p 135) recommended that this involve replacing the provisions around pecuniary interests in section 21 and 22 of the current Act with:

- *a clear statement that no ineligible person or corporation can have a proprietary interest in a pharmacy business;*
- *a definition of proprietary interest to simplify and make consistent the administration of these provisions; and*
- *a provision making it an offence under the act for a person or corporation to apply improper and inappropriate interference on the professional conduct of a pharmacist, and making a pharmacist's acting under such influence a ground for professional misconduct.*

As the COAG Senior Officials' Working Group (2002, p 20) noted, these recommendations acknowledge 'that 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' and aim to give 'pharmacies as much commercial freedom as possible while protecting the integrity of proprietors' ability to control the planning and delivery of pharmacy goods and services in their pharmacies' (2002, p 19).

The Working Group supported this recommendation noting that in response to industry concerns, it had examined a range of options[36] before concluding that the relevant provisions of either the New South Wales *Medical Practice Act 1992*[37] or the Queensland *Pharmacy Registration Act 2001* would form a suitable model that focused upon 'improper practice by the pharmacist' rather than commercial arrangements (2002, pp 19-21).

Discussion

To implement these recommendations, an Act governing the registration of pharmacists would need to include:

- Restrictions on who may hold a proprietary interest in a pharmacy.
- Expanded ownership structures to permit prescribed relatives to hold interests in pharmacist-owned pharmacies.

[36] Including reliance on provisions in the *Trade Practices Act,* development of an industry Code of Conduct, and/or a new legislative provision that renders unenforceable any provisions of a contract or other agreement between a pharmacy business and another party if they purport to influence or direct the professional control of a pharmacist of his or her business (proposed by the Pharmacy Guild)

[37] Recent amendments to the Victorian *Medical Practice Act 1994* (via the *Health Practitioner Acts (Further Amendments) Act 2002*) establish a similar scheme for regulation of employers who direct or incite registered medical practitioners to engage in unprofessional conduct.

- A clear definition of the term 'proprietary interest'.
- Establishment of a 'negative licensing' scheme for non-pharmacist owners, managers or employers who direct or incite registered pharmacists to engage in unprofessional conduct (this is examined in detail section 7.8 of this paper).

Consideration will also be given to what powers the Board will require to administer these aspects of the ownership provisions.

What Are Your Views?

- Do you support the South Australian model of pharmacy ownership as summarised in Table 2, or are there alternative models you feel would be more appropriate?
- Which prescribed relatives do you believe should be able to hold a pecuniary interest in a pharmacy, and under what circumstances they might be required to surrender this interest?
- The National Review suggests 'ownership of, or a partnership, shareholding or directorship in a pharmacy operating entity' as a definition of proprietary interest. Do you support this definition?
- What statutory powers (if any) does the Board need to administer these provisions?

5.3 How Many Pharmacies May an Individual Own?

Restrictions in the Current Legislation

Under subsection 21(2), a pharmacist cannot have an interest in more than 3 pharmacy practices, either solely or in partnership. Subsection 21(3) links this requirement to pharmacy premises rather than the business in which an interest may be held.

For permitted exceptions such as friendly societies, there are no limitations on the numbers that may be owned or operated. Subsection 21(6) also contains grand-parenting provisions for arrangements that were in place before introduction of the 1974 Act.

Section 28 of the current Act requires a pharmacist to be in attendance at all times the pharmacy or pharmacy department is open for business.

Recommendations arising from the National Review

The National Review (2000, p 56) recommended that:

> *State and Territory restrictions on the number of pharmacies that a person may own, or in which they may have an interest, are lifted;*
>
> *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*
>
> *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.*

Lifting Restrictions on Pharmacy Numbers

The Senior Officials Working Group (2002, 12) noted that

> *the lifting of restrictions on the number of pharmacies an owner can operate is one of the most far-reaching reforms contemplated by the Review …(and)…has the capacity to significantly change the nature of community pharmacy.*

While various industry representatives put options to restrict the number of pharmacies that a pharmacist may own to the Working Group for consideration, the Group accepted the evidence presented to the National Review that 'any limits imposed in this way are impractical to enforce and inherently anti-competitive' (2002, p 12) and supported the National Review's recommendation that restrictions on the number of pharmacies owned by a pharmacist be removed.

Monitoring for Adverse Market Effects

In response to concerns raised by some stakeholders, the National Review (2000, p 56) recommended that

> *the effects of lifting the restrictions (on the number of pharmacies a pharmacist may own) be monitored to ensure that they do not lead to undue market dominance or other inappropriate market behaviour.*

The Working Group considered the potential for adverse effects to arise from the proposal to remove restrictions on pharmacy numbers. It noted that while it may be possible for 'isolated pockets of market domination' to develop, 'the potential for raising prices and making large profits is very limited' as various mechanisms exist to safeguard the community against the effects of market domination, such as:

- controls on drug prices exercised via the PBS;
- competition with other retailers on general merchandise; and
- competition from Internet and mail order pharmacies.

The Senior Officials Working Group (2002, pp 12-14) also noted that location restrictions contained in the current Australian Community Pharmacy Agreement

> *have the effect of slowing down movements by existing players so areas of market dominance are not likely to rapidly develop, if at all. Therefore, rather than introduce another layer of regulation to monitor the impact of freeing up restrictions on pharmacy numbers a better approach is to assess the impact of these reforms in discussions in the lead up to the next agreement between the Commonwealth and the Pharmacy Guild of Australia.*

Personal Supervision of a Pharmacy by a Pharmacist

The Senior Officials Working Group (2002, p 13) supported the National Review's recommendation that each pharmacy operate at all times with a registered pharmacist in attendance be accepted, noting that

> *the (National) Review's recognition that this rule ensures safe and competent pharmacy services raises the question of whether superimposing a rule requiring pharmacist ownership, let alone a further rule that limits the number of pharmacies owned, adds anything.*

Discussion

While the recommendation that restrictions on the number of pharmacies an individual can own be lifted is one of the National Review's more controversial recommendations, it is seen to offer potential benefits to both pharmacists and the public, by enabling pharmacists to take advantage of some of the same economies of scale enjoyed by friendly societies and other owners of multiple pharmacies.

Implementation of this recommendation would involve removing the restrictions contained in sections 21(2) and 21(3) of the current Act. The requirement for personal supervision by a pharmacist at all times the pharmacy or pharmacy department is open would be retained.

While some stakeholders have expressed concerns that this proposal may reduce the capacity of a pharmacist owner to ensure quality standards, retaining the requirement for a registered pharmacist to be in attendance at all times the pharmacy is open should ensure professional standards are not compromised.

It is also recognised that discussions regarding the Australian Community Pharmacy Agreement in 2004–2005 may provide further opportunities to re-examine distribution and ownership of pharmacies if necessary.

What Are Your Views?

- Are there other factors that should be taken into account in implementing this recommendation?

5.4 Restrictions Requiring Approval and Oversight of Pharmacy Premises

Current Restrictions

The current legislation contains a range of restrictions on the approval and oversight of pharmacy premises. Section 23 requires the Board to approve premises before a pharmacy or pharmacy department can open and section 24 sets out requirements for approval. Regulation 502 requires that the Board be satisfied that the premises are 'suitable, secure, hygienic and adequately equipped' while regulation 601 establishes a fee to be paid for approval of premises. Part 6 of the Guidelines and several appendices set out the Board's specifications and expectations of premises in considerable detail.

Section 27 prevents pharmacists practising in premises that are not approved by the Board and also prevents a person carrying on 'any form of business not approved by the Board' on an approved premises. In circumstances where a pharmacist wishes to practice away from an approved premise (for example, providing medication counselling services at a nursing home or a pharmacy depot), they must seek prior approval under section 27(1)(b) of the Act[38].

Section 19 of the Act provides that the Board's inspectors may enter pharmacies and examine their records to establish whether the Act and Regulations are being complied with[39].

In addition to these restrictions in pharmacy legislation, Drugs, Poisons and Controlled Substances legislation places detailed controls on how certain drugs are to be stored, relevant security requirements and records that are to be kept[40]. A failure to comply with the Act is an offence, and under s42 of the *Drugs, Poisons and Controlled Substances Act 1981*, authorised officers may enter premises without warrants to ensure the Act and its associated Regulations are being complied with.

Recommendations arising from the National Review

The National Review (2000, p 6) recommended that:

> *Requirements for the registration of pharmacy premises be removed provided that:*
>
> > *Acts, regulations and related guidelines can continue to require pharmacy proprietors and managers to ensure that their premises are of a minimum standard of fitness for the safe and competent delivery of pharmacy services;*

[38] This issue is considered in the context of access to rural pharmacy services in section 8.3 of this paper.
[39] The Board's powers to enter and inspect premises are discussed in Section 7.7.4 of this paper.
[40] Detailed requirements are prescribed in Part 2, Division 4 of the *Drugs, Poisons and Controlled Substances Regulations 1995*. Division 5 outlines requirements for record keeping.

The responsibilities of pharmacy proprietors and managers, and of registered pharmacists, under State and Territory drugs and poisons legislation are not compromised;

Acts or regulations may require the proprietor of a pharmacy to notify a regulatory authority, in writing, of the location or relocation of a pharmacy; and

Regulatory authorities, their employees or agents may enter and inspect pharmacy premises to investigate complaints, conduct spot checks, or act on the reasonable suspicion of guidelines being breached; and

Regulations requiring the registration of pharmacy businesses by regulatory authorities are removed, given that pharmacists are already registered in each State and Territory, and that business registration is not connected to the safe and competent practice of pharmacy.

In examining Victorian pharmacy legislation, the National Review (2000, pp 135–136) recommended that premises approval as a precondition of operating a pharmacy business be removed and replaced with simplified guidelines that concentrate 'solely on ensuring the safe and competent practice of pharmacy to a minimum standard, and (do) not unduly intrude into wide commercial considerations' be used to establish standards for pharmacy premises.

The COAG Senior Officials Working Group (2002, p 22) endorsed 'the principle of pharmacy boards focusing on professional practice and not commercial aspects of pharmacy', stating that 'in this context, the recommendation to limit obligations to register pharmacy premises and businesses is appropriate'. The Working Group (2002, p 23) also noted that Queensland and the Territories 'have no requirements for premises or business registration…(and that) there is no clear evidence that this lack of registration has affected pharmacy or pharmacist standards in those jurisdictions'.

The Working Group (2002, p 22) noted that this recommendation 'ventures into areas that overlap with the NCP Review of Drugs, Poisons and Controlled Substances currently underway[41]' and that jurisdictions may need to consider in detail 'the question of whether, and if so how, poisons laws would need to be adapted to ensure they adequately cover the field of safety matters currently addressed jointly by the poisons and pharmacy registration laws'. This issue is discussed further below.

Discussion

The current requirements for the Board to approve premises before they can operate as a pharmacy place impose quite extensive restrictions upon the owners of pharmacies. As the Senior Officials working group noted, some other jurisdictions do not impose such requirements on pharmacy owners via Pharmacy legislation, although similar controls regarding security, storage of scheduled drugs and record keeping are contained in their Drugs, Poisons and Controlled Substances legislation.

To implement the National Review's recommendations in relation to approval of premises, the Board's extensive powers to approve premises prior to opening and related provisions (such as those contained in s23, 24 and 27) would be removed, although various less restrictive mechanisms could be established if there was a demonstrated need. These might include:

- specific powers for the Board to issue guidelines regarding minimum acceptable standards for pharmacy premises, and/or
- establishment of an offence for a pharmacy owner whose premises do not meet minimum standards; and/or

[41] A National Competition Policy Review of Drugs, Poisons and Controlled Substances was commissioned by State, Territory and Commonwealth Governments in 1999. As the Senior Officials Working Group noted, Australia's obligations under relevant United Nations Conventions were addressed as part of this review. The Working Group also noted that these conventions do not require people who are authorised to perform therapeutic functions to be either licensed nor have their premises licensed.

- establishment of a negative licensing scheme, in which pharmacy owners who are found guilty of the above offence might be prohibited from owning or operating pharmacies. This could be a stand-alone scheme or could possibly be incorporated into the scheme for regulation of non-registered owners of pharmacy business discussed in section 7.9.

Powers for the Board to issue and publish codes for the guidance of registered pharmacists about standards recommended by the Board relating to the practice of pharmacy would be included in a new Act to regulate the practice of pharmacy, consistent with the Victorian model for health practitioner regulation.

For any of the additional mechanisms identified above to be established, it would be necessary to demonstrate that relying on controls within DPCS legislation, in combination with this power to issue guidelines, would not be adequate.

What Are Your Views?

- What are the risks associated with removing the requirement for the Board to approve pharmacy premises prior to their operation? Are the controls contained in *Drugs, Poisons and Controlled Substances* legislation sufficient to protect the public from such risks?
- If not, would the public be adequately protected by:
    - powers for the Board to issue guidelines or codes regarding minimum acceptable standards of pharmacy premises; and/or
    - establishment of an offence for the failure to ensure pharmacy premises meet minimum Board standards; and/or
    - a 'negative licensing' scheme in which owners of pharmacies whose premises do not meet minimum Board standards can be prevented from owning or operating pharmacies?

6 Other Restrictions on Competition

6.1 Advertising

Current Restrictions

Section 37(1)(e) of the *Pharmacists Act 1974* empowers the Governor in Council (the Governor of Victoria), on the recommendation of the Board, to make regulations with respect to advertising by pharmacists. Regulation 404 of the *Pharmacists Regulations 1992* prevents a pharmacist (or any other person) from advertising a pharmacy practice in a manner which:

a) is false, deceptive or misleading; or

b) contains a statement in respect of any drug, medicine or surgical appliance other than a statement that factually describes that product and its intended use and that the product is available at the pharmacy; or

c) directly or indirectly encourages the indiscriminate or unnecessary use of drugs or medicines.

The National Review of Pharmacy legislation did not examine restrictions on advertising in pharmacy legislation since related restrictions were being examined by the National DPCS Review (National Review 2000, p16). Therefore, these restrictions should be examined as part of the current Victorian review.

If pharmacy legislation is to contain restrictions on advertising, it must be demonstrated that such advertising poses a risk to the public and that reliance on existing legislation (such Fair Trading legislation) or other less restrictive approaches are not adequate to protect the public.

Other Restrictions on Advertising

In addition to the restrictions in the *Pharmacy Regulations 1982*, there are other legislative controls on the advertising of certain medicines contained in Victorian Drugs, Poisons and Controlled Substances legislation and the Commonwealth *Therapeutic Goods Regulations.* For example, regulation 6(1) states that a 'person must not publish an advertisement about goods for therapeutic use…that refers to goods included in Schedule 3, 4 or 8 to the Poisons Standard, except goods mentioned in Appendix H of the Standard'.

There are also a number of other avenues through which claims of false or misleading advertising can be pursued. For example:

- False and misleading advertising by pharmacists may be addressed under State and Commonwealth trade practices and fair trading legislation. Fines of up to $50,000 can be imposed under the *Fair Trading Act 1985*, significantly greater than those payable under Victorian health practitioner registration Acts.

- Pharmacy advertising which refers to testimonials that are false or misleading may be subject to the law of fraud and fair trading legislation.

Model Advertising Provisions in the *Medical Practice Act*

Regulation of advertising has been examined in detail as part of various Victorian health practitioner reviews, including the NCP review of the *Medical Practice Act 1994* (State Government of Victoria, 2001). That review examined the restrictions on advertising in detail. A summary of the arguments for and against the retention of advertising restrictions in health practitioner registration Acts is contained in Appendix 5.

The NCP review panel found that there was a net public benefit in retaining legislative restrictions on advertising in the *Medical Practice Act*, as a significant information asymmetry existed between practitioners and their patients:

> *reliance on consumer protection and fair trading laws to regulate advertising of medical services did not provide sufficient protection to the public and that there was a net public benefit in empowering the Medical Practitioners Board to regulate this activity of medical practice*
>
> (State Government of Victoria 2001, p4)

After extensive consultation, the NCP Panel recommended amendment to the advertising provisions in the *Medical Practice Act* to:

- remove the restriction on advertising that prevents practitioners from unfavourably contrasting the services of another practitioner[42];
- include a restriction on advertising that creates an unreasonable expectation of beneficial treatment; and
- retain restrictions on false and misleading advertising, offering gifts and discounts without setting out the conditions of the offer, and use of testimonials or purported testimonials.

It also recommended that the Medical Practitioners Board of Victoria be empowered to issue guidelines on what constituted acceptable advertising by medical practitioners 'in order to further clarify the provisions of the legislation.

The current advertising provisions in the Medical Practice Act should be considered the model for the current review of the Pharmacists Act. These provisions:

- Establish an offence for a person or body corporate to advertise a medical practice or medical services in a manner which:
    - is false or misleading;
    - offers a discount or other inducement without setting out the terms of that offer
    - refers to or uses testimonials; or
    - creates an unreasonable expectation of beneficial treatment.
- Empower the Medical Practitioners Board of Victoria to issue guidelines regarding the minimum acceptable standards for advertising of medical services.

A recent amendment to these provisions has inserted a role for the Minister for Health in approving advertising guidelines prepared by the Board prior to their publication in the Government Gazette.

In establishing these provisions, it is recognised that they should only apply to those aspects of a pharmacists activities directly related to his/her professional services. Retail services (such as the sale of cosmetics and photo processing) would be subject to the controls in *Fair Trading* and other legislation that apply to all retailers providing these services.

Discussion

The key question to be addressed is whether the standard provisions contained in the Medical Practice Act should be applied to the profession of pharmacy. There are a number of issues.

Regulation of advertising of medicines: Is there a need to retain the restriction on advertising of medicines which prevents use of statements other than those which factually

[42] On the grounds that this restriction primarily appeared to protect the profession rather than the public.

describe the product and its intended use and that the product is available at a particular pharmacy? What might be the impact of removing such a provision and relying on regulations in the *TG Act* and the DPCS Act to control this area?

Relevance to Pharmacy: As the nature of the pharmacist–patient relationship varies from the medical practitioner–patient relationship, should the two professions be subject to the same restrictions on advertising? Are the risks associated with advertising by pharmacists sufficient to justify specific restrictions in pharmacy legislation, or would the provisions of fair trading legislation and other existing mechanisms suffice? Are the model advertising provisions contained in the *Medical Practice Act* suitable and/or relevant to the profession of pharmacy?

Unprofessional conduct and the advertising offences: The model advertising provisions are designed to address false and misleading advertising, whether it is by a registered practitioner or a body corporate. False or misleading advertising by a registered practitioner may be considered to fit within the definition of unprofessional conduct. A number of boards have raised concerns that where a registered practitioner is alleged to have committed an offence relating to advertising, the Board has no option but to pursue the matter through the Magistrates Court, rather than by using its powers to regulate unprofessional conduct. The view is that dealing with these problems via powers to regulate unprofessional conduct is a more effective mechanism.

Concerns have also been expressed about whether the current penalty levels in the Act are sufficient, given the costs to a Board of issuing proceedings through the Magistrates Court.

What Are Your Views?

- Is it necessary to include restrictions on advertising in a new Act to regulate the profession of pharmacy? If so, is it necessary for pharmacy legislation to prohibit:
  - False and misleading advertising?
  - Offering gifts and discounts, without setting out terms of the offer?
  - Use of testimonials or purported testimonials?
  - Advertising that creates an unreasonable expectation of beneficial treatment?
  - Advertising of pharmaceuticals?
- What are the risks associated with removing current restrictions on advertising of medicines in a new pharmacists act, given the alternative controls available via the *TG Act* and the *DPCS Act?*
- If controls on advertising are retained in pharmacy legislation:
  - Would the model advertising provisions contained in the *Medical Practice Act* be suitable, or are there other issues unique to pharmacy that need to be taken into consideration?
  - Would it be more desirable for a registered pharmacist who breaches such controls to be subject to disciplinary proceedings, rather than be prosecuted in the Magistrates Court?
  - Are the current penalties associated with advertising offences in the Medical Practice Act sufficient, or should these be increased?
- Is it necessary to provide the Pharmacists Board with statutory power to formulate guidelines regarding minimum acceptable standards for advertising (similar to s64B of the *Medical Practice Act 1994*)?

6.2 Approval of Pharmacy Depots

A pharmacy depot is a secure drop-off point to which a pharmacist can send prescription medicines for collection by patients, thereby providing a mechanism by which pharmaceutical services can be provided to rural and remote communities.

Pharmacy depots are located in smaller rural centres that do not have stand-alone pharmacies. They provide a secure drop-off point to which prescription medicines can be sent for collection by patients, and in some instances, a pharmacist can also sell schedule 2 drugs from a pharmacy depot when he or she is not present.

Pharmacy depots enable people in rural and remote communities to receive prescription medicines, without having to travel to the closest pharmacy. Particularly in more remote parts of Victoria, the existence of a pharmacy depot can save considerable travel time and provide rural communities with more immediate access to certain medicines. Currently, there are 35 Board-approved pharmacy depots in operation in Victoria (Pharmacy Board, 2002B).

Current Restrictions in Pharmacy Legislation

The *Pharmacists Regulations 1982* (r503) require the written approval of the Pharmacy Board before a pharmacist may establish a pharmacy depot (r503) and also set criteria for management of the depot (r504). Part 6, Division 2 of the Board's Guidelines provide additional detail regarding criteria for approval of pharmacy depots, including:

- the information a pharmacist must provide when applying for approval, such as arrangements for the transmission of prescriptions, transportation and storage of medicines and arrangements for counselling of patients (guideline 635c);
- a requirement that the pharmacist provide a written set of procedures for the conduct of the depot (guideline 635d);
- a requirement that the pharmacist visit the depot at least every 2 months (guideline 635 f);
- requirements regarding which medications may be kept at a pharmacy depot under what circumstances (guideline 635g); and
- requirements for the supply of schedule 2 substances from a pharmacy depot (guideline 635h).

Discussion

The Board's requirements regarding approval of pharmacy depots effectively restrict the number and nature of depots that can be established in Victoria. While DPCS legislation places most of the controls over which scheduled medicines can be stored at depots, the Board's Guidelines place additional imposts upon pharmacists or non-pharmacists who wish to establish and maintain pharmacy depots in rural and regional Victoria.

As section 8.3 of this paper discusses in further detail, pharmacy depots provide obvious benefits to communities in rural and regional Victoria, particularly given the current workforce shortages and difficulties in recruiting and retaining qualified pharmacists in these regions.

The issue to be considered in the Victorian review is what is the minimum level of regulation of pharmacy depots required to achieve adequate protection of the public, taking into account the controls over the storage and supply of scheduled medicines that exist in DPCS legislation. To be consistent with the Victorian model of health practitioner registration, any powers to regulate pharmacy depots would be incorporated into the Act (rather than the regulations).

What Are Your Views?

- If professional pharmacy practice is regulated under the *Pharmacists Act* and storage and supply of scheduled medicines is regulated under DPCS legislation, what regulatory controls over pharmacy depots are required in an Act governing the registration of pharmacists? What factors should be considered in determining this?

- Under the Victorian model of health practitioner legislation, the Board would have powers to issue guidelines regarding standards of pharmacy practice. Does it need specific powers to issue guidelines regarding minimum acceptable standards for the operation of pharmacy depots?

PART C – OTHER REGULATORY ISSUES

7 Updating the Regulatory Framework

The current review will update Victorian pharmacy legislation to reflect the Victorian model of health practitioner regulation. At the same time, it is recognised that aspects of the pharmacy profession differ from other health professions and unique regulatory solutions may be required. This section provides an overview of the proposed model, highlighting a range of issues for consultation.

7.1 Purpose of Registration

The main purposes of the current Act are to set out the functions, powers and responsibilities of the Pharmacy Board of Victoria ('the Board') and regulate matters relating to the ownership of pharmacies and operation of pharmacies in Victoria (National Review 2000, p 131).

The new Act will make it clear that the primary purpose of registration is to protect the public by providing for the registration of pharmacists, investigations into the professional conduct, fitness to practise and professional performance of registered pharmacists. This is consistent with the recommendations of the National Review (2000, p 107).

7.2 Definitions

The definitions contained in the current *Pharmacists Act* will be revised to bring them up-to-date with the Victorian model, remove ambiguity and support implementation of NCP reforms. This is expected to include:

- Establishing definitions for 'pharmacy business', 'proprietary interest', 'professional indemnity insurance', 'registered pharmacist', 'friendly society' and 'unprofessional conduct[43]'.
- Revising definitions of 'pharmacy department', 'student' and 'trainee' as necessary, to reflect current legislation and training.
- Removing those definitions not considered essential for operation of a new Act.

7.3 The Pharmacy Board

7.3.1 Composition of the Board

Under the current Act, the Board is composed of 10 pharmacists, 5 of whom are appointed by the Minister for Health from panels nominated by pharmacy organisations and 5 who are elected by registered pharmacists. There is no capacity to appoint persons who are not pharmacists to the Board, nor is there a requirement for the Board to include a legally qualified member.

Independent, non-practitioner membership on statutory registration boards is considered to be important to ensure they 'broadly reflect a balance of community interests' (Health Department Victoria 1990, p 6) and remain focused on protection of the public. In the Victorian model, boards have between 7 and 12 members of whom 2 are lay persons, and 1 is legally qualified. The remainder are registered practitioners.

What Are Your Views?

- What would be a suitable size for the Board?

[43] The proposed definition of unprofessional conduct is discussed in detail in Section 7.7.1 of this paper.

7.3.2 Appointments to the Board

Under the proposed model, appointments to the Board will be made by the Governor in Council, on the recommendation of the Minister for Health, rather than by election or nomination by stakeholders[44]. The Act will not specify how the Minister selects candidates for recommendation. This structure is consistent with the recommendations of the National Review (2000, pp 137-138).

Terms of appointment will be set by Governor in Council, and will not exceed 3 years. Initial appointments to the new Board will be for 1, 2 or 3 years (depending upon the size of the Board) to allow reappointments to be staggered. A Board member may resign or may be removed by the Governor in Council.

7.3.3 Appointment of Office Bearers

The current Act empowers the Governor in Council to appoint the President of the Board upon election by Board members. Under the proposed model, the President and Deputy President of the Board will be nominated by the Minister and appointed by the Governor in Council.

All Victorian health practitioner registration Acts (with the exception of the *Chinese Medicine Registration Act 2000*) require that only registered practitioners be appointed to office bearing positions. It has, however, been suggested that enabling non-practitioner members to be appointed to these positions may help ensure the public interest is protected.

In most cases, practitioner members would be appointed to the office bearing positions. However, in some instances where a single Board regulates a number of different professions or segments of a profession or whether the smooth operation of a Board is at risk of being comprised by interpersonal or factional conflicts, it may be desirable for the Minister to have the flexibility to appoint non-practitioner members as office bearers.

What Are Your Views?

- What are the issues that should be considered in determining which Board members may be appointed President and Deputy President? Are there potential risks to the public associated with appointing non-practitioner members to positions of office?

7.3.4 Relationship between the Board and Government

The Board will be independent of Government but will be required to consult the Minister and take notice of his/her views. The Board must be incorporated so as to avoid any personal liability for Board members.

The Board will be self-funding, and will be responsible for setting its own fees, and meeting all its expenses. The Board may be empowered to issue guidelines, but will not have the power to make regulations[45]. This power rests with the Governor in Council.

7.3.5 Powers and Functions of the Board

As the National Review (2000, p 137) noted, the Board's functions under section 5 of the current Act

> *are wide in relation to the practice of pharmacy and the regulation of pharmacists in Victoria*…(and currently the Board)…*has the ability, and indeed the statutory responsibility, to oversee all aspects of professional education and training, practice, and professional development.*

[44] A Review of Registration for Health Practitioners conducted by Health Department of Victoria (1990, p 6) concluded that 'one of the fundamental principles to be observed is that membership rights do not accrue to particular groups, since Board are not intended to be representative bodies as such'. In this context, the review recommended that as the Boards 'fulfil an important role on behalf of the Minister for Health…the Minister should ensure that the Board contain a range of relevant expertise'.

[45] The Board's powers to issue guidelines are discussed in greater detail in section 7.10 of this paper.

Under the proposed model, the main powers of the Board will be:

- to register suitably qualified persons and/or persons meeting approved competency standards so that they may practise in Victoria;
- to investigate complaints about, and inquire into, the conduct, ability to practise and professional performance of persons registered under the act;
- to regulate the standards of practice of the profession in the public interest;
- to issue guidelines about appropriate standards of pharmacy practice; and
- to carry out such other functions as are vested in the Board by or under its Act.

What Are Your Views?

- Are these powers adequate to protect the public?
- Are there additional powers the Board requires to address issues unique to the practice of pharmacy?

7.4 Registration

7.4.1 Categories of Registration

Subject to mutual recognition principles, the Board will continue to have the power to register a pharmacist if the applicant:

- possesses or is entitled to receive an accredited qualification;
- has attained a recognised level of skill or competence;
- has passed a prescribed examination[46].

The Board would be empowered to refuse a grant of registration if:

- that the character of the applicant is such that it would not be in the public interest to allow the applicant to practise as a registered pharmacist;
- that the applicant is unfit to practise as a registered pharmacist because she or he is an alcoholic or drug-dependent person;
- that the applicant has been found guilty of an indictable offence in Victoria or an equivalent offence in another jurisdiction;
- that the applicant has been found guilty of an offence where the ability of the applicant to practise is likely to be affected because of the finding of guilt, or where it is not in the public interest to allow the applicant to practise because of the finding of guilt;
- that the applicant has previously been registered under the current Act or any corresponding previous enactment and during the course of that registration, had been subject to disciplinary proceedings and those proceedings have never been finalised;
- that, in the opinion of the Board, the applicant is unfit to be registered because she or he has a physical or mental impairment which significantly impairs her or his ability to practise as a registered pharmacist;
- that the applicant's competency in speaking or communicating in English is not sufficient for that person to practise as a registered pharmacist;
- that the applicant has previously held a right to practise as a pharmacist in another country, being the equivalent of registration as a pharmacist under the Act, and that

[46] Educational requirements for registration are discussed in Section 4.3.2 of this paper.

right has been cancelled or suspended and not restored because of conduct which, if committed within Victoria would entitle the Board to suspend or cancel registration;

- that, in the opinion of the Board, the pharmacist does not have adequate arrangements for professional indemnity insurance that meet the minimum terms and conditions set out in the guidelines of the Board.

The proposed model would also empower the Board to grant general, provisional, or specific registration, each of which may be subject to any condition, limitation or restriction the Board thinks fit. This would include powers for the Board to grant 'non-practising' registration to individuals who wish to remain on the register but will not be practising pharmacy within the registration period. Registration will continue to be on an annual basis.

7.4.2 Provision of Information

Under the proposed model, a registered pharmacist would be required to notify the Board within 30 days:

- information about the amount of damages or other compensation a court has ordered him/her to pay, arising from claims of professional negligence; and
- of any committal for trial, conviction or finding of guilt made against him or her in relation to an indictable offence.

Individuals applying for registration or renewal of registration would also be compelled to set out details of such matters in their application.

7.4.3 Student Registration

The Pharmacy Board of Victoria does not currently register pharmacy students or trainees, although section 12 of the Act (and Part 4 of the Regulations) give it significant power over where pharmacy trainees may undertake practical training and the scope of such training.

Under the recently amended *Medical Practice Act 1994*, the Medical Practitioners Board of Victoria registers medical students and establishes powers for the Board to sensitively manage medical students whose ability to have direct contact with the public may be affected by physical or mental impairment, drug or alcohol dependence or other incapacity.

What Are Your Views?

- Is it necessary to register pharmacy students who have clinical contact with patients, or are there less restrictive mechanisms that would ensure adequate protection of the public?

7.5 Professional Indemnity Insurance

The Commonwealth Department of Human Services and Health (1995) and the Victorian Law Reform Committee (1997) conducted reviews of the legal liability of health services providers. Both reviews strongly advocated that adequate professional indemnity insurance (PII) be held by all health practitioners, on the grounds that this offered significant benefits to the community.

Several Victorian health practitioner registration Acts have been amended to incorporate such provisions and under the proposed model, the Pharmacy Board will:

- be empowered to issue guidelines about the minimum terms and conditions of professional indemnity insurance for registered pharmacists;
- have the discretion to refuse to grant or renew registration on the grounds that a pharmacist, in the opinion of the Board, does not have adequate arrangements for

professional indemnity insurance that meet the minimum terms and conditions set out in the guidelines of the Board; and

- be empowered to grant registration subject to the condition that the pharmacist has professional indemnity insurance that meets the minimum terms and conditions set out in the Board's guidelines.

7.6 Disciplinary and Hearings Functions

The proposed model for the investigation of complaints will formalise procedures relating to the conduct of investigations and hearings, replace the term 'complaint' with 'notification', provide a broader range of determinations and findings and establish alternative mechanisms for managing impaired pharmacists and poorly performing pharmacists.

The model to be adopted is that set out in the *Medical Practice Act 1994,* incorporating the amendments contained in the *Health Practitioner Acts (Further Amendments) Act 2002*. Interested parties are encouraged to examine both Acts for further details.

7.6.1 Definition of 'Unprofessional Conduct'

Section 18 of the current *Pharmacists Act 1974* creates the power for the Board to inquire into and punish 'discreditable conduct'.

Under the Victorian model, a standard definition of 'unprofessional conduct' will replace the current 'discreditable conduct'. The definition contained in the *Medical Practice Act 1994* (as amended by the *Health Practitioner Acts (Further Amendments) Act 2002*) includes:

- professional conduct which is of a lesser standard than that which the public might reasonably expect of a registered practitioner; or
- professional conduct which is of a lesser standard than that which might reasonably be expected of a practitioner by her or his peers; or
- professional misconduct; or
- infamous conduct in a professional respect; or
- providing a person with health services of a kind that is excessive, unnecessary or not reasonably required for that person's well-being; or
- influencing or attempting to influence the conduct of a registered practitioner's practice in such a way that patient care may be compromised; or
- the failure to act as a registered practitioner when required under an Act or regulations to do so; or
- a finding of guilt of--
    - an indictable offence in Victoria, or an equivalent offence in another jurisdiction; or
    - an offence where the practitioner's ability to continue to practise is likely to be affected because of the finding of guilt or where it is not in the public interest to allow the practitioner to continue to practise because of the finding of guilt; or
    - an offence under this Act or the regulations; or
    - an offence as a medical practitioner under any other Act or regulations; or
- the contravention of, or failure to comply with a condition, limitation or restriction on the registration of the registered practitioner imposed by or under this Act; or
- the breach of an agreement made under relevant sections of the Act between a registered practitioner and the Board; or
- unsatisfactory professional performance.

7.6.2 Investigation of Notifications

The Board will be required to investigate all notifications that are not vexatious or frivolous and are not investigated by the Health Services Commissioner (HSC).

The Act will formalise the relationship between the Board and the HSC under the *Health Services (Conciliation & Review) Act 1987* including:

- requiring the Board to forward a copy of the notification to the HSC prior to dealing with it;
- if the notification is suitable for conciliation the HSC will deal with it;
- if the notification is not suitable for conciliation or is referred back, the Board will deal with it.

It will also contain relevant provisions for the management of notifications regarding pharmacists made in relation to the *Health Records Act 2001.*

Investigations will be undertaken by the Board, or delegated in writing to an officer of the Board, a legal practitioner or investigator retained by the Board and/or a subcommittee of no more than 3 members of the Board. If the investigator is a Board member that member must not later sit as a hearing panel member.

The Board will have the power to investigate the:

- capacity of person to carry out the functions of a pharmacist ('fitness to practise');
- professional conduct of a pharmacist; and
- professional performance of a pharmacist.

7.6.3 Formal and Informal Hearings

For informal hearings:

- a panel of up to 3 persons[47] may be appointed;
- there is no entitlement to representation, but the practitioner may be accompanied by an adviser;
- it is closed to the public;
- the practitioner who is the subject of the complaint may seek review of the panel's decision by a formal hearing panel.

At a formal hearing:

- there is a panel of up to 5 persons of which one must be a lawyer[48];
- there is an entitlement to legal representation;
- the panel has all the power of a board of inquiry under the *Evidence Act*;
- it is open to the public but there is a power to embargo all or part of the hearing;
- there is statutory power for a pre-hearing conference to be convened; and
- the avenue of appeal is to the Victorian Civil and Administrative Tribunal (VCAT).

A decision of a hearing panel is a decision of the Board.

7.6.4 Warrant Provisions

Most Victorian health practitioner registration acts contain common warrant provisions, outlined in Appendix 6.

[47] These will typically be Board members, but there will also be the capacity to appoint non-Board members who are pre-approved by Governor in Council for this purpose (similar to s38 of the *Chinese Medicine Registration Act 2000*).
[48] These will typically be Board members, but there will also be the capacity to appoint non-Board members who are pre-approved by Governor in Council for this purpose (similar to s45 of the *Chinese Medicine Registration Act 2000*).

The current *Pharmacists Act* has no equivalent provisions to these, however, it does have powers to enter and inspect premises:

- Section 19(1) establishes powers for an inspector of the Board to enter at any reasonable time any pharmacy or other place where medicines are sold or dispensed and amongst other matters make or cause to be made copies of or extracts from books, records or other documents therein.
- Section 19(2) states that those copies/extracts may be certified by the inspector to be true and correct copies or extracts for the purposes of inquiries under the Act or appeals arising from those inquiries.
- Section 20 establishes powers for the Board to examine and make copies of books, records or other documents kept by a pharmacist in connection with the conduct of a pharmacy practice.
- Section 19(3) establishes offences for failure to cooperate with these activities.

These provisions are effectively complemented by powers of search and entry contained within the *Drugs, Poisons and Controlled Substances Act 1981.* Under s42 of that Act, an officer authorised under that Act may, 'for the purpose of ascertaining whether the provisions of (the) Act and the regulations are being complied with' may, at any reasonable time, enter and examine any premises occupied by a pharmacist or other person authorised to possess scheduled medicines.

Given that pharmacists are responsible for the safe custody of large quantities of controlled substances, the Pharmacy Board (2001B) believes that it must retain its current powers if the public is to be adequately protected. If provisions outlined in Appendix 3 were applied to the Pharmacists Act, the Board's inspection activities would move from proactive inspections of pharmacies (unannounced) to more reactive inspections, where the cooperation of the pharmacist or a search warrant would be required.

The question to be considered is whether the harms associated with pharmacy practice (and in particular, the storage, labelling and dispensing of scheduled medicines) are sufficient to justify retention the Board's current powers of entry and inspection, or whether limited inspection powers for the Board (i.e. entry with cooperation of pharmacist or a search warrant) in combination with the existing inspectorial powers in the *DPCS Act* would be adequate.

While not considered in detail, the National Review (2000, p 136) stated that the Board's ability to conduct compliance inspections of premises and pharmacy records in accordance with section 19 of the current Act could be justified in the public interest. Similarly, the recent Victorian Law Reform Committee Inquiry (2002, p 246), while emphasising that it did not wish to influence the outcome of this current review, cited pharmacy legislation as:

> *a potential example of a case where the desirability of consistency among inspectors' powers gives way to other considerations such as the need to protect against what can be serious threats to public health and safety.*

What Are Your Views?

- What issues should be considered in determining what powers of entry and inspection are necessary in pharmacy legislation to protect the public?
- What are the risks associated with removing the Board's current powers to enter and search premises without a warrant? Would the model provisions outlined in Appendix 3 ensure, in combination with existing powers of inspection contained in DPCS legislation, adequately protect the public?
- Are there alternative methods to regular and routine Board inspections for maintaining standards of pharmacy care, such as self-assessment or other existing standards?

7.6.5 Power to Conduct Disciplinary Hearings for Practitioners Who Have Let Their Registration Lapse

Under the current Act, the Board cannot conduct an inquiry or impose sanctions on a pharmacist who has ceased to be registered. Under the proposed model, it will be possible for:

- a person to make a notification to the Board about the conduct of a person while practising as a registered pharmacist, regardless of whether the person is still registered at the time the notification is lodged; and
- the Board to continue an investigation or hearing into such a notification and make a finding or determination, even if the person is no longer registered.

7.6.6 Sanctions

Under the proposed model, a hearing panel will have the power to make various determinations, according to the type of hearing.

Where an **informal hearing** is conducted, the panel may make one or more of the following determinations:

- Require the practitioner to undertake counselling.
- Require that the practitioner undertake further education of the kind stated in the determination and to have completed it within the period specified in the determination.
- Caution the practitioner.
- Reprimand the practitioner.

Where a **formal hearing** is conducted, the panel may make one or more of the following determinations:

- Require the practitioner to undergo counselling.
- Caution the practitioner.
- Reprimand the practitioner.
- Require the practitioner to undertake further education of the kind stated in the determination and to complete it within the period specified in the determination.
- Impose conditions, limitations or restrictions on the registration of the practitioner.
- Impose a fine.
- Suspend registration for the period specified in the determination.
- Cancel registration.
- Where registration is cancelled, set a period of time in which the practitioner cannot apply for registration.

7.6.7 Recovering Costs

Under section 18(e)(ii) of the current Act, the Board may require a pharmacist who is the subject of an adverse finding to pay the 'costs of and incidental to the inquiry by the Board'.

Power to recover costs from registrants who are subject to disciplinary proceedings has not formed part of the Victorian model. Currently, all other health practitioner registration Boards must meet the costs associated with conduct of their disciplinary and hearings functions, via registration fees.

Discussion

In the period 1996–2001, the Board has recouped almost 90 per cent of costs incurred in the conduct of inquiries via its powers under section 18 of the Act[49]. The Board's view is that the power to recover costs in this manner enables it to fulfil its role in protecting the public in a cost-effective manner. In the absence of this power, the costs associated with the Board's disciplinary functions would be borne by all registered pharmacists (via registration fees), rather than the small minority who are the subject of such proceedings.

This is considered by some to be inequitable and increases the cost of pharmacy services to the public. The National Review (2000, pp 142-143) supported powers for the Board to recover costs from a 'party found at fault' on the grounds that it might act as both a penalty and a deterrent. It considered such powers to be justifiable in the public interest.

These considerations must be balanced against the need to ensure the Board's decision making processes remain independent and are not compromised by financial considerations. For example, the Victorian Review of the *Dentists Act 1972* and *Dental Technicians Act 1972* concluded that the Board should not be able to recover the costs of hearings from guilty providers as it would be 'inappropriate for the Board to have a financial incentive to penalise providers' (Department of Human Services 1998A, p 33).

What Are Your Views?

- Should the Board retain its power to recover costs from practitioners, where they are found to have engaged in unprofessional conduct of a serious nature?
- What issues should be considered in determining whether this is an appropriate power for the Board?

7.6.8 Notice of Determinations

Under the proposed model, the Board will be required to advise the person who lodged the notification:

- of whether a hearing is to be conducted and details of this;
- if a hearing is to be held and if so, whether that person has a right to make submissions; and
- the findings and determinations of any hearing arising from a notification and the reasons for these.

In addition, if a determination is made by a panel to impose conditions, limitations or restrictions, or to suspend or cancel the registration of a pharmacist, it is proposed that the Board be required to give notice of this determination:

- in the Government Gazette;
- to other medical registration authorities in Australia and New Zealand;
- to the Health Services Commissioner;
- if the pharmacist is an employee, to his/her employer;
- any Commonwealth body responsible for the funding of pharmaceuticals;
- any national body with responsibility for accreditation of pharmacists;
- to any pharmacist registration authority outside Australia, if that body requests information regarding the pharmacist in question.

[49] Source: Pharmacy Board of Victoria, October 2001

What Are Your Views?

- Are there other individuals or organisations that the Board should have a statutory obligation to inform?
- Is there other information you believe the Board should have a statutory obligation to provide? To whom do you believe this information should be provided?

7.6.9 Impaired Practitioners

Within the current Act, there is no mechanism for alternative management of impaired practitioners, outside the formal disciplinary pathway.

Under the proposed model, an alternative mechanism that focuses upon remediation rather than pure disciplinary sanctions will be established to deal with pharmacists whose ability to practise is affected by physical or mental impairment.

7.6.10 Appeal from Board Decisions

Under the proposed model, appeals from certain Board decisions will be to the Victorian Civil and Administrative Appeals Tribunal (VCAT) rather than directly to the Supreme Court of Victoria. This is designed to streamline the process of review and reduce the costs associated with such actions.

A right of appeal would be established for persons whose interests are affected by a Board decision, finding or determination where this involves:

- refusal of registration, endorsement, or renewal of registration;
- suspension of registration;
- conditions, limitations or restrictions placed on registration; and
- a finding or determination made at a formal hearing.

The *Victorian Civil and Administrative Appeals Tribunal Act 1998* provides for appeal to the Supreme Court from decisions of VCAT, in certain circumstances.

7.7 Continuing Competence and Regulation of Poorly Performing Practitioners

One of the primary roles of health practitioner registration boards is to ensure that registered practitioners are competent to practise their respective professions.

Within the current Act, the Board's assessment of competence is based on the initial registration criteria, the operation of the complaints and disciplinary system and each practitioner's professional obligations to maintain his/her skills.

In addition, regulation 306 sets out a process by which the Pharmacy Board may require a qualified pharmacist, who has not practised as a pharmacist for a period in excess of 2 years, to undergo a retraining program to satisfy the Board that the pharmacist is competent to practice pharmacy. Part 3 of the Guidelines provides further detail regarding requirements for pharmacists seeking restoration to the register.

While pharmacists who have not practised for over two years may be required to undertake prescribed training prior to restoration to the register, there is no formal mechanism for ensuring ongoing competency of those pharmacists in continuous practice.

Discussion

The National Review (2000, pp 112–114) briefly examined the issue of whether renewal of registration should be linked to a requirement to demonstrate competence to practise and concluded that:

> *Existing re-registration requirements for pharmacists re-entering the profession following a period out of practice (should be) retained; and*
>
> *Regulations enabling regulatory authorities to impose conditional registration, or supervised or restricted practice prior to re-registration, for pharmacists returning to practice or constricted in their abilities to practice, (should be) retained.*

In addition, the National Review (2000, p 18) recommended that

> *within three to five years, States and Territories should implement competency-based mechanisms as part of re-registration processes for all registered pharmacists.*

In Victoria, it is accepted that registration should provide the public with an assurance that practitioners who are registered are safe and competent to practise. A recent review of the *Medical Practice Act 1994* examined a much broader range of options for linking registration and professional competence than those considered by the National Review. These are summarised in Appendix 7.

Taking into account a broad range of factors (including stakeholder views), statutory requirements for medical practitioners to provide evidence of recency of practise and/or participation in professional education upon application for renewal of registration were not introduced. Instead, a more flexible scheme was established via the *Health Practitioner Acts (Further Amendment) Act 2002* ('the *HPAFA Act'*).

The *HPAFA Act* extended the Medical Practitioners Board's powers to deal with poorly performing medical practitioners by allowing that Board to actively conduct performance assessments and reviews and impose conditions on practice in relation to a practitioner's professional performance. These reforms[50] empower the Medical Practitioners Board to:

- receive a notification of poor performance concerning a registered medical practitioner, conduct a performance assessment and/or performance review[51], and where necessary, impose educational requirements or other conditions on the practitioner's registration;
- initiate a performance assessment of a practitioner on its own motion;
- provide a 'non-practising' form of registration; and
- on application for registration, restoration and/or renewal of registration, require practitioners to provide additional information regarding clinical activities and participation in Continuing Professional Development (CPD).

It is proposed to introduce similar powers into an Act governing Victorian pharmacists. These amendments will enable the Board to track a practitioner's participation in CPD in relation to their areas of professional activity, and to initiate a performance assessment if the Board is of the view that their lack of clinical experience and/or discipline specific education may place them at higher risk of poor professional performance.

[50] Yet to be proclaimed.

[51] A *performance assessment* is an informal assessment of a practitioner's professional performance. It aims to identify issues of concern and seek practitioner agreement on any reasonable actions required to address these. A *performance review* is a more detailed, formal process conducted by two or more persons, following which the Board may decide to impose conditions, limitations or restrictions on a practitioner's registration.

What Are Your Views?

- Is there a net public benefit in establishing powers for the Board to regulate poorly performing pharmacists, or are there other less restrictive means of protecting the public interest?
- What 'triggers' (e.g. non-participation in CPD, lack of recent practise) might prompt the Board to initiate a performance assessment of its own motion?
- Should the Board have powers to issue guidelines outlining its requirements for CPD?
- If powers were established for the Pharmacy Board to regulate poorly performing pharmacists (including powers to initiate performance assessments and/or reviews on its own motion):
    - Would it be necessary to retain current requirements for re-entry to practice?
    - What are the risks associated with removing such requirements from statute and relying upon the powers to assess professional performance?
    - If such restrictions were retained, would provisions similar to those in s14 of the *Nurses Act 1993* be appropriate?
- Should there be a statutory obligation for a practitioner to advise the Board if they intend to resume pharmacy practice after a period out of practise? If so, what should this period be and should it be contained in the legislation or in a Board guideline?

7.8 Disciplinary Actions against Non-Pharmacist Owners

Overview

Under the current Act, the Board can only inquire into the conduct of registered pharmacists, and does not have power to impose sanctions against non-pharmacist owners or managers of pharmacies or pharmacy departments who direct or incite registered pharmacists to engage in discreditable conduct.

A range of stakeholders across a number of professions have identified this as an area of concern. For example, the review of the *Dentists Act 1972* and the *Dental Technicians Act 1972* examined mechanisms for addressing concerns about inappropriate influence of non-registered owners over dental care and concluded that 'it should be an offence for an employer to unduly influence an employee to perform dentistry in a manner detrimental to the welfare of the consumer' (Department of Human Services 1998A, p 18). Section 65 of the *Dental Practice Act 1999* establishes this offence.

Regulation of corporate owners of medical practices was also recently been explored in the Department's discussion paper *Regulation of Medical Practitioners and Nurses in Victoria* (Department of Human Services, 2001, pp 13-23). A range of options were examined, including reliance on existing mechanisms such as civil and criminal remedies for fraudulent activity by individuals who conduct a business[52]. A summary of the options considered is contained in Appendix 8.

The review concluded that the Board required stronger powers to regulate 'employers' who direct or incite medical practitioners to engage in unprofessional conduct and subsequent reforms to the *Medical Practice Act 1994* were contained in the *Health Practitioner Acts (Further Amendments) Act 2002* ('*the HPAFA Act*'). These amendments:

[52] These include the Commonwealth *Crimes Act 1914* and the *Criminal Code (CW) 1995* (which address fraudulent conduct) and the Victorian *Fair Trading Act 1985* and the *Therapeutic Goods Act 1958* (both of which make provision for false and misleading advertising).

- Established an offence for 'employers' to direct or incite registered medical practitioners to engage in unprofessional conduct.
- Extended the definition of 'employer' for the purposes of these offences to include all directors, secretary or executive officer as defined in *Corporations Law*.
- Empowered the Secretary of the Department to prohibit those found guilty of such offences from providing medical services, or attach conditions to their service provision.
- Established an offence for breach of such prohibition or conditions.
- Exempted organisations such as public and private hospitals where such powers exist in other Acts[53].

The *HPAFA Act* establishes a similar scheme for nurses' agents who direct or incite registered nurses to engage in unprofessional conduct and should it be demonstrated that existing mechanisms for regulating non-registered owners of pharmacies are not sufficient, a similar scheme could be incorporated into pharmacy legislation.

The National Competition Review of Pharmacy Legislation (2000, p 135) recommended that existing provisions in section 21 and 22 of the Pharmacists Act that address pecuniary interests in pharmacy be removed and replaced by a scheme that allows action to be taken when a non-registered pharmacy owner directs or incites a pharmacist to engage in unprofessional conduct. It is proposed that a scheme similar to that outlined above be established to implement this recommendation, however opinions are sought regarding the perceived problems in this area and whether the negative licensing scheme proposed is considered adequate to address these.

What Are Your Views?

- What evidence is available to indicate that non-pharmacist owners are pressuring their employee pharmacists to engage in unprofessional conduct?
- What deficiencies exist, if any, in the current regulatory and self-regulatory frameworks that govern the provision of safe and ethical pharmacy services by corporations?
- Would a negative licensing scheme (similar to that established in the *Medical Practice Act 1994*) provide an adequate regulatory solution?
- Should there be differential penalties for bodies corporate for such offences?

7.9 Powers to Make Regulations and Issue Guidelines

Section 37 of the current Act empowers the Governor in Council, on the recommendation of the Board, to make regulations in relation to a wide range of matters. The *Pharmacists Regulations 1992* contain sections relating to applications for registration, pharmaceutical education and training, standards of pharmacy practice (including advertising by pharmacists), approval of pharmacy premises and pharmacy depots, elections to the Pharmacy Board and fees payable to the Board. The current review will examine which aspects of the current regulations are necessary in new pharmacy legislation, and whether they would be more appropriately placed in the Act or the Regulations.

In addition, the Pharmacy Board issues its *Guidelines for Good Pharmaceutical Practice* on an annual basis. The guidelines contain detailed information regarding diverse aspects of pharmacy practice and premises. In addition to those already considered in previous sections of this paper, the Board's guidelines contain restrictions on a broad range of issues including:

- Control of access to pharmacy (guidelines 411-413).

[53] These provisions are contained in section 30 of the *Health Practitioners Act (Further Amendments) Act 2002.*

- Dispensing issues, including labelling, use of purified water, resale of dispensed medicines, dose administration containers and dispensing scales (guidelines 421-469).
- The reference texts a pharmacist must possess, including requirements that these be the current editions (guidelines 493).
- Restrictions on a pharmacist practising 'any form of alterative therapy' while practising as a pharmacist in approved premises, except in certain circumstances (guidelines 494).
- Specifications regarding signage (guidelines 496-498).
- Design of pharmacy premises, including guidelines on temperature, humidity, access, security requirements and a statement that the Board will not approve premises for use as a pharmacy if it contains a solarium (guideline 616).
- Pregnancy and other pathology testing by pharmacists (guideline 702).
- Relationships between pharmacists and service companies (guideline 704).

In their current form, the Board's guidelines appear to contain a broad range of restrictions on how registered pharmacists can practice or conduct their businesses. While the guidelines are not legislative instruments, they are often couched in terms which make them appear to be quasi-regulations—the term 'must' is used throughout.

The current review will examine the need for and appropriateness of guidelines for applying restrictions, what aspects of pharmacy practice the guidelines should address and whether some parts of the current guidelines should be included in a new pharmacists Act or Regulations.

Discussion

Pharmacy Board representatives have advised that the Guidelines were developed at a time when few other professional standards for pharmacy had been published. As a result, they provide detail on a broad range of issues not directly related to the Act and Regulations. Over time, organisations such as the Pharmacy Guild and the Pharmaceutical Society of Australia have released a broad range of professional standards and/or guidelines. Thus, it is timely to consider what information Board Guidelines should contain.

Under the proposed model, the Act will contain any provision considered to be integral to the operation of the regulatory scheme and the use of regulations will largely be restricted to prescribing fees and other machinery provisions. The Board would be empowered to issue and publish codes for the guidance of registered pharmacists about standards recommended by the Board relating to the practice of pharmacy. As discussed in previous sections, the Board might also be empowered to issue specific guidelines regarding:

- minimum terms and conditions of professional indemnity insurance for registered pharmacists; and/or
- minimum acceptable standards for advertising of pharmacy services; and/or
- minimum acceptable standards for pharmacy premises.

This more minimalist approach would be consistent with the National Review's recommendation (2000, p 107) that

> *Pharmacy Acts, 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.*

It is however recognised that the additional information contained in current Board guidelines may be helpful to pharmacists. One option would be to split the Board's current publication into two sections, one containing Board guidelines issued under the provisions of the Act to interpret

the Acts and Regulations, the other providing additional information that may be useful to registered pharmacists.

The National Review (2000, p106) also proposed a role for Government in approving Board guidelines prior to their publication, recommending that

> *Pharmacy Acts 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.*

To achieve this objective, the National Review (2000, pp 106- 107) suggested that

> *any standards that regulatory authorities, professional bodies or consumer organisations proposed as necessary therefore should not have force until they are ratified by government action….(as a means of) ensuring that governments act on a broad range of advice, and that regulatory authorities do not have a monopoly on providing it.*

Implementation of this recommendation might involve a legislative requirement for Board guidelines to be approved by the Minister prior to public release and/or publication.

What Are Your Views?

- Many aspects of the Regulations have been examined in earlier sections of this paper. Are there any other restrictions in the *Pharmacists Regulations 1992* that you believe should be retained in legislation?
    - What are the risks associated with removing these restrictions?
    - Are there alternative, less restrictive approaches that could be adopted to protect the public from these risks?
- The Board's guidelines contain many restrictions. Some of these have been considered in earlier sections of this paper. Are there other restrictions that you believe should be retained?
    - What are the risks associated with adopting a more minimalist approach?
    - Are there guidelines that you believe should be included in the Act or Regulations?
- The Board's guidelines are very detailed. Is it necessary to retain this level of detail in the guidelines, or would a less prescriptive approach provide greater flexibility?
- Would there be merit in clarifying which guidelines relate to the Board's statutory powers and which are provided for general information?
- Under the Victorian model, the Minister for Health would be required to endorse advertising guidelines prior to their publication in the Government Gazette. Do you believe government should have a role in approving other Board guidelines prior to public release?

8 Evolving Issues

In addition to meeting the State's NCP obligations and updating pharmacy legislation to achieve consistency with the Victorian model for health practitioner registration, this review provides an opportunity for interested parties to make comment on evolving issues directly related to the pharmacy profession. This section highlights three issues, for consideration:

- Regulation of dispensary assistants.
- Proposals for a national registration scheme.
- Access to rural and remote pharmacy services.

8.1 Regulation of Dispensary Assistants

Background

The Pharmacy Board's *Guidelines for Good Pharmacy Practice* (2002A, p 35) define a dispensary assistant[54] as:

> *a person who assists a pharmacist in the dispensing area of a pharmacy or Friendly Society pharmacy or in any area where a pharmacist is approved to practice under s27 (1)(b) of the Act, or in a hospital pharmacy department, but who is not a pharmacist, a pre-registrant or a pharmacy student.*

The current Act and regulations do not provide express powers for the Board to regulate dispensary assistants, however the Board's Guidelines (2002A, pp 35- 37):

- Set out the responsibilities of the pharmacist in charge in relation to the activities of dispensary assistances (guidelines 482, 483).
- State that pharmacists may only employ persons as dispensary assistants if they have completed a training course approved by the Board, or are enrolled in such a course and set out guidelines for approval of such courses (guidelines 483, 484A, 484B).
- Set out the duties of dispensary assistants (guidelines 485, 486).
- Detail the records that a pharmacist in charge must maintain in relation to dispensary assistants, which set out names, training and responsibilities of each assistant (guidelines 487, 488).

In addition, other controls exist in relation to the activities of dispensary assistants, including:

- The requirement that a pharmacist be present at all times and provide ongoing supervision of the assistant's activities[55].
- Statutory controls within the *Drugs, Poisons and Controlled Substances Act 1981* that restrict access to medications to certain authorised persons.
- Other policies and procedures promulgated by peak bodies, such as the standards contained within the Pharmacy Guild's Quality Care framework.

[54] For the purposes of this discussion, this includes hospital pharmacy technicians.
[55] Given the recommendations that there continue to be a statutory requirement for a pharmacist to be in attendance at all times (see pp 25-26 of this paper), it is expected that this will remain unchanged.

Discussion

The Pharmacy Board of Victoria believes that the activities of dispensary assistants should be regulated to ensure adequate protection of the public, given that these persons have access to controlled substances and also interact with the public. In particular, the Board believes it is necessary to set minimum training standards for dispensary assistants, to ensure only suitably qualified persons undertake these roles.

If a need for restrictions on the activities of dispensary assistants can be demonstrated, a range of alternative approaches might be considered, including:

- Self regulation, via voluntary codes of conduct and practice.
- Statutory powers for the Board to issue guidelines for pharmacists regarding minimum acceptable standards of training for dispensary assistants (similar to the current guidelines).
- A negative licensing scheme, to prevent dispensary assistants who are found to have contravened pharmacy or drugs, poisons and controlled substances legislation from performing such roles.
- Statutory registration of dispensary assistants via legislation registering pharmacists, or statutory registration of dispensary assistants via other legislation.

The appropriate regulatory response will depend upon the potential risks associated with the activities undertaken by dispensary assistants.

Should there be adequate evidence to suggest statutory registration of dispensary assistants could be justified, a submission addressing the AHMAC criteria for assessment of regulatory requirements for unregulated health occupations would need to be made to the Victorian Government for consideration. Appendix 9 provides further detail on these criteria and the process for seeking statutory registration.

What Are Your Views?

- What are the potential risks to the public associated with the activities of dispensary assistants?
- The review seeks comments on the need for and appropriateness of the current restrictions on dispensary assistants contained in the Pharmacy Board's Guidelines. Should they be removed, retained or strengthened?
- If restrictions on the activities of dispensary assistants are retained, should they be included in the Act or in Board guidelines?

8.2 National Registration

Despite significant harmonisation of regulatory requirements for the registered professions over the past 10 years, limitations with the current system of mutual recognition of health professions remain (Department of Human Services 2002, p 42).

Various bodies have issued discussion papers recently on how these issues might be addressed for the medical profession, including the Australian Medical Council (2001) and the Australian Council for Safety and Quality in Health Care (2001B). The Department for Human Services also canvassed stakeholder views regarding national registration in its August 2001 Discussion Paper, *Regulation of Medical Practitioners and Nurses in Victoria* and more recently, an AHMAC

Working Group has released a discussion paper examining models for a nationally consistent approach to medical registration (Commonwealth Department of Health and Ageing 2002B) [56].

Many of the issues regarding a national system of registration for medical practitioners are also common to pharmacy, and should a suitable model for increasing consistency of medical registration be agreed via the current AHMAC process, it may be appropriate to consider whether a similar approach could be applied to registration systems for pharmacists.

The benefits of adopting a national approach to registration of pharmacists were highlighted by the National Review (2000, p 117), which recommended that,

> *in the interests of promoting occupational and commercial mobility, the Commonwealth, States 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.*

The Pharmacy Board has indicated its support for establishment of consistent legislative provisions, and has noted that the Council of Pharmacy Registering Authorities (COPRA) may provide a vehicle for promoting consistency across all jurisdictions.

What Are Your Views?

While the establishment of a national scheme for registration of pharmacists may be beyond the scope of the current review, the review seeks views on whether interested parties believe there would be a net public benefit in developing nationally consistent legislation for the registration of pharmacists.

8.3 Rural and Remote Pharmacy

The provision of pharmaceutical services is subject to heavy regulation via a range of State and Commonwealth legislation. Such controls exist to protect the public and ensure high standards of professional practice, but in some instances, they may also have the unintended effect of contributing to reduced access to pharmacy services in rural and remote areas. This section examines some of the current difficulties identified by rural and remote pharmacy stakeholders and proposes a range of strategies that could be considered to improve access to pharmacy services in these areas.

8.3.1 Background

In many areas of rural and regional Victoria, access to pharmaceutical products and services at a local area level is limited or non-existent. Workforce shortages and difficulties recruiting pharmacists to rural and regional areas have reduced the number of pharmacists working in community and hospital settings[57], and smaller and more remote communities often lack a local pharmacy, although some may have a pharmacy depot[58].

Pharmacy depots and regional health services such as bush nursing services provide some access to prescription medications for rural and regional Victorians, but there is usually no pharmacist on site and the range of medications available and circumstances under which they can be supplied is quite limited, due to current restrictions within the *Pharmacists Act, Drugs,*

[56] Copies of this discussion paper are available through the Commonwealth Department of Health and Ageing website at www.health.gov.au/workforce

[57] As discussed in section 3.1.3 of this paper

[58] As discussed in section 6.2 of this paper, a pharmacy depot is a secure drop off point to which a pharmacist can send prescription medicines for collection by patients, thereby providing a mechanism by which prescription medicines can be provided to rural and remote communities.

Poisons and Controlled Substances (DPCS) legislation and funding and location restrictions exercised via the Pharmaceutical Benefits Scheme (PBS).

8.3.2 The Rural Pharmaceutical Pilot Project

The Department of Human Services ('the Department') recognises the importance of ensuring adequate access to medicines for rural and regional communities. To this end, it has established a Rural Pharmaceutical Pilot Project ('RPPP') to develop a response to the range of issues affecting access to pharmacy services in rural and regional Victoria. This project forms part of the Victorian Rural Human Services Strategy (VRHSS)[59], an initiative that aims to 'address issues affecting the delivery and provision of human services to rural and regional communities throughout Victoria' (Department of Human Services 2002, p 2).

In examining options for enhancing rural access to pharmacy services, the RPPP has initially focused upon the pharmacy depot system and whether current arrangements could be enhanced. In the first instance, this has involved a pilot project to evaluate the effectiveness of installing a videophone link between a private pharmacy practice in Bairnsdale and a registered pharmacy depot in Omeo.

Prior to introduction of the videophone in the depot, local residents could contact a pharmacist directly using a toll-free number, or by having the pharmacy assistant in the depot phone Bairnsdale. While local residents could obtain information immediately, they still had to wait until the next day for non-prescription medications to be couriered up to Omeo (or have someone collect these when visiting Bairnsdale).

Outcomes of the Videophone Project

An independent evaluation of the RPPP was commissioned in April 2002. The evaluation documented several advantages arising from the videophone service:

- Access to more immediate advice on routine health matters (of particular concern in Omeo, which has limited access to general practitioner services).
- Benefits arising from multiple channels of communication and feedback (visual and audio), which include both the ability to form a more personal relationship with the 'local' pharmacist and the capacity to benefit from visual diagnosis by a trained observer[60].
- More immediate access to S2 medications.

The evaluation report (2002, pp 24–25) noted that

> *the pilot pharmacy videophone project has been successful in demonstrating that pharmacy advice and consultation can be delivered effectively by videophone…(and that) the very low overall establishment and recurrent costs of the videophone technology in the pilot indicates that an effective and valued service can be delivered in a cost effective manner*

8.3.3 Facilitating Rural and Remote Access to Pharmacy Services

Through the RPPP and broader consultation undertaken via the VRHSS, several key concerns have been identified in relation to rural pharmacy services:

- Many rural communities do not have stand-alone pharmacies, pharmacy depots or health services through which medications can be provided and thus lack ready access to medications and/or health advice regarding common conditions.

[59] Further information regarding the Rural Pharmaceutical Pilot Project can be accessed at the VRHSS website, http://www.dhs.vic.gov.au/vrhss

[60] This would be expected to result in more effective and/or accurate advice regarding medications, with the potential to reduce the incidence of adverse reactions.

- The scope of services and range of medications available from existing pharmacy depots is very limited, and residents cannot readily access S2 and S3 medications in their own communities that can be purchased over-the-counter in stand-alone pharmacies (including those used to treat chronic conditions).

- After hours access to medications in rural areas is extremely limited or non-existent[61].

The following sections outline a range of initiatives that could be explored and/or implemented to address the current concerns regarding access to medicines in rural and regional Victoria.

8.3.3.1 Expand the Scope of Services Available at Pharmacy Depots in Victoria

As the Omeo pilot project has demonstrated, the use of technology such as videophones may provide a cost-effective means of increasing the scope of services available to rural communities by:

- Facilitating immediate access to advice regarding routine health concerns—of particular importance in areas that may not have regular access to GP or nursing services).

- Establishing a more personalised, face-to-face service, helping community members and the 'local' pharmacist to establish an ongoing relationship.

- Providing the capacity for community members to benefit from a visual diagnosis undertaken by a trained observer. Potential benefits include reduced risk of adverse drug reactions, timely referrals, greater likelihood that medications will be used effectively and the potential for the pharmacist to provide a health screening role.

- Facilitating immediate access to S2 medications.

The RPPP Project Evaluation Report highlighted the potential for videophone technology to be used to supplement or complement existing services. The scope for this would depend upon a range of factors, including where the depot was located—whether it was stand-alone or co-located with other health services—and what technology was used. A multi-channel system would be required for use in clients' homes.

8.3.3.2 Expand the Number of Pharmacy Depots in Victoria

The RPPP Project Evaluation Report identified three main models involving the participation of a private pharmacy practice that could be considered to improve rural access to non-prescription medicines and pharmacy advice via pharmacy depots:

1. **Stand-alone private pharmacy model**, in which a private pharmacy owns and operates one or more pharmacy depots. Several variations of this scheme are explored in the report, including:
   - Establishment of a centralised service, in which a single pharmacy practice supports several pharmacy depots.
   - A mobile service, in which a pharmacist operates across several towns, maintaining depots in each[62].
2. **Private pharmacy co-located with a private business**, in which a pharmacy depot co-locates with another private health service (such as a general medical practice) or other business (such as a post office).

[61] Limited access to after hours pharmacy services is not a problem unique to rural areas: consumers living in parts of metropolitan Melbourne and regional centres may also experience similar difficulties.
[62] The feasibility of this model is currently limited by restrictions within the PBS, that prevent 'portability' of pharmacy approval numbers for the purposes of PBS.

3. **Private pharmacy co-located with a public organisation**, in which a pharmacy depot is established or co-located with or within a public organisation, such as a community health centre, hospital, bush nursing centre or local government facility.

A summary of the potential advantages and disadvantages of each is contained in Table 3. The appropriate depot model will depend upon the size of the community, existing infrastructure, existing health services and the capacity and/or willingness of a registered pharmacist to participate.

Ideally, any expansion of the pharmacy depot scheme should complement any existing medication services provided to rural communities by Bush Nursing Centres, community health centres and other health services under Health Services Permits[63] and where possible, make use of existing video-link technology[64].

8.3.3.3 Develop Programs to Enhance Medication Planning, Integration of Services and Access to After Hours Medications

While expanding the pharmacy depot scheme may improve some aspects of rural access to medications, there would also appear to be a role for the development of programs that enhance medication planning and service integration to ensure that the benefits associated with pharmacy depots are maximised.

Commonly used medications can be broadly categorised into two groups, according to the nature of the conditions they are used to treat:

- Those used to treat chronic or commonly occurring conditions[65], for which a need can be anticipated in advance.
- Those used to treat acute conditions[66], for which urgent treatment may be required and needs cannot be anticipated in advance.

A significant proportion of medicines prescribed are used in the treatment of chronic or commonly occurring conditions. If people using such medicines in rural areas could be encouraged to anticipate their medication needs and purchase accordingly. Also, if their practitioners could be encouraged to always consider what level of access a consumer has to pharmacy services in prescribing, it may be possible to reduce some of the current problems currently associated with limited access to medicines in rural areas.

Obviously, medications used to treat acute conditions are not so readily anticipated, so different strategies would appear necessary to help promote timely access to these. As a short term strategy, various programs could be developed to reduce or avoid some of the current problems, particularly in relation to after hours access (discussed in further detail in section 8.3.3.6 of this paper). This might include programs/communication strategies designed to:

- make local prescribers aware of hours of operation of local pharmacy and pharmacy depot services; and/or
- encourage regional pharmacists and medical practitioners to develop coordinated hours of operation; and/or
- encourage medical practitioners to utilise existing mechanisms (such as the doctors' bag) to provide medications to treat acute and urgent conditions, when these medications cannot be accessed in a timely manner via a pharmacist.

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[63] Issued under s19 of the *DPCS Act*.

[64] Various Government programs (such as the Human Services' Productivity Investment Fund) have funded the establishment of video-link technology in rural and regional areas. Further examination of where this technology is in place and whether there is the capacity for it to be utilised for the delivery of video pharmacy services may be merited.

[65] This might include medications used to treat diabetes, asthma and various mild heart conditions, as well as medications used to treat cold, flu and/or seasonal allergies.

[66] Such as antibiotics to treat acute infections or strong oral pain killers.

In considering such an option, the experience and knowledge gained by the Western Division of General Practice via its GP/Pharmacy Liaison Project[67], may be of assistance, as well as that of other projects designed to improve collaboration and coordination between the professionals that prescribe and dispense medications.

Table 3 Pharmacy Depot Models Identified in the RPPP Evaluation Report

	Advantages	Disadvantages
Stand-alone private pharmacy model	• Pharmacist retains responsibility for all professional and operating decisions and employment of staff, which is seen to promote high quality standards. • Particularly suited to towns in danger of losing pharmacy. • Has the potential to facilitate establishment of a centralised service and/or mobile pharmacy services. • Can operate without assistance or support of public sector, although public sector involvement may enhance business case for maintaining depot.	• May not be sufficient business case to establish stand-alone depot in smaller towns. • If videophone technology introduced, its use might be limited to pharmacy-related advice and consultations.
Private pharmacy co-located with a private business	• Costs and support services shared with another business, hence may be suitable in areas where there is not a sufficient business case for a stand-alone depot. • Could utilise existing infrastructure, with (word missing)to be integrated with primary health services. • May be expanded in commercial scope if co-located with other health services. • If video technology installed, could be used for non-pharmacy as well as pharmacy purposes.	• Success would depend in part on the existence of sufficient controls over professional standards and appropriately trained staff.
Private pharmacy co-located with a public organisation	• Could utilise existing infrastructure, with (word missing) to be integrated with primary health services—may be particularly suitable to townships with existing public health services. • May complement activities of remote area nurses in sparsely populated areas. • May be expanded in commercial scope if co-located with other health services. • If video technology installed, could be used for non-pharmacy as well as pharmacy purposes.	• May not be sufficient business case for private pharmacist to participate unless some level of support from public organisation or government. • Need to clearly delineate public vs. private service responsibilities and ensure any processes for establishment are clear and transparent. • Success would depend in part on the existence of sufficient controls over professional standards and appropriately trained staff.

8.3.3.4 Enhance Rural Access to S2 and S3 medications

In addition to recommending the introduction of videophone technology to enhance the services providing via pharmacy depots, the RPPP evaluation (2002) noted that

> *there would appear to be considerable support for the broadening of the range of medicines at pharmacy depots to (some) Schedule 3 or 'pharmacist only' medicines (namely Ventolin and anginine)' as there would be considerably greater health benefit to remote communities if some of … (these) medicines that treat urgent medical conditions could be available in a timely manner.*

[67] The GP/Pharmacy Liaison Project was established to examine the 'potential, the gaps and the barriers to better collaboration between GPs and pharmacists in a rural area' (WVDGP 2001, p 5), with financial support obtained via the innovation funding pool of Australian Divisions of General Practice.

Increasing the range of pharmaceuticals available at depots was also seen as a potential means of enhancing the viability of pharmacy depots, which in turn could facilitate an expansion of the pharmacy depot network and thus improve access to pharmacy services amongst rural communities. At the same time, it is noted that medications are placed on schedules because of the potential for their use to cause harm, and an assessment would be required of whether the potential costs arising from the misuse or theft of such drugs from pharmacy depots was outweighed by the symptomatic relief some of these drugs provide patients.

Currently, *Drugs, Poisons and Controlled Substances* legislation limits who may obtain, supply or sell certain drugs and poisons according to their schedule in the Victorian Poisons List. This restricts the supply of medications as follows:

- Supply of S2 medications is restricted to pharmacies[68] (or where a pharmacy service is not available, from a licensed person).
- S3 to pharmacists[69] (without the need for prescriptions).
- S4 and higher schedules to pharmacists (on a prescription from an authorised person).

In addition, the Pharmacy Board of Victoria has issued guidelines regarding:

- The Board's requirements for a pharmacist-owned pharmacy depot that intends to store and sell S2 substances. This limits supply of S2s to those depots owned by pharmacists which operate 'an audio-visual link approved by the Board' (Guideline 635h).
- Pharmacists' responsibilities in relation to the supply of S3 medications, which refer to both DPCS legislation and standards established by the Pharmaceutical Society of Australia[70].

For the range of medicines available at pharmacy depots to be expanded, there would potentially need to be changes made to both Drugs, Poisons and Controlled Substances legislation, as well as the controls administered by the Pharmacy Board of Victoria[71]. Professional Standards issued by peak bodies such as the Pharmaceutical Society of Australia would also require consequential amendment.

The nature and extent of such changes would depend upon various factors including:

- **The schedule of medicines to be made available.**
  For example, if S3 medicines were to be kept in pharmacy depots and made available to patients following a video-link consultation with a pharmacist, it would be necessary to amend DPCS legislation to remove the requirement for a pharmacist to be physically present at the time the S3 medicine was dispensed.

- **The specific medicines that the pharmacy depot would be empowered to stock; and the criteria by which these would be determined.**
  Medicines are scheduled according their potential to do harm. There are various potential harms associated with the use of scheduled medicines, including those arising from inappropriate use[72] or illicit use[73].While those medicines that can be used illicitly pose significant security risks to pharmacies[74] and would pose similar concerns to pharmacy depots, there may be certain commonly prescribed medications which could be safely stored in pharmacy depots. These could, for example, include:

[68] The current definition of 'pharmacy' in the *Pharmacists Act 1974* refers to 'any premises in or upon which a pharmacist practises as a pharmacist'. Current advice suggests that this would include pharmacy depots owned by pharmacists, and that provision of S2 drugs from a pharmacist-owned pharmacy depot would thus not contravene DPCS legislation..
[69] Under regulation 63 of the *DPCS Regulations*, a pharmacy selling a s3 poison must personally supervise its delivery (which requires the 'actual presence' of that person), unless it is being sold or supplied on the prescription of a medical practitioner or dentist.
[70] *Standards for the Provision of Pharmacist Only and Pharmacy Medicines in Community Pharmacy* (1999).
[71] These currently include guidelines issued regarding appropriate standards for dispensing of S3 medications and also guidelines regarding requirements for approval of pharmacy depots.
[72] Corticosteroid medication is prescription only, as there are a range of side-effects and contraindications associated with its use.
[73] For example, Rohypnol (flunitrazepam) was moved to a higher schedule on the Poisons List in response to concerns that it had been the subject of widespread abuse.
[74] There has been a rapid increase in the number of pharmacy break-ins over recent years, associated with certain drugs commonly used for illicit purposes.

- S3 medicines used to treat common and/or chronic conditions.
- S4 medicines that are repeats of a prescription issued by a medical practitioner.

In both instances, dispensing of such medications would need to be subject to appropriate conditions and/or consultation, which may be determined by the Pharmacists Board.

- **The mechanism by which they were made available**
  For example, changes to the scheduling of certain S3 medicines could be sought to permit their storage in designated rural areas of pharmacy workforce shortage, or s19 of the *DPCS Act 1981* amended such that a general dealer's license could authorise its holder to obtain and sell for retail certain S3 medications as well as S2s. As scheduling of drugs and poisons is undertaken via a national process (see Appendix 3), attempts to have certain medicines rescheduled (or the description of who may access those medicines) would be likely to take considerable time and negotiation at a national level.

Given the complexity of the regulations governing scheduled medicines and the potential harms that can arise from misuse or abuse of these substances, further examination of options for reform and the associated costs and benefits will be required if this option is to be pursued.

8.3.3.5 Examine Other Models for Expanding Access to Common Medicines

In addition to models based on expansion of the pharmacy depot scheme, other strategies could be considered to improve rural access to medicines in smaller communities where a pharmacy depot may not be viable and/or other health services do not exist, such as:

- Promoting the use of phone-based pharmacy services, mail order and/or Internet pharmacy services.
- Expanding the use of General Dealer's Licences to enable smaller communities to access S2 drugs approved for retail sale by the Secretary of the Department.

Further exploration and consultation regarding changes to DPCS legislation may be merited, although detailed consideration of such issues is beyond the scope of the current review of the *Pharmacists Act*.

8.3.3.6 After Hours Access to Pharmacy Services

While limited after hours access to pharmaceuticals is a problem experienced by both metropolitan and rural communities, various rural stakeholders have raised concerns regarding delays encountered in accessing prescription medications via the pharmacy depot scheme, particularly in smaller towns where the depot may only be open for a few hours on selected week days. It has been noted that this can become problematic if doctors' appointments are conducted towards the end of the week and consumers cannot obtain urgent medications until the following Monday.

As part of its GP/Pharmacy Liaison Project, the Western Division of General Practice (WDGP) established a Rural After Hours Medication Supply Working Party[75] to address the issues of after hours medication supply. Via a meeting of interested parties and an Issues Paper, the project identified a range of strategies that could be utilised to improve after hours access to medications, including:

- Consumer education, encouraging rural consumers to plan ahead to avoid running out of their medications and also addressing issues regarding the quality use of medicines.
- Use of starter packs.

[75] This comprises representatives from the Australian Medical Association (Victoria), the West Vic Division of General Practice, the Society of Hospital Pharmacists, the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia.

- Promotion of a 'rural emergency supply' or a 'rural doctors' bag'; the latter could be explored under the PBS.
- Medical practitioners to purchase medications for dispensing/resale to patients.
- Development of a mobile pharmacy scheme.
- Use of technology to facilitate remote dispensing.
- Establishment of an after hours imprest box of key drugs[76].

The Western Division of General Practitioners (2001, p 61) noted that the imprest box was 'the most favoured model by health professionals working in rural and remote areas…(and was) the only model that has the potential for 24-hour coverage'[77].

Most of the strategies proposed in this section not only have the potential to enhance the number and scope of pharmacy services provided by pharmacy depots, but may also at least partially address the concerns regarding access to medicines to treat chronic conditions, given that the need for these can generally be anticipated.

For example, development of communication strategies that promote coordination between pharmacists and medical practitioners within a rural or regional area—in combination with consumer information designed to promote both effective medication planning and appropriate use of medications—could result in more effective use of the pharmacy depot scheme. By encouraging consumers to anticipate their medication needs (for example, repeat medicines used to treat chronic conditions and/or common seasonal conditions), the demand for after hours services might be significantly reduced.

Identifying initiatives that have the capacity to facilitate timely access to urgent medicines (those whose use cannot reasonably be anticipated in advance) poses additional challenges in both rural and metropolitan settings. As pharmacists can only prescribe S4 drugs in certain emergency situations[78], the involvement of a medical practitioner or other authorised prescriber is necessary in many cases. Strategies that can integrate both the prescription and provision of medicines would be required.

8.3.4 Enhancing Access to Rural Pharmacies—Model for Discussion

As the previous discussion has highlighted, a range of strategies could be employed to improve access to rural pharmacy services. Some options, such as expansion of video-link facilities through pharmacy depots could be implemented almost immediately, while options such as the proposal to expand the range of available medications available at depots would require much broader analysis over a longer period of time. It is considered important that any initiatives supported by the Department complement and, where possible, integrate with existing structures and programs.

Adopting an incremental approach to such reforms would allow the Department to monitor how effective each strategy is in addressing the concerns raised regarding rural access to pharmacy services. Particularly in relation to after hours access to pharmacy services, there may be merit

[76] As part of the project, a list of 10-20 commonly used medications in emergency situations was developed.

[77] Concerns have, however, been raised regarding various aspects of this proposal:
- The rural medicine box initiative would rely heavily on telephone instructions from the prescribing doctor, a procedure which has significant potential for abuse.
- Non-medically trained persons (such as Community Health Centre Managers) might be given responsibility for the security of the supply of medicines, which is considered inappropriate by some parties.
- Legislative reform would be necessary to expand the number of persons who can legally supply prescription only drugs and in what settings.
- The potential for such initiatives to impact on pharmacy incomes and ultimately, the viability of rural pharmacies.

[78] Regulation 12(2) of the *Pharmacists Regulations 1982* enables a pharmacist to supply a Schedule 4 poison once, if it is considered necessary to ensure continuity of treatment, there is an immediate need for the medication, it is impracticable for the patient to obtain a prescription in time to meet that need, the medication has previously been prescribed by a medical practitioner for treatment of that condition, the patient is aware of the appropriate dosage and not more than 3 days' supply is given.

in promoting the use of existing mechanisms (such as use of doctors' bags for provision of medication in emergency situations) and assessing the effectiveness of these when used in combination with other identified strategies, before developing additional mechanisms to facilitate reasonable access after hours.

In view of the above, a three-stage approach to enhancing access to rural pharmacy services is proposed:

	Initiative	Timeframe
STAGE ONE	Install video-link technology in existing depots.	short term
	Develop and implement communication/ liaison strategies and information to promote: • Better medication planning. • Improved coordination of services. • Effective use of existing mechanisms to enhance A/H medication supply.	short term
	Data collection and analysis (assess effectiveness of videophone in improving access to and quality of care).	short term
STAGE TWO	Explore options to co-locate additional pharmacy depots with health services in centres without current services; implement where indicated.	short to medium term
	Re-assess need to expand range of medications stocked in pharmacy depots and progress as required.	medium term
	Assess effectiveness of various initiatives in addressing after hours issues.	medium term
STAGE THREE	Explore alternative strategies for promoting after hours access to pharmaceuticals in rural areas (consider also applicability to metropolitan and regional centres).	medium to long term

What Are Your Views?

The model above has been developed to stimulate discussion around how access to medications can be improved for rural communities. Are there other strategies that should be considered in developing a model to enhance rural access to medicines?

8.4 Other Issues

- Are there other issues specific to the practice of pharmacy that should be considered for inclusion in a new Act?

Appendix 1 National Competition Policy Review of Pharmacy Legislation–Summary of Recommendations

Recommendation 1: Pharmacist-Only Ownership of Pharmacies The Review recommended that: (a) Legislative restrictions on who may own and operate community pharmacies are retained; and (b) With existing exceptions, the ownership and control of community pharmacies continues to be confined to registered pharmacists.	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.
Recommendation 2: Residential And Local Registration Requirements The Review recommended that: (a) Any State or Territory's residential requirements for pharmacy ownership are removed; and (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.	Accept Recommendations 2(a) and (b).
Recommendation 3: Ownership Structures The Review recommended that: (a) Pharmacy ownership structures permitted by various State and Territory *Pharmacy Acts* be retained as being consistent with the defined principle of pharmacist ownership and effective control of pharmacy businesses; (b) *Pharmacy Acts* recognise, in addition to sole trading pharmacists and pharmacist partnerships, corporations with shareholders who are: (1) All registered pharmacists; and (2) Registered pharmacists and prescribed relatives of those pharmacists; and (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.	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 4: Number of Pharmacies Owned by Proprietors and Pharmacist Supervision of Pharmacies The Review recommended that: (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; (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 (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.	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 5: Permitted Exceptions to Pharmacist Ownership The Review recommended that: (a) Friendly societies may continue to operate pharmacies, but that: (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; (b) Permitted corporately-owned pharmacies continue to be restricted under grand-parenting arrangements where these apply; (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 (d) The findings of any such inquiry may be taken into account as part of legislative reform processes in this regard.	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). 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.

Recommendation 6: Pecuniary Interests in a Pharmacy Business The Review recommended 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 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 pharmacy services in that pharmacy, provisions in *Pharmacy Acts* relating to and including: (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 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.	Accept Recommendation 6(a) Accept Recommendation 6(b) Accept Recommendation 6(c) Accept Recommendation 6(d)
Recommendation 7: Registration of Pharmacy Premises and Pharmacy Businesses The Review recommended that: (a) Requirements for the registration of pharmacy premises be removed provided that: (1) Acts, regulations and related guidelines can continue to require pharmacy proprietors and managers to ensure that their premises are of a minimum standard of fitness for the safe and competent delivery of pharmacy services; (2) The responsibilities of pharmacy proprietors and managers, and of registered pharmacists, under State and Territory drugs and poisons legislation are not compromised; (3) Acts or regulations may require the proprietor of a pharmacy to notify a regulatory authority, in writing, of the location or relocation of a pharmacy; and (4) Regulatory authorities, their employees or agents may enter and inspect pharmacy premises to investigate complaints, conduct spot checks, or act on the reasonable suspicion of guidelines being breached; and (b) Regulations requiring the registration of pharmacy businesses by regulatory authorities are removed, given that pharmacists are already registered in each State and Territory, and that business registration is not connected to the safe and competent practice of pharmacy.	Accept Recommendation 7(a) Accept Recommendation 7(b)

Recommendation 8: Miscellaneous The Review recommended that Commonwealth, State and Territory governments ensure that legislation and agreements for the delivery of professional pharmacy and health care services negotiated with pharmacy proprietors and their representatives, require: An acceptable range of services to be provided; and Appropriate quality assurance and professional practice standards to be adopted by community pharmacies covered by the agreements.	Note Recommendation 8.
Recommendation 9: New Pharmacy Approvals The Review recommended that: (a) Some form of restriction on the number of pharmacies as outlets for the Pharmaceutical Benefits Scheme (PBS) is retained; (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 (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 under serviced communities, particularly in rural and remote areas. **Recommendation 10: Relocation of Existing Pharmacies** The Review recommended that Pharmaceutical Benefits Scheme (PBS) related restrictions on the relocation of pharmacies from one site to another are phased out. **Recommendation 11: Timing of Proposed Changes** 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.	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 anticompetitive 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.
Recommendation 12: Rural and Remote Pharmacies The Review recommended that: (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 (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.	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.

Recommendation 13: Medical Centres and Aged Care Facilities The Review recommended that, should new pharmacy and relocated pharmacy approval restrictions continue after 1 July 2001, that: (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 (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.	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 14: General Regulatory Principles The Review recommended that: (a) *Pharmacy Acts*, 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; (b) Legislation sets out clearly the roles, responsibilities and powers of decision-making, regulatory and reviewing authorities in administering that legislation; and (c) *Pharmacy Acts* 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.	Accept Recommendation 14(a) Accept Recommendation 14(b) Accept Recommendation 14(c)
Recommendation 15: Regulatory Authorities The Review recommended that: (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 (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.	Accept Recommendation 15(a) 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.

Recommendation 16: Registration of Pharmacists The Review recommended that: (a) Pharmacy remains a registrable profession, and that legislation governing registration should be the minimum necessary to protect the public interest by promoting the safe and competent practice of pharmacy; (b) Legislative requirements restricting the practice of pharmacy, with limited exceptions, to registered pharmacists are retained; (c) Legislative limitations on the use of the title "pharmacist" and other appropriate synonyms for professional purposes are retained; (d) Legislative requirements for a registered pharmacist to have particular personal qualities, other than appropriate proficiency in written and spoken English, and good character, are removed; (e) Legislative requirements for membership of a professional association or society as being necessary for registration as a pharmacist are removed; (f) Legislative requirements specifying qualifications, training and professional experience needed for initial registration as a pharmacist are retained; but (g) States and Territories should move towards replacing qualifications-based criteria with solely competency-based registration requirements if and as appropriate workable assessment mechanisms can be adopted and applied.	Accept Recommendation 16(a) Accept Recommendation 16(b) as an interim measure and revisit at the same time as other retained legislation. The only practices that should be considered for protection are those that (1) cannot be controlled by other legislation, and (2) pose a substantially higher risk of significant harm to the public. Accept Recommendation 16(c) Accept Recommendation 16(d) Accept Recommendation 16(e) Accept Recommendation 16(f) Accept Recommendation 16(g), noting that jurisdictions will give further consideration to the implementation of competency based assessment as and when suitable mechanisms are developed.
Recommendation 17: Ongoing Practice as a Pharmacist The Review recommended that: (a) Existing re-registration requirements for pharmacists re-entering the profession following a period out of practice are retained; and (b) Regulations enabling regulatory authorities to impose conditional registration, or supervised or restricted practice prior to re-registration, for pharmacists returning to practice or constricted in their abilities to practice, are retained.	Accept Recommendation 17(a) Accept Recommendation 17(b)
Recommendation 18 The Review recommended that, within three to five years, States and Territories should implement competency-based mechanisms as part of re-registration processes for all registered pharmacists.	Accept Recommendation 18 noting that jurisdictions will give further consideration to the implementation of competency-based assessment as and when suitable mechanisms are developed.
Recommendation 19: Disciplinary Processes The Review recommended that: (a) Complaints and disciplinary processes are set out clearly in *Pharmacy Acts* and delegated legislation; (b) Grounds for the incompetence to practise of, and professional misconduct by a pharmacist, are defined clearly in legislation; and (c) Complaints investigation, disciplinary processes, and penalties imposed by regulatory authorities are accessible, public, transparent and subject to the principles of natural justice and external review.	Accept Recommendation 19(a) Accept Recommendation 19(b) Accept Recommendation 19(c)
Recommendation 20: National Consistency of Pharmacy Regulation The Review recommended that, in the interests of promoting occupational and commercial mobility, the Commonwealth, States 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.	The Council of Australian Governments has provided a whole-of-government response to this and all other Recommendations arising from the National Competition Policy Review of Pharmacy.

Appendix 2 Model Act for Registration of Victorian Health Practitioners

- The legislation makes clear that the purpose of regulation is to protect the public rather than professional interests.
- The main privilege of registration is the right to use the relevant title, rather than to define the practice of the profession.
- Recommendations to the Governor in Council for regulations should be made by the Minister for Health.
- There is provision for temporary and conditional registration in appropriate circumstances.
- It is an offence for non-registered persons to use the relevant title or to hold themselves out as being registered.
- Registration boards must be incorporated as legal entities.
- Members of boards are appointed on recommendation from the Minister for Health.
- Positions on boards should not be allocated by statute to particular groups; people appointed should provide a range of perspectives and skills.
- All boards must include legal and community representation.
- Primary role of boards in handling complaints is to determine alleged breaches of standards, rather than to resolve disputes, as this is the function of the Health Services Commissioner.
- Boards have a broader range of disciplinary options, including informal hearings in appropriate cases and the capacity to act against lapsed registrants and lay owners of practices.
- A standard definition of 'unprofessional conduct' is adopted.
- Legislation includes standard powers of boards to deal with false and misleading advertising where such is shown to be necessary to protect the public.
- Boards have the power to immediately suspend the registration of a practitioner if necessary, in order to protect the public.
- Formal hearings are open to the public
- Complainants have the right to be present at a hearing.
- Sanctions should include remedial and educative measures, as well as discipline of practitioners.
- Appeals from a decision are directed to the Victorian Civil and Administrative Appeals Tribunal.
- All registered practitioners are required to maintain professional indemnity insurance.

Appendix 3 Scheduling of Drugs, Poisons and Controlled Substances

Drugs, poisons and controlled substances may be placed in any of 9 poisons schedules, according to their potential for harm. Schedules 2, 3, 4, 8 and 9 apply to poisons for therapeutic use and reflect an increasing degree of restriction. Schedules 5, 6 and 7 refer to poisons for agricultural, industrial and domestic use. A summary of each schedule is provided below.

SCHEDULE	DESCRIPTION OF CONTENTS
Schedule 1.	Currently un-named and empty.
Schedule 2: **Pharmacy Medicine**	Substances, the safe use of which may require advice from a pharmacist and which should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person.
Schedule 3. **Pharmacist Only Medicine**	Substances, the safe use of which requires professional advice, but which should be available to the public from a pharmacist, without a prescription.
Schedule 4. **Prescription Only Medicine, or Prescription Animal Remedy**	Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription.
Schedule 5. **Caution**	This schedule includes a range of substances for therapeutic and other uses.
Schedule 6. **Poison**	Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.
Schedule 7. **Dangerous Poison**	Substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply.
Schedule 8. **Controlled Drug**	Substances that should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.
Schedule 9. **Prohibited Substance**	Substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.
Appendices to the Schedule	In addition to the schedules, the appendices cover a range of related issues such as exemptions, labelling requirements, and conditions for availability. For example, Appendix C and Appendix D list substances that are prohibited for possession, sale, supply or use.

While many legislative controls over medications are exercised at a State level, the decisions regarding which schedule a medication should be placed in (which in turn influences how readily it can be accessed and who can prescribe it) are made at a national level. A national Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) is produced on a regular basis, and its contents adopted into State based legislation, including the Victorian Poisons List.

To determine which schedule a medication should be placed in, a national committee (the National Drugs and Poisons Schedules Committee[79]) conducts an evidence-based assessment of each medication against a set of established criteria and schedules them according to their potential risk for harm. In addition to assessing new drugs for inclusions in the SUSDP, the

[79] This committee is established under the *Commonwealth Therapeutic Goods Act 1989,* with its membership appointed by the Australian Health Ministers' Advisory Council (AHMAC). The NDPSC has 20 members, including representatives of all Australian jurisdictions and of New Zealand, relevant Commonwealth and New Zealand government agencies, industry, professionals, consumers and experts.

NDPSC also reassesses drugs that are already listed and may reschedule these if considered necessary.

Appendix 4 Licenses and Permits Issued under DPCS Legislation

Section 19(3) of the Victorian *DPCS Act 1981* allows the Secretary of the Department to issue a licence, permit or warrant subject to terms, conditions, limitations or restrictions determined by the Secretary. In practice, such conditions are used to limit the range of medications and/or circumstances under which medications may be obtained, supplied and/or sold.

Contravention of or non-compliance with a licence or permit condition constitutes an offence under section 46 of the *Drugs Poisons and Controlled Substances Act*.

Licenses and permits last for a 12 month period from their date of issue.

General Dealers License

Section 20(1) of the Act authorises a person who holds a license to manufacture, sell and/or supply certain drugs poisons and controlled substances. Currently, S2 medicines are the only drugs, poisons and controlled substances for human use that a person with such a license can sell for retail purposes. This is termed a General Dealer's License and it is understood that approximately 6 of these licenses have been issued, primarily to the operators of milk bars and corner stores in areas of rural Victoria.

At this time, the Secretary has approved a relatively small list of S2 medicines for retail sale by persons holding a General Dealers' License. As a result, while this may provide access to some S2 medicines to rural communities that don't have a pharmacy or pharmacy depot, the range of medications available is significantly smaller than that which could be made available via pharmacist-owned depots that are not subject to such restrictions.

Health Services Permit

Section 20(3) of the Act authorises a person who holds a permit to purchase or otherwise obtain poisons or controlled substances for the provision of health services. This is termed a Health Services Permit, and is specific to a Bush Nursing Centres and Community Health Centres have been issued with permits under these provisions to purchase poisons and controlled substances in the various schedules, including Schedules 2, 3, 4 and 8.

Many of the Health Services Permits held by centres in remote areas have been issued subject to the conditions such as:

> *A nurse who administers a drug of addiction or restricted substance named on the permit does so only-*
>
> - *on the written authorisation of a medical practitioner; or*
> - *in an emergency –*
>   - *where contact with a medical practitioner is practical, on the oral instruction of the medical practitioner, in whose opinion an emergency exists; or*
>   - *where contact with a medical practitioner is not practical, if during the previous twelve months the nurse has demonstrated competence in physical assessment skills relevant to the condition for which the drug of addiction or restricted substance is administered.*

Appendix 5 Costs and Benefits of Restrictions on Advertising in Health Practitioner Legislation

(Reproduced from *Review of Nurses Act 1993 and Medical Practice Act 1994 – Discussion Paper, October 1998* pp 8-9)

ARGUMENTS FOR LIMITING THE POWERS OF HEALTH PRACTITIONER REGISTRATION BOARDS IN RELATION TO ADVERTISING:

- Advertising is about the dissemination of information. Restrictions on advertising that exacerbate the fundamental disparities in market information can eliminate or constrain normal forms of competitive behaviour. Such restrictions can deny consumers normal forms of information about the availability, quality and price of services provided by competing practitioners, and therefore have adverse effects on efficiency, costs and prices.
- Consumers very rarely make complaints to the Medical Practitioners Board, for example, about advertising. Complaints received are generally from other registered medical practitioners arguably prompted by commercial rivalry rather than concern with quality of care and protection of consumers.
- The advertising provisions in the *Medical Practice Act* and other Acts duplicate unnecessarily, the powers of other bodies, for example:
    - false, misleading and deceptive advertising powers may be more effectively dealt with under State and Commonwealth trade practices and fair trading legislation. Fines of up to $50,000 can be imposed under the *Fair Trading Act 1985*, as compared with fines of up to $5,000 for a natural person and $10,000 for a body corporate under the *Medical Practice Act*.
    - the disparaging comments provision may be adequately covered by the law of libel and, it is argued, may act to protect professionals more than it protects the public.
    - abuses in advertising which refer to testimonials that are false or misleading may be covered by law of fraud and fair trading legislation.
- The Medical Practitioners Board and other health practitioner registration boards have encountered difficulties in enforcing the advertising provisions due to the length of time taken to receive and investigate a complaint and then refer it to the Magistrates Court for action and the impact of the 12 month Statute of Limitations.
- The Medical Practitioners Board and other health practitioner registration boards have existing powers under the provisions relating to 'unprofessional conduct' to investigate and discipline practitioners whose advertising breaches the standards expected by the community and by their peers.

ARGUMENTS FOR STRENGTHENING THE POWERS OF HEALTH PRACTITIONER REGISTRATION BOARDS TO REGULATE ADVERTISING:

- The registration boards are in many cases the most suitable bodies to discipline their members for unprofessional advertising since they are more closely involved on a day-to-day basis with the professions than are other regulatory bodies such the Office of Fair Trading and Business Affairs or the Australian Competition and Consumer Commission (ACCC). They may, therefore, be better equipped to identify and deal with the less serious examples of unprofessional or dishonest advertising that the ACCC and the Office of Fair Trading may not have the resources to deal with effectively.

- The sanctions that registration boards have available are very immediate, direct and timely. A practitioner at risk of losing his/her livelihood is most likely to take notice of Board, particularly when the Board is made up of their peers. Civil courts do not have the power to prevent a practitioner from practising his or her provision.
- To abandon or restrict further the powers of registration boards to regulate advertising might effectively shift the costs of such regulation from the private sector to the public sector. That is, the regulatory role of registration boards is funded via the annual registration fees levied on registered practitioners. If the Office of Fair Trading, the Health Services Commissioner or other Government funded bodies were to deal with complaints traditionally dealt with by registration boards, then there would be increased demand on public sector resources.
- To abandon restrictions on use of testimonials in advertising may lead to a flood of potential abuses which are likely to be very costly for a registration board to investigate and prosecute, with questionable improvements in access to information for consumers on which to make informed health care choices.

Appendix 6 Warrant Provisions

Identification

1. The Board must issue an identification card to each person appointed by the Board to apply for or execute search warrants for the purposes of this Act.

2. A person appointed by the Board must, in the course of performing his or her functions under this Act, produce his or her identification card to any person who requests its production.

Powers of Entry with Warrant

1. A person appointed for that purpose by the Board may apply to a magistrate for the issue of a search warrant in relation to particular premises if that person believes, on reasonable grounds:

    a. that there is or has been a contravention of this Act or the regulations on the premises; or

    b. that entry into or onto the premises is necessary for the purpose of investigating a complaint made under this Act which, if substantiated, may provide grounds for the suspension or cancellation of registration of a registered chiropractor.

2. If a magistrate is satisfied by evidence on oath, whether oral or by affidavit, that there are reasonable grounds for suspecting that there is on the premises a particular thing that may be evidence of the commission of an offence against this Act or the regulations or of grounds for the suspension or cancellation of the registration of a chiropractor, the magistrate may issue a search warrant authorising any person named in the warrant:

    a. to enter the premises, or the part of the premises, named or described in the warrant; and

    b. to search for and seize a thing named or described in the warrant; and

    c. to bring the thing before the Court so that the matter may be dealt with according to law.

3. In addition to any other requirement, a search warrant issued for the purposes of this section must state:

    a. the offence or grounds of suspension or cancellation suspected; and

    b. the premises to be searched; and

    c. a description of the thing to be searched for; and

    d. any conditions to which the warrant is subject; and

    e. whether entry is authorised to be made at any time or during stated hours; and

    f. a day, not later than 7 days after the issue of the warrant, on which the warrant ceases to have effect.

4. A search warrant must be issued in accordance with the *Magistrates' Courts Act 1989* and in a form prescribed under that Act.

5. The rules to be observed with respect to search warrants mentioned in the *Magistrates' Courts Act 1989* extend and apply to warrants under this section.

Announcement before entry

1. Immediately before executing a search warrant, a person named in the warrant must announce that he or she is authorised by the warrant to enter the premises.

2. The person need not comply with sub-section (1) if he or she believes on reasonable grounds that immediate entry to the premises is required to ensure the safety of any person or that the effective execution of the search warrant is not frustrated.

Copy of Warrant to Be Given to Occupier

If the occupier or another person who apparently represents the occupier is present at premises when a search warrant is being executed, the person or persons named in the warrant must:

a. identify themselves to that person by producing their identification card for inspection by that person; and

b. give to that person a copy of the execution copy of the warrant.

Copies or Receipts to Be Given

1. If a person seizes :

    a. a document, disk or tape or other thing that can be readily copied; or

    b. a storage device the information in which can be readily copied -

under a warrant the person, on request by the occupier, must give a copy of the thing or information to the occupier as soon as practicable after the seizure.

2. If a person seizes a thing under a warrant and has not provided a copy of the thing or information under sub-section (1) the person must provide a receipt for that thing as soon as practicable after the seizure.

Appendix 7 Mechanisms for Maintaining Professional Competence

One or more of the following could be established to ensure ongoing competence of pharmacists:

- Retention of current powers for the Board to require a pharmacist who has not practised for over 2 years to undertake further education prior to resumption of practice[80].
- Discretionary powers for the Board to develop or recognise CPE programs and promote these to registrants as a 'board endorsed' means of retaining current knowledge (similar to section 266 of the Queensland *Medical Practice Act 2001)*.
- Powers for the Board to require practitioners to provide evidence of participation in continuing education activities to a standard set by the Board.
- Powers for the Board to conduct performance assessment of pharmacists on reasonable grounds to be specified in legislation (similar to the scheme for regulation of poorly performing medical practitioners contained in the *Health Practitioner Acts (Further Amendments) Act 2002*).
- Powers for the Board to conduct performance audits of those pharmacists who have not provided sufficient evidence of their continuing competence at re-registration (similar to proposals issued for discussion by the Australian Medical Council).
- Powers for the Board to conduct routine performance assessment for all pharmacists seeking to renew their registration (similar to reforms to medical registration proposed in the United Kingdom).

An alternative approach is to rely on a combination of other non-statutory and statutory mechanisms such as:

- Existing CPE programs operated by the professions and/or employers.
- CPE requirements established professional bodies representing pharmacists).

This Appendix is adapted from Chapter 5 (pp 31-39) of the Department of Human Services Discussion Paper, *Regulation of Medical Practitioners and Nurses, August 2001*[81]. Additional background information on mechanisms for linking demonstration of professional competence is contained in that paper.

[80] This might incorporate a statutory obligation for a pharmacist to advise the Board if s/he intends to resume practice after 2 or more years.
[81] This paper can be accessed at www.dhs.vic.gov.au/pdpd/

Appendix 8 Options for the Regulation of Non-Registered Owners of Medical Practices

Reproduced from the Department's August 2001 Discussion Paper, Regulation of Medical Practitioners and Nurses in Victoria, pp 21-22).

Option 1. Reliance on existing legislative and non-legislative mechanisms (No extension to the powers of the Medical Practitioners Board of Victoria)

The main arguments in support of the status quo are:

- Individual practitioners are accountable for the standard of the medical services and care they provide regardless of their employment arrangements, and are subject to the disciplinary processes of the MPBV if a practitioner fails to meet acceptable standards.
- Corporate owners who engage in unethical or illegal practices in the provision of medical services may be adequately dealt with through other mechanisms including:
    - The powers of the ACCC under the *Trade Practices Act 1984.*
    - The powers of the Health Insurance Commission under the *Health Insurance Act 1973.*
    - Codes of practice developed by the Commonwealth addressing ethical conduct by corporate medical practices.
    - Existing systems of voluntary accreditation of general practices, such as the AGPAL.
- The Commonwealth has indicated its intention to work with the major corporations to establish a voluntary code of conduct to self regulate their involvement in general practice.
- There are also pressures on the Commonwealth Government to strengthen controls over corporations, for example to strengthen the powers of the Health Insurance Commission to better regulate corporations. Before reforms at the State level are framed, sufficient time should elapse to assess the impact of corporatisation and whether existing mechanisms are adequate to prevent or address any abuses.

Option 2. Strengthen the powers of the Medical Practitioners Board to regulate unprofessional conduct by medical practitioners arising from the activities of corporate providers

Some of the approaches to strengthening the powers of the Medical Practitioners Board to regulate corporate medical practices include:

- Empower the MPBV to require notification of names and addresses of directors/owners of corporate medical practices, similar to the provisions of the SA Medical Practice Bill 2001 and the Queensland Medical Practice Bill Section 170.
- Establish an offence in the *Medical Practice Act* for 'employers' to direct or incite registered medical practitioners to engage in unprofessional conduct, similar to the NSW *Medical Practice Act* Section 116A and the Queensland *Medical Practice Act* Section 170.

- Empower the Secretary of the Department of Human Services to prohibit those found guilty of such offences from providing medical services or attach conditions to the provision of their services, (a form of 'negative licensing' that would apply only to those who had committed offences).

- Require all medical practices owned by unregistered persons to have a medical practitioner identified to the Board as being responsible for professional standards, similar to sections 127 and 115 of the NSW *Medical Practice Act* that require a medical practitioner to be nominated as responsible for record-keeping and advertising.

Option 3. Amend the Health Services Act to introduce a system of licensing of corporate medical practices.

Part 4 of the *Health Services Act 1988* sets out legislative requirements for registration of health service establishments. These include private hospitals and day procedures centres. Sections 83(1)(c) and (d) of that Act empower the Chief General Manager of the Department to consider whether the applicant who is seeking to register a health service establishment is a fit and proper person to carry on the establishment, and if a body corporate, whether each director or other officer of the body corporate who exercises control is a fit and proper person. Extension of this system of regulation to registration of medical practices would allow the Secretary of the Department to:

- Require applicants for registration of a medical service to be approved by the Secretary of the Department as fit and proper, and undergo various probity checks.

- Renew, suspend or revoke a registration or attach conditions, limitations or restrictions to a registration.

- Prohibit persons who are not "fit and proper" from operating a business that involves the provision of medical services.

This would allow the Secretary of the Department to attach conditions to a registration or to prohibit a person who was found not to be fit and proper to provide medical services only where it was necessary to protect the public. Those who have been found guilty of offences under the *Trade Practices Act* or the Criminal Code might be prohibited from providing medical services. The *Health Services Act* may be a more suitable vehicle for this type of regulation than the *Medical Practice Act* since:

- There are other similar functions carried out under the *Health Services Act* for registration of private hospitals and day procedures centres.

- The role of the Medical Practitioners Board is to regulate the professional standards and conduct of **individual** practitioners, rather than to regulate corporate behaviour.

However, licensing of every corporate medical practice is a costly and intrusive form of regulation and other less restrictive options may provide sufficient protection to the public.

Appendix 9 AHMAC Criteria and Process for Assessment of Regulatory Requirements for Unregulated Health Occupations

The Australian Health Ministers Advisory Council (AHMAC) is made up of the heads of all State and Commonwealth health departments, and meets regularly to make recommendations to State, Territory and Federal Health Ministers on matters of common concern (Department of Human Services, 1997).

In 1993, AHMAC agreed that before any State proceed with a proposal to register an unregistered health occupation, a majority of States should agree that such registration was required.

AHMAC established a working group with representatives from a number of States to examine and make recommendations concerning the need for occupational registration of any new health practitioner group.

The working group developed a process to address claims for registration from unregistered health professions and also formulated **6 criteria** against which applications would be assessed. These are summarised below.

PROCESS FOR ADDRESSING CLAIMS FOR REGISTRATION/REGULATION

1. Application by an unregistered occupational group may be presented to a State, or a State may see reason for pursuing registration of a group.

2. The receiving Department makes a preliminary assessment of the proposal according to the criteria:
   (i) if it does not meet the criteria then takes no further action. Notification of the request and reasons for rejection should be provided to other States/Territories/Commonwealth;
   (ii) if the Department considers criteria have been met, go to step 3.

3. The Department refers the proposal to AHMAC.

4. AHMAC either rejects the referral or establishes a Working Group to assess the proposal.

5. The Working Group would assess the proposal having regard to the need to:
   - Coordinate consultation with relevant parties including Governments;
   - assess the proposal against the criteria; and
   - report to AHMAC with recommendations (including detailed definitions of the occupation/activity that needs to be controlled).

6. AHMAC makes recommendation to AHMC (to ensure uniform acceptance/adoption).

(AHMAC, 1995, p 7)

Criteria for Assessment of Regulatory Requirements for Unregulated Health Occupations

(adapted from AHMAC, 1995)

1	**It is appropriate for Health Ministers to exercise responsibility for regulating the occupation in question, or does the occupation more appropriately fall within the domain of another Ministry?**
2	**Do the activities of the occupation pose a significant risk of harm to the health and safety of the public?** The following should be considered when assessing whether there is significant risk of harm to the health and safety of the public: • The nature and severity of the risk to the client group. • The nature and severity of the risk to the wider public. • The nature and severity of the risk to the practitioner. Areas which could be explored to identify a risk to public health and safety are: • To what extent does the practice of the occupation involve the use of equipment, materials or processes which could cause a serious threat to public health and safety? • To what extent may the failure of a practitioner to practice in particular ways (i.e. follow certain procedures, observe certain standards, or attend to certain matters), result in a serious threat to public health and safety? • Are intrusive techniques used in the practice of the occupation, which can cause a serious or life threatening danger? • To what extent are certain substances used in the practice of the occupation, with particular emphasis on pharmacological compounds, dangerous chemicals or radioactive substances? • Is there significant potential for practitioners to cause damage to the environment or to cause substantial public health and safety risk? Epidemiological or other data, (e.g. coroners' cases, trend analysis, complaints), will be the basis for determining the demonstration of risk/harm.
3	**Do existing regulatory or other mechanisms fail to address health and safety issues?** Once the particular health and safety issues have been identified, are they addressed through: • Other regulations, e.g. risk due to skin penetration addressed via regulations governing skin penetration and/or the regulation of the use of certain equipment, or industrial awards? • Being supervised by registered practitioners of a related occupation? • Self-regulation by the occupation?
4	**Is regulation possible to implement for the occupation in question?** When considering whether regulation of the occupation is possible, the following need to be considered: • Is the occupation well-defined? • Does the occupation have a body of knowledge that can form the basis of its standards of practice? • Is this body of knowledge, with the skills and abilities necessary to apply the knowledge, teachable and testable? • Do the members of the occupation require core and government accredited qualifications?
5	**Is regulation practical to implement for the occupation in question?** When considering whether regulation of the occupation is practical the following should be considered: • Are self-regulation and/or other alternatives to registration practical to implement in relation to the occupation in question? • Does the occupational leadership tend to favour the public interest over occupational self-interest? • Is there likelihood that members of the occupation will be organised and seek compliance with regulation from their members? • Are there sufficient numbers in the occupation and are those people willing to contribute to the costs of statutory regulation? • Do all Governments agree with the proposal for regulation?
6	**Do the benefits to the public clearly outweigh the potential negative impact?**

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